

**AUSTRALIAN GUIDELINES
FOR THE TREATMENT OF ADULTS
WITH
ACUTE STRESS DISORDER AND
POSTTRAUMATIC STRESS DISORDER**

**Abbreviated Title: Australian ASD and PTSD treatment
guidelines**

ACPMH, Melbourne Uni, NHMRC LOGOS

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Copies of the full Guidelines, and brief guides for practitioners and the public are available online: www.acpmh.unimelb.edu.au and www.nhmrc.gov.au

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Legal Disclaimer

This document is a general guide to appropriate practice, to be followed only subject to the practitioner's judgement in each individual case.

The guidelines are designed to provide information to assist decision making and are based on the best information available at the date of compilation.

In recognition of the pace of advances in the field it is recommended that the guidelines be reviewed and updated in five years time.

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Executive summary

Acute Stress Disorder (ASD) and Posttraumatic Stress Disorder (PTSD) are psychological reactions that develop in some people following the experience of traumatic events such as major disaster, war, sexual or physical assault, motor vehicle accidents, and torture. Exposure to a traumatic event is not an uncommon experience. Large community surveys in Australia and overseas reveal that 50% - 65% of people report at least one traumatic event in their lives. Most people will have some kind of psychological reaction to trauma – feelings of fear, sadness, guilt and anger are common. However, the majority recover over time with only a small proportion developing ASD or PTSD. It is estimated that 1.3 per cent of Australians have experienced PTSD in the last year, and that between 5 and 10 % of people have had PTSD at some point in their lives.

ASD and PTSD are very similar psychological disorders, sharing the following core symptoms:

- Reexperiencing- Intrusive distressing recollections of the traumatic event; flashbacks; nightmares; intense psychological distress or physical reactions, such as sweating, heart palpitations or panic when faced with reminders of the event.
- Avoidance and emotional numbing- Avoidance of activities, places, thoughts, feelings, or conversations related to the event; restricted emotions; loss of interest in normal activities; feeling detached from others
- Hyperarousal- Difficulty sleeping; irritability; difficulty concentrating; hypervigilance; exaggerated startle response

In addition, ASD includes dissociative symptoms such as detachment, reduced awareness of surroundings, derealisation, depersonalisation, and dissociative amnesia.

The main difference between ASD and PTSD is the time that has elapsed since the traumatic event. ASD is diagnosed between two days and one month after a traumatic incident, and PTSD is diagnosed after the first month.

The volume of research studies on the treatment of Acute Stress Disorder (ASD) and Posttraumatic Stress Disorder (PTSD) published over the past decade and the emerging consensus from those studies warrants the development of clinical practice guidelines. In recent years practice guidelines have been developed in both the United Kingdom (National Institute for Clinical Excellence: NICE, 2005) and the United States (American Psychiatric Association, 2004; Department of Veterans Affairs/Department of Defence: VA/DoD, 2004). While the Australian guidelines are tailored to the needs of our population and health care system, where appropriate they have drawn from the systematic reviews underpinning the NICE (2005) and VA/DoD (2004) guidelines.

The Guidelines were developed in accord with NHMRC guideline development requirements, by a working party comprising key trauma experts from throughout Australia, in consultation with a multidisciplinary panel comprising representatives of the range of health professionals involved in the care of people with ASD and PTSD and service users. The systematic review of the literature was undertaken by Adelaide

Health Technology Assessment (AHTA) and economic considerations were addressed by an independent health economist.

Eighteen research questions underpinned the systematic review. Eight of these updated questions previously addressed by the NICE (2005) guidelines, five updated questions previously addressed by the VA/DoD (2004) guidelines and five were new questions, representing gaps identified in the previous reviews. The findings of the previous systematic reviews were combined with the findings of the current systematic review to determine the current state of the evidence. Recommendations for practice were then developed by the Working Party on the basis of the current evidence. For areas of practice not addressed by current research, recommendations were developed on the basis of expert consensus opinion. Where gaps were identified in the existing evidence-base, recommendations were made for future research.

In addition to the systematic review of the literature and treatment and research recommendations arising from the review, this Guideline document contains background information on ASD and PTSD, screening and assessment, intervention planning and issues to consider in the application of the guideline recommendations to a range of specific trauma-affected populations. The guidelines are intended as a framework of best practice around which treatment provided by qualified professionals should be structured. They are not intended to be used prescriptively but applied with clinical judgment to each person's unique circumstances and overall mental health care needs.

The guideline recommendations along with key background information are presented in two brief companion documents developed for health practitioners and the public respectively. These documents, available from the Australian Centre for Posttraumatic Mental Health website (www.acpmh.org.au), are:

Australian guidelines for the treatment of Adults with Acute Stress Disorder and Posttraumatic Stress Disorder: Practitioner Guide

Australian guidelines for the treatment of Adults with Acute Stress Disorder and Posttraumatic Stress Disorder: Information for People with ASD and PTSD, their Families and Carers

Summary of Guideline Recommendations

The research evidence and/or expert opinion underpinning these recommendations is presented in the full text of the document. The relevant sections of the document are cited for each recommendation. Similarly the grading system for each recommendation is fully explained in the document (Section 1.5.2.4). As a quick guide, recommendations are graded A through D according to the quality of the evidence upon which they are based, with A being the highest quality evidence. In the absence of research evidence, expert clinical consensus is indicated by the designation Good Practice Point (GPP). Please note the use of abbreviated forms of Posttraumatic Stress Disorder (PTSD) and Acute Stress Disorder (ASD) in this summary.

SCREENING, ASSESSMENT AND TREATMENT PLANNING

Screening, Assessment and Diagnosis (Section 2.4)

- For people presenting to primary care services with repeated non-specific physical health problems it is recommended that the primary care practitioner consider asking whether the person has experienced a traumatic event and describe some examples of such events. (GPP)
- Service planning should consider the application of screening of individuals at high-risk for PTSD after major disasters or incidents. (GPP)
- Programs responsible for the management of refugees should consider the application of culturally appropriate screening for refugees and asylum seekers at high-risk for developing PTSD (GPP)
- Screening should be undertaken in the context of a service system that includes adequate provision of services for those who require care. (GPP).

Comprehensive assessment of PTSD (Section 2.4.2)

- A thorough assessment is required, covering PTSD and related diagnoses, quality of life and psychosocial functioning, trauma history, general psychiatric status (noting extent of comorbidity), physical health, substance use, marital and family situation and vocational and social status. (GPP)
- Assessment should include assessment of strengths and resilience (GPP)
- Assessment and intervention must be considered in the context of the time that has elapsed since the traumatic event occurred. Assessment needs to recognise that whereas the majority of people will display distress in the initial weeks after trauma exposure, most of these reactions will remit within the following three months. (GPP)
- Assessment and monitoring should be undertaken throughout treatment. When adequate progress in treatment is not being made, the practitioner should revisit the

case formulation, reassess potential treatment obstacles and implement appropriate strategies (GPP)

Differential diagnosis (Section 2.4.4)

- Assessment should cover the broad range of potential posttraumatic mental health problems beyond PTSD (GPP)

Assessment instruments (Section 2.4.7)

- It is recommended that practitioners be guided in their assessment of PTSD, comorbidity and quality of life by the available validated self-report and structured clinical interview measures (GPP)
- It is recommended that practitioners also use self-report measures to support their assessments of treatment outcomes over time. (GPP)

Intervention Planning (Section 2.5)

- Mental health practitioners are advised to note the presence and severity of comorbidities in their assessments, with a view to considering their implications for treatment planning. (GPP)

(Please note also recommendations regarding PTSD and comorbidity in section 4.1.11.5)

- The development of a robust therapeutic alliance should be regarded as the necessary basis for undertaking specific psychological interventions and may require extra time for people who have experienced prolonged and/or repeated traumatic exposure (GPP)
- Mental health practitioners should provide a clear rationale for treatment and promote realistic and hopeful outcome expectancy. (GPP)

Treatment goals (Section 2.5.2)

- The practitioner should assess immediate needs for practical and social support and provide education and referrals accordingly (GPP)
- Appropriate goals of treatment should be tailored to the unique circumstances and overall mental health care needs of the individual and established in collaboration with the person (GPP)
- From the outset, there should be a collaborative focus on recovery and rehabilitation between the person and practitioners and, where appropriate, family members (GPP)

Cultural and linguistic diversity (Section 2.5.3)

- Recommended treatments for PTSD should be available to all Australians regardless of cultural and linguistic background (GPP)

The impact of PTSD on family (Section 2.5.4)

- Wherever possible family members should be included in assessment processes, education and treatment planning, and their own needs for care considered alongside the needs of the person with PTSD (GPP).

General professional issues (Section 2.5.5)

- Primary care practitioners, especially in rural and remote areas, who assume responsibility for the care of people with ASD and PTSD in the absence of specialist providers should be supported with accessible education and training (GPP)
- In their self-care, practitioners should pay particular attention to skill and competency development and maintenance including regular supervision, establishing and maintaining appropriate emotional boundaries with PTSD sufferers, and effective self-care including maintaining a balanced and healthy lifestyle and responding early to signs of stress (GPP).
- For those practitioners who work in an organisational context, broader policies and practices should support individual practitioners in these self-care measures. (GPP)

INTERVENTIONS FOR ADULTS WITH PTSD

Psychological interventions for adults with PTSD (Section 4.1.1)

- Adults with PTSD should be provided with trauma focused interventions (trauma focused CBT or eye movement desensitization and reprocessing in addition to in vivo exposure). (A)
- As available evidence does not support the importance of eye movements per se in EMDR, it is recommended that practitioners who use EMDR be aware that treatment gains are more likely to be due to the engagement with the traumatic memory, cognitive processing and rehearsal of coping and mastery responses (GPP)
- Where symptoms have not responded to one form of first line trauma-focused interventions (trauma focused CBT or EMDR in addition to in vivo exposure), health practitioners may consider the alternative form of trauma-focused interventions. (GPP)
- Non trauma-focused interventions such as supportive counselling and relaxation should not be provided to adults with PTSD in preference to trauma-focused interventions. (B)
- Where symptoms have not responded to a range of trauma focused interventions, evidence-based non trauma focused interventions (such as stress management) and/or pharmacotherapy (see section 3.1.3.6) should be considered. (C)
- Sessions that involve imaginal exposure require 90 minutes to ensure that therapy is adequate in those sessions. (C)

- Following diagnosis, assessment and treatment planning, eight to 12 sessions of trauma focused treatment is usually sufficient (D)
- For PTSD sufferers with several problems arising from multiple traumatic events, traumatic bereavement or where PTSD is chronic and associated with significant disability and comorbidity, further sessions using specific treatments to address those problems may be required. (GPP)
- Where adults have developed PTSD and associated features following exposure to prolonged and/or repeated traumatic events, more time to establish a trusting therapeutic alliance, more attention to teaching emotional regulation skills and a more gradual approach to exposure therapy may be required. (GPP)

Individual and group psychological interventions (Section 4.1.3)

- Group CBT (trauma focused or non trauma focused) may be provided as adjunctive to, but should not be considered an alternative to, individual therapy. (C)

Self-delivered interventions (Section 4.1.4)

- For adults with PTSD, self-delivered interventions should not be prescribed in place of evidence-based practitioner delivered interventions. (B)
- Facilitated although non face-to-face interventions such as interapy may be considered where face-to-face practitioner delivered interventions are not available (D)
- Self-delivered interventions may be useful as adjunctive to practitioner delivered interventions (GPP)

Pharmacological interventions for adults with PTSD (Section 4.1.5)

- Drug treatments for PTSD should not be used as a routine first line treatment for adults, either by general medical practitioners or by specialist mental health professionals, in preference to a trauma focused psychological therapy (A) (see also Combined psychological and pharmacological treatment Recommendation 3.1.7.6.1)
- Where medication is considered for the treatment of PTSD in adults, SSRI antidepressants should be the first choice for both general practitioners and mental health specialists (B).
- Other new generation antidepressants (notably mirtazapine) and the older tricyclic antidepressants should be considered as a second line option. Phenelzine should be considered for use by mental health specialists for people with treatment resistant symptoms (B)
- Antidepressant medication should be considered for the treatment of PTSD in adults when:

- the sufferer is unwilling to engage in trauma-focused psychological treatment (GPP)
- the sufferer is not sufficiently stable to commence trauma-focused psychological treatment (as a result, for example, of being actively suicidal or homicidal, or of severe ongoing life stress such as domestic violence) (GPP)
- the sufferer has not gained significant benefit from trauma-focused psychological treatment (GPP)
- the sufferer is experiencing a high level of dissociative symptoms that are likely to be significantly exacerbated by trauma-focused therapy (GPP)
- Where a decision has been made to commence pharmacotherapy, the person's mental state should be regularly monitored with a view to commencing adjunctive psychological treatment if/when appropriate. In the interim, supportive psychotherapy with a substantial psychoeducational component should be offered. (GPP)
- Where significant sleep disturbance or excessive distress does not settle in response to reassurance, simple psychological first aid, or other non-drug intervention, cautious use of hypnotic medication may be appropriate in the short term. If the sleep disturbance is of more than one month duration and medication is likely to be of benefit in the management of the person's PTSD, a suitable antidepressant should be considered. The risk of tolerance and dependence are relative contraindications to the use of hypnotics for more than one month except if their use is intermittent (GPP)
- Antidepressant medication (see 2 above) should be considered as an adjunct to psychological treatment in adults where core PTSD symptoms are of sufficient severity to significantly interfere with the sufferer's ability to benefit from psychological treatment (GPP)
- Where conditions comorbid with the PTSD (e.g., depression, other anxiety conditions) are of sufficient severity to significantly interfere with the sufferer's ability to benefit from psychological treatment, or where a more rapid relief of symptoms is likely to offer significant clinical benefit, drug treatments that have a demonstrable evidence-base for the treatment of that condition should be considered (GPP)
- Where symptoms have not responded adequately to pharmacotherapy, consideration should be given to:
 - increasing the dosage within approved limits (GPP)
 - switching to an alternative antidepressant medication (GPP)
 - adding risperidone or olanzapine as an adjunctive medication (GPP)
 - reconsidering the potential for psychological intervention (GPP)
- When an adult sufferer with PTSD has responded to drug treatment, it should be continued for at least 12 months before gradual withdrawal (B)

- Best practice prescribing procedures should be adopted when using drug treatments for PTSD in adults, including provision of information prior to commencement, monitoring and management of side effects, monitoring of suicide risk, and appropriate discontinuation and withdrawal practices (GPP)
- Adult PTSD sufferers receiving pharmacotherapy should be seen at least weekly if there is a significant risk of suicide; if there is no significant risk of suicide, fortnightly contact is recommended initially, dropping to less frequent after 3 months if the response is good. The role of the clinician in providing information and support is an important component of the management. (GPP)

Combined pharmacological interventions (Section 4.1.6)

- Where symptoms have not responded to pharmacotherapy, consideration should be given to adding olanzapine as an adjunctive medication (C)

Initial psychological or pharmacological intervention (Section 4.1.7)

- Drug treatments for PTSD should not be used as a routine first line treatment for adults, either by general medical practitioners or by specialist mental health professionals, in preference to a trauma-focused psychological therapy (B)

Combined psychological and pharmacological interventions (Section 4.1.8)

- In cases where the person has not gained benefit from first line psychological treatments, health practitioners may wish to consider commencing adjunctive pharmacotherapy. (GPP)
- Where a decision has been made to commence treatment pharmacotherapy, the person's mental state should be constantly monitored with a view to commencing adjunctive psychological treatment if/when appropriate. In the interim, supportive psychotherapy with a substantial psychoeducational component should be offered. (GPP)

Psychosocial rehabilitation (Section 4.1.9)

- There should be a focus on vocational, family and social rehabilitation interventions from the beginning of treatment (GPP)
- Where symptoms of PTSD have been present for 3 months or longer, psychosocial rehabilitation should be considered as an intervention to prevent or reduce disability associated with the disorder. (GPP)
- In cases where people with PTSD have not benefited from a number of courses of evidence-based treatment, psychosocial rehabilitation interventions may reduce disability, improve functioning and community tenure. (GPP)

- Healthcare professionals should be aware of the potential benefits of psychosocial rehabilitation and promote practical advice on how to access appropriate information and services. (GPP)
- Psychosocial rehabilitation interventions should be provided by competent and appropriately qualified practitioners who received regular supervision. (GPP)
- Psychosocial rehabilitation may be used as an adjunctive therapy in combination with psychotherapy or pharmacotherapy. (GPP)

Physical therapies and exercise (Section 4.1.10)

- As part of general mental health care, practitioners may wish to advise people with PTSD that regular aerobic exercise may be helpful in managing their symptoms and as part of self-care practices more generally. (GPP)

Sequencing treatment in the context of comorbidity (Section 4.1.11)

- In the context of comorbid PTSD and depression, health practitioners may consider treating the PTSD first as the depression will often improve with treatment of the PTSD. (B)
- Where the severity of comorbid depression precludes effective engagement in therapy and/or is associated with high-risk suicidality, health practitioners are advised to manage the suicide risk and treat the depression prior to treating the PTSD. (GPP)
- In the context of PTSD and substance use disorders, practitioners should consider treating both conditions simultaneously. (C)
- In the context of PTSD and substance use disorders, the trauma-focused component of PTSD treatment should not commence until the PTSD sufferer has demonstrated a capacity to manage distress without recourse to substance use and to attend sessions without being drug or alcohol affected. (D)
- In the context of PTSD and substance use disorders where the decision is made to treat substance use disorders first, treatment should include information on PTSD and strategies to deal with PTSD symptoms as the person controls their substance abuse. (GPP)

EARLY INTERVENTION

Treatment for all: Psychological interventions (Section 5.1.1)

- For adults exposed to trauma, structured psychological interventions such as psychological debriefing should not be offered on a routine basis. (C)
- For adults exposed to trauma, clinicians should implement psychological first aid in which survivors of potentially traumatic events are supported, immediate needs met, and monitored over time. Psychological first aid includes provision of information,

comfort, emotional and instrumental support to those seeking help. Psychological first aid should be provided in a stepwise fashion tailored to the person's needs. (GPP)

- Adults exposed to trauma who wish to discuss the experience, and demonstrate a capacity to tolerate associated distress, should be supported in doing so. In doing this the practitioner should keep in mind the potential adverse effects of excessive ventilation in those who are very distressed. (GPP)
- For adults who develop an extreme level of distress or are at risk of harm to self or others, immediate psychiatric intervention should be provided (GPP)

Treatment for all: Pharmacological interventions (Section 5.1.2)

- For adults exposed to trauma, drug treatments should not be used non-selectively as a preventive intervention (C)

Treatment for ASD: Psychological interventions (Section 5.2.1)

- Adults displaying ASD or PTSD reactions at least two weeks after the traumatic event should be offered trauma focused cognitive behaviour therapy including exposure and/or cognitive therapy once a clinical assessment has been undertaken. (A)
- For adults with ASD, treatment should be provided on an individual basis. (B)
- For adults with ASD, trauma focused CBT should, under normal circumstances, be provided in 5 – 10 sessions. (C)
- For adults with ASD, ninety minutes should be allowed for sessions that involve imaginal exposure. (C)
- Trauma focused interventions should not commence within two weeks of trauma exposure. (GPP)
- Combination psychological interventions for ASD should not be used routinely. (C)

Treatment for ASD: Pharmacological interventions (Section 5.2.2)

- Drug treatments should generally not be used to treat ASD or related conditions (i.e., within four weeks of symptoms onset) in adults unless the severity of the person's distress can not be managed by psychological means alone, particularly when there is a pattern of extreme hyperarousal. (GPP)
- In individuals who have a prior history of depression that has responded well to medication, the prescription of an antidepressant should be considered if a progressive pattern of clinically significant symptoms, such as persistent intrusions with increasing affective distress, begin to emerge. (GPP)
- Where significant sleep disturbance does not settle in response to reassurance and simple psychological first aid, cautious use of hypnotic medication or other drug treatment may be appropriate for adults in the short term. (GPP)

Combined interventions for adults with ASD (Section 5.2.3)

- Trauma-focused CBT should be used for the treatment of ASD and acute PTSD. (A)

ECONOMIC CONSIDERATIONS (Section 6)

- Conduct a comprehensive assessment of the economic burden associated with PTSD.
- Implement economic evaluation studies along side clinical evaluations of various treatment options.
- Review financing arrangements from the treatment of PTSD in Australia.

1 Introduction

1.1 What are clinical practice guidelines

Clinical practice guidelines are systematically developed statements formulated to assist clinicians, consumers and policy makers to make appropriate decisions about health care. Such statements of ‘best practice’ are based on a thorough evaluation of the evidence from published research studies on the outcomes of treatment or other health care procedures (NHMRC, 2000b, page vii).

1.2 Rationale for developing practice guidelines on the treatment of Acute Stress Disorder and Posttraumatic Stress Disorder

Over the last decade there have been an increasing number of published research studies on the outcomes of a range of treatments for Acute Stress Disorder (ASD) and Posttraumatic Stress Disorder (PTSD). As such, it is now possible to generate evidence-based clinical practice guidelines. In recent years both the United Kingdom National Institute for Clinical Excellence (National Institute for Clinical Excellence, 2005) and the United States (American Psychiatric Association, 2004; Department of Veterans Affairs/Department of Defence, 2004) have published treatment guidelines for PTSD. In the development of these Australian clinical practice guidelines, we drew on the systematic reviews that underpinned the NICE (2005) and VA/DoD (2004) guidelines, including the adaptation of recommendations made in these previous guideline documents where appropriate. However there is a need to develop guidelines tailored to Australian needs and its health care system.

1.3 Objective of these guidelines

These guidelines aim to support high quality treatment for adults with ASD and PTSD by providing a framework of best practice around which to structure treatment. The guidelines have been designed to be used by: the range of general and mental health practitioners planning treatment across clinical settings; consumers making decisions about their treatment; and funding bodies making service purchasing decisions. These guidelines should not be regarded as an inflexible prescription for the content of treatment, and they should not limit treatment innovation and development that is based upon scientific evidence, expert consensus, practitioner judgment of the needs of the person and the person’s preferences.

1.4 Scope of the guidelines

These guidelines provide information and recommendations about evidence-based methods of treating adults who, following exposure to traumatic events, have developed (or are at risk of developing) problems consistent with the criteria for ASD and PTSD. The guideline developers recognise that there are a number of interventions that are widely used in clinical practice that have not been adequately tested and it is important to acknowledge that the absence of evidence does not necessarily mean that these interventions are ineffective. The gap between evidence-

based interventions and routine clinical practice should help define the research agenda into the future.

The guidelines have been formulated with the assumption that treatment will be provided by qualified professionals who are skilled in the relevant psychosocial and medical interventions, as assessed against the prevailing professional standards. The guidelines do not substitute for the knowledge and skill of competent individual practitioners. The recommendations are not intended to be used prescriptively, but as a guide to appropriate interventions in the context of each person's unique circumstances and their overall mental health care needs. Practitioners should use their experience and expertise in applying these guidelines in routine clinical practice. In the application of these guidelines to the Australian health care setting, consideration needs to be given to the availability and accessibility of appropriate and relevant services in rural and remote settings and of appropriate education and training to support practitioners in the delivery of the recommended evidence-based interventions.

In regard to the pharmacotherapeutic recommendations outlined in these guidelines doctors, when prescribing in Australia, should be mindful of regulations that may apply where the cost of the medicine is subsidised by the Government (Pharmaceutical Benefits Schedule) or another third party.

While adults suffering PTSD in combination with broader posttraumatic mental health problems or other mental health problems may require additional treatment and care, the recommendations in these guidelines are still relevant and applicable. The guidelines are intended to include the care of older adults who do not have significant age-related comorbidity but do not include the care of children for whom there is an independent evidence-based care literature. The UK (National Institute for Clinical Excellence, 2005) recommendations for the care of children with PTSD are included as an addendum to the special populations section.

Most of the evidence reviewed in this guideline comes from clinical efficacy trials. In order to determine the efficacy of treatment, clinical efficacy trials need to have carefully controlled conditions. This often involves substantial deviation from usual care, for example, "*eliminating treatment preferences, providing free care, using specialised providers and settings, maintaining high treatment compliance, and excluding patients with major comorbid conditions.*" (Wells, 1999). In contrast, effectiveness trials evaluate the effects of treatment under standard practice conditions.

While the recommendations outlined in these guidelines are applicable and appropriate to the Australian healthcare context, there is a need for further evaluation of the recommended interventions under conditions approximating usual care.

1.5 Guideline Recommendations

The guidelines have been developed using the NHMRC pilot process, blending the current official NHMRC levels with the interim levels of evidence and system for grading recommendations. Recommendations included in the guideline are graded according to the strength of the evidence upon which they are based. The grading ranges from **A** for the strongest evidence through to **D** for the weakest evidence. The designation ***Good Practice Point (GPP)*** is given to recommendations based on expert

consensus opinion, in the absence of an evidence-base. The approach to guideline development is described in detail in Section 3, with the grading system outlined in detail in Section 3.2.4.2.

Recommendations regarding assessment and treatment practices are made throughout the guideline document. The recommendations are not intended to be used prescriptively but rather as guidelines to assist the practitioner. In each case assessment and treatment decisions should be based on guideline recommendations combined with the clinical judgement of the practitioner and the person's preferences.

1.6 Approach to guideline development

1.6.1 The development of clinical practice guidelines

The National Health and Medical Research Council (NHMRC) have developed a series of "Guidelines for Guidelines" handbooks to assist developers with the process of producing and disseminating clinical practice guidelines (NHMRC, 1999, 2000a, 2000b, 2001). These guideline handbooks have been followed in the production of the Practice Guidelines for Acute Stress Disorder and Posttraumatic Stress Disorder.

Evidence-based guidelines are practice-based action statements based on the results of systematic literature reviews. Systematic literature reviews use explicit, systematic methods to review the literature underpinning a specific clinical query. Since the technique limits bias and reduces the effect of chance in the review, it provides a more reliable and consistent evidence-base upon which to draw conclusions and to develop clinical practice guidelines.

These reviews are characterised by:

1. The development and statement of a specific research question or hypothesis.
2. A transparent methodical process defined *a priori* (i.e. a review protocol).
3. An exhaustive search for relevant primary (and secondary) research on the topic.
4. Application of inclusion criteria and critical appraisal of the research.
5. An attempt to answer the research question(s) and to resolve conflicts in the literature.
6. The identification of issues central to future research on the topic and the practical application of results.
7. The development of guidelines or recommendations that are based on this evidence (research), and are applicable to the target population or patient group (Clarke & Oxman, 2000; Cooper & Hedges, 1994; Mulrow et al., 1997; NHMRC, 1999, 2000a, 2000b, 2001).

The current guidelines were in the preliminary stages of development when ASD and PTSD treatment guidelines were published in the UK (National Institute for Clinical Excellence: NICE, 2005) and the US (Department of Veterans Affairs/ Department of Defense: VA/DoD, 2004). The guideline development working party decided to build on those high quality systematic reviews and recent guidelines wherever possible, rather than replicating existing reviews. As such, where questions asked in the previous systematic reviews were similar to those planned in the current systematic review, the same questions were repeated with updated search periods (2002-2005 for questions from the VA/DoD systematic review and 2004-2005 for the NICE review).

In this way the previous evidence could be combined with new evidence for the current guideline. The guideline development working party identified only a small number of additional questions, for which a new search (1996-2005) was conducted. The composition of the guideline working party can be seen in Appendix A.

Research questions for the current review were formulated on the combined basis of questions asked in previous reviews, the working party's knowledge of the literature, expert consensus opinion on questions of relevance to the field and consultation with a multidisciplinary panel comprising representatives of mental health professionals and consumers. The composition of the multidisciplinary panel can be seen in Appendix B.

The research questions investigated are listed below. Questions used in previous reviews are marked accordingly.

1. For adults exposed to trauma, do early psychological interventions improve outcomes compared to no intervention? (NICE, 2005)
2. For adults exposed to trauma, does any early psychological intervention confer any advantage over other early psychological interventions? (NICE, 2005)
3. For adults with PTSD, do psychological interventions improve outcomes compared to no intervention? (NICE, 2005)
4. For adults with PTSD, does any psychological intervention confer any advantage over other psychological interventions? (NICE, 2005)
5. Is individual therapy more effective than group therapy for PTSD? (VA/DoD, 2004)
6. For adults with PTSD, is the combination of individual therapy and group therapy more effective than either alone? (New review)
7. Are established interventions for PTSD effective when self-delivered or self-delivered with practitioner support? (New review)
8. For adults exposed to trauma, do early pharmacological interventions improve outcomes compared to no intervention? (NICE, 2005)
9. For adults exposed to trauma, does any early pharmacological intervention confer any advantage over other early pharmacological interventions? (NICE, 2005)
10. For adults with PTSD, do pharmacological interventions improve outcomes compared with placebo? (NICE, 2005)
11. For adults with PTSD, does any pharmacological intervention confer any advantage over other pharmacological interventions? (NICE, 2005)
12. For adults with PTSD, does psychosocial rehabilitation improve outcomes compared to no intervention? (New search)
13. For adults with PTSD, does psychosocial rehabilitation confer an advantage over any other psychological or pharmacological interventions? (New search)
14. For adults with ASD or PTSD, do physical interventions or exercise confer an advantage over psychological or pharmacological interventions? (New search)
15. For people exposed to trauma, is a single early intervention more effective than multiple early interventions? (VA/DoD, 2004)

16. For adults with PTSD, is a single intervention more effective than multiple interventions? (VA/DoD, 2004)
17. For adults with PTSD, is initial pharmacotherapy more effective than initial psychotherapy? (VA/DoD, 2004)
18. In the context of PTSD and comorbidity, is sequencing of intervention per diagnosis more effective than simultaneous interventions for both diagnoses? (VA/DoD, 2004)

1.6.2 Overview of methodology

As noted in the previous section, this systematic review was designed to update the systematic reviews performed by NICE, (2005) and VA/DoD (2004). Both performed systematic reviews consistent with the NH&MRC process. The method of reporting findings differed, however, with the method reported by NICE [evidence statements including number of studies (k), Standardised Mean Difference (SMD) and Confidence Intervals (CI)] lending itself to easier integration of subsequent evidence. For this reason and due to the more recent literature review conducted by NICE, the current review was designed to update the NICE review wherever possible. Where the current review asked questions not addressed by NICE, the VA/DoD review was updated. Where the current review asked questions not addressed by either of the previous reviews, the systematic review was conducted from 1996 onwards. The composition of the personnel from Adelaide Health Technology Assessment (AHTA) who conducted the evidence review on behalf of the working party can be seen in Appendix C.

1.6.2.1 Inclusion criteria

Criteria for including studies in this systematic literature review are provided in the Process Report in Appendix D. In order to ensure that the selection of studies to answer specific research questions was not biased, these criteria were delineated prior to collating the literature. The type of Population, Intervention (treatment), Comparator (against which the treatment's effectiveness is measured), and Outcomes of interest were made explicit – these are known as the PICO criteria and they relate directly to each research question that was addressed. Additional limits to the literature search were also made clear, such as restricting the search to studies of a certain research design(s) (e.g., those studies likely to provide unbiased or more reliable results), or to a certain search period or language.

Studies were excluded if:

- they did not meet the inclusion criteria;
- data on outcomes was inadequate e.g., data presented graphically, missing information, or data were of type or format unable to be used;
- they were updates of previous studies by the same research group on the same research question for the same participants, with follow-up of less than 50%; or
- the article could not be located.

To be included, studies needed:

- PTSD symptoms to be measured;
- the main target of the treatment to be ASD or PTSD or preventing the development of these disorders;

- (for questions pertaining to PTSD) at least 70 percent of the participants to have PTSD, and the remaining participants to have symptoms of PTSD following a traumatic event;
- participants over 16 years old; and
- data on at least 50 percent of the intent-to-treat sample assessed at the relevant time point.

In studies reporting updates of previous research, only additional follow-up information was included in the current review.

1.6.2.2 Literature sources

To be consistent with the two evidence-based guidelines documents that were being updated (NICE and Department of Veterans Affairs/ Department of Defense), the following databases were searched: Medline, Embase, Cinahl, PsychINFO, the Dartmouth College Published International Literature on Traumatic Stress (PILOTS) catalogue and the Cochrane Library. To meet NHMRC requirements, Clinical Evidence and the Internet (GoogleScholar, and websites of specialty organisations) along with economic databases (ECONLIT, National Health Service Economic Evaluation database and Health Economic Evaluations Database (HEED)) were also searched, and the reference lists of all included studies were perused for potentially relevant studies (See Appendix D).

Also to be consistent with the previous evidence-based guideline documents, the searches were restricted to English language literature and to the highest level of evidence available to answer the research question i.e., if a question could not be answered by a systematic review/meta-analysis of randomised controlled trials (level I evidence), then the search was extended to randomised controlled trials only (level II evidence), then - if unsuccessful - to non-randomised controlled trials/cohort studies (level III evidence) if that was what was required by the inclusion criteria

1.6.2.3 Search strategies

Since the search strategies used for the two previous reviews (NICE and VA/DoD) were quite different, this review utilises elements of both strategies.

A series of five separate literature searches were conducted to extract comparative studies relating to psychological interventions, pharmacological interventions, psychosocial rehabilitation, physical therapies and exercise and comorbidities, from which relevant papers were identified for each research question.

The search terms used are listed in Appendix D. The search terms were developed on a PubMed platform. Similar search strategies were used for the different bibliographic databases, with the same text words being used along with the relevant alternatives to MeSH headings.

1.6.2.4 Validity Assessment

Included studies were critically appraised – in terms of internal and external validity - and the statistical and clinical relevance and applicability of results were determined utilising the NHMRC dimensions of evidence (NHMRC, 2000a, 2000b) and the recently developed NHMRC interim levels and grades of evidence (see Appendix

D). Designated levels of evidence for intervention research questions are presented in Table 3 below:

Level	Intervention
I	A systematic review of level II studies
II	A randomised controlled trial
III-1	A pseudorandomised controlled trial (i.e., alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> • Non-randomised, experimental trial † • Cohort study • Case-control study • Interrupted time series with a control group
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> • Historical control study • Two or more single arm study ‡ • Interrupted time series without a parallel control group
IV	Case series with either post-test or pre-test/post-test outcomes

The levels of evidence noted for the NICE evidence statements were as reported in the NICE guidelines. The NICE evidence rating system can be seen in Appendix vvvv . VA/DoD summary statements did not report levels of evidence.

Critical appraisal of the included systematic reviews, randomised and non-randomised studies occurred using the NHMRC quality criteria (NHMRC, 2000a, 2000b) see Appendix D. As noted above, the guidelines have been developed using the NHMRC pilot process, blending the current official NHMRC levels with the interim levels of evidence and system for grading recommendations. This approach has been followed as much as possible, bearing in mind that recommendations 1) often married evidence reported in the NICE and VA/DoD systematic reviews with that of the current review, and 2) spanned more than one research question.

The NHMRC dimensions of evidence (Appendix D) consider three main aspects that are critical to an assessment of evidence: strength of the evidence, size of the effect and relevance of the evidence. The first domain is derived directly from the literature identified as informing a particular intervention. The last two require expert clinical input as part of their determination. These three dimensions of evidence were applied to individual studies during the critical appraisal process.

Table 4 Evidence dimensions

Type of evidence	Definition
Strength of the evidence	
Level	The study design used, as an indicator of the degree to which bias has been eliminated by design.*
Quality	The methods used by investigators to minimise bias within a study design.
Statistical precision	The p -value or, alternatively, the precision of the estimate of the effect. It reflects the degree of certainty about the existence of a true effect.
Size of effect	The distance of the study estimate from the “null” value and the inclusion of only clinically important effects in the confidence interval.
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

Data Extraction and Analysis

The process of study selection went through six phases and the number of literature citations retrieved and retained at each phase was documented (See Appendix D).

Evidence tables were used as a guide to summarise the extraction of data from the individual studies (See Appendix E) (NHMRC, 2005b). Intention-to-treat analyses (ITT) should be used in preference to completer data as it limits the effect of selection bias on the results. Therefore intention-to-treat data was used in preference to completer data, when it was available. However when such data was not available, completer data were presented and clearly labelled as such.

Meta-analyses for some of our specific research questions were conducted originally in the NICE (2005) guidelines document and were updated - where appropriate – by the results of the new randomised controlled trials identified for this report. Meta-analyses were conducted using a fixed effects model when studies were homogenous or a random effects model in the presence of between-study heterogeneity (where that heterogeneity could not be explained). Effect measures that were extracted or calculated for individual or pooled results included Relative Risk (RR) for count data and standardised mean differences (SMD) for continuous data. Heterogeneity in the meta-analysis was assessed using the Cochran Q statistic and publication bias was tested using the Begg funnel plot. Where a meta-analysis could not be conducted, a qualitative synthesis of the data was undertaken.

Development of evidence statements

Effect sizes were interpreted using methodology developed by NICE (quoted below):

“For each outcome a clinical statement describing the evidence found was developed. To assess clinical importance where a statistically significant summary was obtained (after controlling for heterogeneity) the Group set thresholds for determining clinical importance, in addition to taking into account the trial population and nature of the outcome.

Two separate thresholds for determining clinical importance were set. For comparisons of one active treatment against waiting list or non-active interventions, a higher threshold was applied than for comparisons of active treatments against one another.

For comparisons of one active treatment against another treatment the following thresholds were applied: for dichotomous outcomes an RR of 0.80 or less was considered clinically important and for continuous outcomes an effect size of approximately 0.5 (a 'medium' effect size; Cohen, 1988) or more was considered clinically important.*

For comparisons of active treatment against waiting list the following thresholds were applied: for dichotomous outcomes a RR of 0.65 or less was considered clinically important and for continuous outcomes an effect size of approximately 0.8 (Cohen) or more was considered clinically important.*

In cases where the point estimate of the effect was judged clinically important, a further consideration was made about the precision of the evidence by examining the range of estimates defined by the CI. For level I evidence, where the effect size was judged clinically important for the full range of plausible estimates, the result was described as evidence favouring intervention x over intervention y (i.e. statement 1, or S1). For non-level-I evidence or in situations where the point estimate was clinically important but the CI included clinically unimportant effects, the result was described as limited evidence favouring intervention x over intervention y (i.e., S2). Where a point estimate was judged as not clinically important and the CI did not include any clinically important effects, the result was described as unlikely to be clinically important (i.e., S3). Alternatively, if the range of estimates defined by the CI included clinically important benefits as well as no effect or harmful effects, the result was described as inconclusive (i.e., S4).

S1= There is evidence favouring x over y on...

S2= There is limited evidence favouring x over y on...

S3= There is evidence suggesting that there is unlikely to be a clinically important difference between x and y on...

S4= The evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between x and y on....”

(Extract from NICE, 2005 p. 45)

**An error in the NICE document indicating that a medium effect size of 0.5 or less was considered clinically important for comparison between treatments, and a large effect size of 0.8 or less was considered clinically important for comparison of one treatment with waitlist has been corrected in this reproduction.*

NHMRC designations of level of evidence were used (Appendix D). The levels of evidence assigned to the evidence statements reflect the highest level of evidence of a single study amongst those that address the question. All statistical calculations and testing were undertaken using the biostatistical computer package, Stata version 8.2 (StataCorp, 2004). Calculations of effect sizes (Hedges G) for individual studies were performed using The Effect Size Generator version 2.3 (Deville, 2004) and meta-analyses were undertaken using Comprehensive Meta-analysis (Biostat, 2000).

Grading the evidence

The NHMRC pilot process of blending the current official NHMRC levels with the interim levels of evidence and system for grading recommendations, was followed as much as possible given that recommendations were based on combined evidence from previous and current reviews and sometimes spanned more than one research question.

Once each included study was assessed according to the three dimensions of evidence, a grade for the whole body of evidence supporting each recommendation can be determined (See Appendix D).

NHMRC grades of recommendation are provided to assist users of the clinical practice guideline in making clinical judgements and to indicate the strength of the recommendation. Grade A and B recommendations are generally based on a body of evidence which can be trusted to guide clinical practice, whereas Grade C and D recommendations must be applied carefully to individual clinical and organisational circumstances and should be followed with care (NHMRC, 2005b).

Grade of recommendation	Description
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution

In addition and following NICE (2005), the designation **Good Practice Point (GPP)** is given to recommendations based on expert consensus opinion, in the absence of an evidence-base.

The applicability (whether the body of evidence is applicable to the Australian healthcare context) and generalisability (the degree to which the body of evidence is generalisable to the target population for the guideline) of the evidence, has also been included in the evidence statements. For example, where the evidence is deemed to be both applicable and generalisable, the evidence statement reads *There is relevant and applicable evidence favouring x over y on*

1.6.3 Limitations of the review

This systematic review of the treatments for ASD and PTSD is limited by the following factors. The review:

- Does not assess levels of evidence lower than randomised controlled trials (level II intervention evidence) for many questions due to the inclusion criteria specified in the guidelines documents that this review was updating;
- Does not provide a comprehensive review of potential safety issues (i.e., most studies were too small to detect many adverse events, particularly rare adverse events) – this is of specific relevance to the section on pharmacological treatments;
- Duplicates some of the NICE guidelines document as the search periods overlapped for some months in 2004.
- Was based on the NICE systematic review and the VA/DoD guidelines, which both have their own limitations. In updating these guidelines, some of these

limitations must be acknowledged, despite the use of a near identical methodology.

- The NICE guidelines stated that intention-to-treat data would be used where available, however, in at least one instance completer data was used where intention-to-treat data was available (Kubany et al., 2004).
- Effect sizes were calculated on the difference in posttreatment scores between the groups, the assumption being that randomisation negated any potential baseline differences between the groups. This assumption may be valid for large trials but is not necessarily correct for small trials.
- Some of the studies included in the reviews presented statistical testing on a large range of outcomes, without correction for multiple comparisons in their analysis. This increases the likelihood that a statistically significant difference will be identified, just through chance.

2 PTSD and ASD

2.1 Background to PTSD and ASD

2.1.1 Trauma, traumatic event and potentially traumatic event

The word *trauma* is used inconsistently within the mental health field, referring at times to an event and at other times to psychological injury arising from an event. Literally, *trauma* means an injury or wound and so, in mental health terms, it refers to an injury or wound to the 'psyche': that is, damage to a person's emotional or psychological health with its biopsychosocial underpinnings.

Potentially traumatic event (PTE) will be used in these guidelines to refer to events that meet the DSM IV (American Psychiatric Association, 1994) stressor criterion for PTSD. This term reflects the importance of the subjective component of the experience. A particular event, regardless of how threatening it may seem, is not necessarily going to cause 'psychic injury' to all who experience it.

Traumatic event will be used in these guidelines to refer to an event that has actually resulted in psychic injury and *trauma* will be used to refer to the psychic injury itself.

2.1.2 Potentially traumatic events

As defined by DSM IV (American Psychiatric Association, 1994), PTEs include any threat, actual or perceived, to the life or physical safety of the individual, their loved ones or those around them. PTEs include, but are not limited to, war, torture, sexual assault, physical assault, natural disasters, accidents and terrorism. Experiences may be single or repeated events. By their very nature, some events are more likely than others to be experienced as extremely traumatic, and cause ongoing difficulties and clinically diagnosable symptoms of ASD and/or PTSD. Intentional acts of interpersonal violence, such as torture and assault, and prolonged and/or repeated events such as childhood sexual abuse and concentration camps are more likely than natural events to result in a traumatic response. It is important to note the definition of PTE's above includes "perceived" threat. As such, it is the appraisal of the event as a threat to safety or physical integrity that is the critical factor in determining whether an event is considered a PTE.

Although beyond the conceptualisation of PTEs in DSM IV it is important to recognise the potential for transgenerational effects of trauma, in which the impact of systematic torture, genocide or family violence is seen in mental health problems in the next generation.

Generally, events that do not include an element of serious physical threat are not considered PTEs even if they constitute significant threats to psychological integrity or well being. Thus, events such as divorce or separation, loss of a job, and verbal abuse/harassment would not be considered PTEs.

2.1.3 Common responses to potentially traumatic events

A degree of psychological distress is very common in the early aftermath of traumatic exposure and can therefore be considered a part of the normal response. In cases of severe traumatic events, most people may be symptomatic in the initial fortnight after the event. Traumatized people are likely to experience emotional upset, increased anxiety, and sleep and appetite disturbance. Some will have additional reactions such as fear, sadness, guilt or anger. In most cases, psychological symptoms of distress settle down in the days and weeks following the traumatic event as people make use of their customary coping strategies and naturally occurring support networks to come to terms with the experience. However, in a minority of people the symptoms persist and develop into ASD and/or PTSD

2.1.4 Resilience in the face of potentially traumatic events

While the primary focus of this guideline is the treatment of people who develop ASD and/or PTSD following traumatic experience, it needs to be emphasized that the majority of people exposed to trauma do not go on to develop these conditions (see for example Bonanno et al.'s (2006) investigation of the consequences of the 9/11 terrorist attacks in New York). Resilience, defined as “the ability to adapt and cope successfully despite threatening or challenging situations” (Agaibi & Wilson, 2005, p.198), is the usual outcome following traumatic exposure (Shalev et al., 2004).

2.1.5 Traumatic stress syndromes

When the individual's psychological distress following exposure to a traumatic event persists, and is severe enough to interfere with important areas of psychosocial functioning, it can no longer be considered a normal response to traumatic exposure. The possibility of a posttraumatic mental health syndrome or disorder, including ASD or PTSD should be considered. It should be noted that the range of other mental health syndromes including anxiety, affective, substance misuse or even psychotic disorders may be present either alone or together with ASD or PTSD.

2.2 Acute Stress Disorder (ASD)

After an individual has been exposed to a traumatic event they may experience significant distress and/or impairment in social, occupational or other important areas of functioning. When this lasts longer than two days, a diagnosis of Acute Stress Disorder (ASD) may be considered.

The DSM-IV (APA, 1994) requires six criteria to be met in order for the diagnosis of ASD to be made (see Table 1). Criterion A requires that the individual experiences or witnesses an event that involved the actual or threatened death or serious injury to self or others, and responded with fear, helplessness or horror. Criterion B refers to dissociative symptoms during or after the event (three or more of - a subjective sense of numbing, detachment or absence of emotional responsiveness, reduced awareness of one's surroundings, derealisation, depersonalisation, and dissociative amnesia). Criterion C requires one or more reexperiencing symptoms (reliving the event through one or more of – recurrent images, thoughts, dreams, illusions, flashbacks, sense of reliving the experience or distress on exposure to reminders of the event). Criteria D, E and F involve marked avoidance of reminders; marked anxiety or increased arousal, and evidence of significant distress or impairment, respectively. These symptoms must last for a minimum of two days and a maximum of four weeks following the

event, after which time a diagnosis of PTSD should be considered. Not surprisingly, a growing body of evidence indicates that individuals who experience ASD are at high-risk of developing PTSD (Difede et al., 2002; Harvey & Bryant, 1999b; Holeva et al., 2001). However, there is also a large body of evidence indicating that many of those who go on to develop PTSD did not meet criteria for ASD (e.g. Creamer et al., 2004). Thus, having an ASD diagnosis is predictive of PTSD, but not having an ASD diagnosis should not necessarily be interpreted as indicating a good prognosis.

Table 1: DSM-IV CRITERIA FOR ACUTE STRESS DISORDER

- A.** The person has been exposed to a traumatic event in which both of the following were present:
- (1) The person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death or serious injury, or a threat to the physical integrity of self or others
 - (2) The person's response involved intense fear, helplessness, or horror.
- B.** Either while experiencing or after experiencing the distressing event, the individual has three (or more) of the following dissociative symptoms:
- (1) A subjective sense of numbing, detachment or absence of emotional responsiveness
 - (2) A reduction in awareness of his or her surroundings (e.g., “being in a daze”)
 - (3) Derealisation
 - (4) Depersonalisation
 - (5) Dissociative amnesia (i.e., inability to recall an important aspect of the trauma)
- C.** The traumatic event is persistently re-experienced in at least one of the following ways: recurrent images, thoughts, dreams, illusions, flashback episodes, or a sense of reliving the experience; or distress on exposure to reminders of the traumatic event.
- D.** Marked avoidance of stimuli that arouse recollections of the trauma (e.g., thoughts, feelings, conversations, activities, places, people).
- E.** Marked symptoms of anxiety or increased arousal (e.g., difficulty sleeping, irritability, poor concentration, hypervigilance, exaggerated startle response, motor restlessness).
- F.** The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning or impairs the individual's ability to pursue some necessary tasks, such as obtaining necessary assistance or mobilising personal resources by telling family members about the traumatic experience.
- G.** The disturbance lasts for a minimum of 2 days and a maximum of 4 weeks and occurs within 4 weeks of the traumatic event.
- H.** The disturbance is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition, is not accounted for by Brief Psychotic Disorder, and is not merely an exacerbation of a preexisting Axis I or Axis II disorder.

2.3 Posttraumatic Stress Disorder (PTSD)

As seen in Table 2, DSM-IV requires six criteria to be met in order for the diagnosis of PTSD to be made. Criterion A defines the stressor, including features relating to the event itself (Criterion A1) and the response to the stressor (Criterion A2). The B, C, and D criteria refer to reexperiencing, avoidance and numbing, and hyperarousal symptom clusters respectively. One of five, three of seven and two of five criteria are required in each of those symptom clusters respectively to qualify for the diagnosis. Criterion E stipulates that the symptoms of clusters B, C and D need to have been present for at least one month. Criterion F requires that that the disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning. PTSD is specified as *acute* when the duration of the symptoms is less than three months, and *chronic* if the duration of the symptoms is three months or more. In instances where the onset of symptoms is at least six months following the event, the disorder is specified as *delayed onset*.

2.3.1 Reexperiencing Symptoms

The reexperiencing symptoms are often regarded as the hallmark feature of traumatic stress. Reexperiencing symptoms include intrusive and unwanted thoughts and images of the event and distressing dreams or nightmares. Reexperiencing symptoms can also include “flashbacks” where sufferers may lose awareness of their surroundings and become immersed in the memory of the event. These flashbacks may be so vivid that people feel as if they are experiencing the traumatic event again. People can become upset or distressed when reminded of what happened, and have intense physical reactions like sweating and rapid heart beat.

2.3.2 Avoidance and Numbing Symptoms

Avoidance and numbing symptoms are combined in DSM-IV but are generally understood to result from different underlying mechanisms. Avoidance is characterised by deliberate attempts to keep memories of the traumatic event out of mind. Such avoidance can result in a person going to extreme lengths to avoid people, places, and activities that trigger distressing memories. While avoidance symptoms involve effortful behaviour, numbing symptoms are involuntary. Numbing symptoms are reflected through a loss of interest in activities that formerly brought enjoyment, detachment or estrangement from others, restricted emotional responses (e.g., being unable to experience joy or love), and a sense of foreshortened future. These numbing symptoms are thought to particularly characterise more chronic and severe forms of the disorder. As such, they are usually considered to be a poor prognostic indicator.

2.3.3 Arousal Symptoms

PTSD is associated with a sustained increase in sympathetic nervous system activity, well beyond its adaptive function in response to the traumatic event. The individual experiences ongoing increased arousal, as though the ‘fear system’ has been recalibrated to a higher idling level. Increased arousal is evident in a range of symptoms such as poor concentration and memory, irritability and anger, difficulty in falling and staying asleep, being easily startled, and being constantly alert to signs of danger (hypervigilance).

Table 2: DSM-IV CRITERIA FOR POSTTRAUMATIC STRESS DISORDER

- A.** The person has been exposed to a traumatic event in which both of the following were present:
- (1) The person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death or serious injury, or a threat to the physical integrity of self or others
 - (2) The person's response involved intense fear, helplessness, or horror. Note: In children, this may be expressed instead by disorganised or agitated behaviour
- B.** The traumatic event is persistently re-experienced in one (or more) of the following ways:
- (1) Recurrent and intrusive distressing recollections of the event, including images, thoughts or perceptions. Note: In young children, repetitive play may occur in which themes or aspects of the trauma are expressed
 - (2) Recurrent distressing dreams of the event. Note: In children, there may be frightening dreams without recognisable content
 - (3) Acting or feeling as if the traumatic event were recurring (includes a sense of reliving the experience, illusions, hallucinations, and dissociative flashback episodes, including those that occur on awakening or when intoxicated). Note: In young children, trauma-specific reenactment may occur
 - (4) Intense psychological distress at exposure to internal or external cues that symbolise or resemble an aspect of the traumatic event
 - (5) Physiological reactivity on exposure to internal or external cues that symbolise or resemble an aspect of the traumatic event

Table 2: DSM-IV CRITERIA FOR POSTTRAUMATIC STRESS DISORDER (cont'd)

- C.** Persistent avoidance of stimuli associated with the trauma and numbing of general responsiveness (not present before the trauma), as indicated by three (or more) of the following:
- (1) Efforts to avoid thoughts, feelings or conversations associated with the trauma
 - (2) Efforts to avoid activities, places, or people that arouse recollections of the trauma
 - (3) Inability to recall an important aspect of the trauma
 - (4) Markedly diminished interest or participation in significant activities
 - (5) Feeling of detachment or estrangement from others
 - (6) Restricted range of affect (eg: unable to have loving feelings)
 - (7) Sense of a foreshortened future (eg: does not expect to have a career, marriage, children, or a normal life span)
- D.** Persistent symptoms of increased arousal (not present before the trauma), as indicated by two (or more) of the following:
- (1) Difficulty falling or staying asleep
 - (2) Irritability or outbursts of anger
 - (3) Difficulty concentrating
 - (4) Hypervigilance
 - (5) Exaggerated startle response
- E.** Duration of the disturbance (symptoms in Criteria B, C, and D) is more than 1 month.
- F.** The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
-

2.3.4 Associated features

In addition to these core symptoms, PTSD is also commonly associated with a range of features including anger/aggression (Forbes et al., 2003), guilt (Kubany et al., 1995; Kubany et al., 1996), dissociation (van der Hart et al., 2005) and physical health problems (Schnurr et al., 2005).

A subset of individuals with PTSD, more commonly those who have experienced events of an interpersonal, prolonged and repeated nature (e.g. childhood sexual abuse, imprisonment, torture), often referred to as Type II trauma (Terr, 1991), present with a constellation of characteristic features alongside the core PTSD symptoms. These features can include: impaired emotional control; self-destructive and impulsive behaviour; impaired relationships with others; hostility; social withdrawal; feeling constantly threatened; dissociation; somatic complaints; feelings of ineffectiveness, shame, despair or hopelessness; feeling permanently damaged; and a loss of prior beliefs and assumptions about their safety and the trustworthiness of others (van der Kolk et al., 2005). Issues of chronic self harm and/or suicidal ideation are more common in this group.

People exhibiting this constellation of features are often referred as having complex PTSD (Herman, 1992) or Disorders of Extreme Stress Not Otherwise Specified (DESNOS: APA; 1994).

2.3.5 Comorbid conditions

In chronic cases of PTSD (beyond 3 months) the core symptoms rarely exist in isolation. More commonly they exist alongside a number of the associated features described above as well as other comorbid mental health disorders. Epidemiological data drawn from the Australian National Mental Health & Well Being study (Creamer et al., 2001) found that 85% of men and 80% of women with PTSD also met criteria for another axis 1 disorder. Most commonly this included depression (51% of men and 65% of women), generalised anxiety disorder (40% of men and 22% of women), social phobia (23% of men and 13% of women), panic disorder (15% of men and 17% of women), alcohol abuse/dependence (37% of men and 12% of women), and drug abuse/dependence (22% of men and 15% of women). These figures are largely consistent with those found in the American National Comorbidity Survey (Kessler et al., 1995). A small number of studies examine the prevalence of comorbid personality disorder, although these are primarily studies of US male combat veterans with chronic PTSD. These studies (Bollinger et al., 2000; Southwick et al., 1993) suggest that a high comorbidity of personality disorder with chronic PTSD in combat veterans.

In addition to complexities arising from comorbidity, clinicians working with more chronic cases of PTSD often find themselves having to work with a myriad of psychosocial problems that have evolved secondary to the core disorder.

2.3.6 Prevalence and incidence of PTSD

Rates of PTSD should be considered in the context of rates of exposure to PTEs in the general community. Large community surveys (Kessler et al., 1995; Creamer et al., 2001) reveal that 50% - 65% of people report at least one PTE in their lives, with many reporting two or more events. In Australia, the most commonly reported PTEs are witnessing death or injury to others (reported by about 35% of the population),

accidents (27%), natural disasters (20%), and physical assaults (15%) (Creamer et al., 2001).

When examining PTSD rates, both prevalence and incidence figures are used. Prevalence refers to the proportion of a population that has had PTSD during a given period of time, and incidence refers to the rate at which new diagnoses of PTSD occur following exposure to a PTE.

Reports of lifetime prevalence of PTSD (percentage of the population who have had PTSD at some time in their lives), in community samples range between 5-10%. This can be interpreted to mean that approximately 15-25% of people exposed to PTEs have also had a PTSD diagnosis (Breslau, 2001). These lifetime prevalence rates may be somewhat misleading however, as around half those people who develop PTSD recover in the first 12 months regardless of treatment (Kessler et al., 1995). Reports of 12 month prevalence of PTSD (percentage of the population who have had PTSD in the past year) vary between 1.3% in Australia (Creamer et al., 2001) and 3.9% in the U.S. (Kessler et al., 1999).

An important risk factor for developing PTSD following a PTE is the nature of the traumatic exposure. Creamer et al. (2001) found the highest 12 month prevalence of PTSD was associated with a prior history of rape and molestation and that the lowest 12 month prevalence of PTSD was associated with natural disasters and witnessing someone being badly injured or killed. These findings closely resemble those of Kessler et al. (1995) from the US data. PTSD has traditionally been associated with military combat and amongst Australia's Vietnam veterans, the 6 month and lifetime prevalence of PTSD has been found to be 11.6%, and 20.9% respectively (O'Toole et al., 1996). Comparable, or slightly lower, rates have been found among veterans of other conflicts both in Australia and overseas (Creamer & Forbes, 2003). The prevalence of PTSD following acts of terrorism has been estimated at between 28 and 35% (Lee et al., 2002a).

Currently, prevalence rates of ASD in the general Australian community are not available. However, studies examining the incidence of ASD following particular PTEs have found rates of 16-21% following road traffic accidents (Harvey & Bryant, 1999a; Holeva et al., 2001), and 19% following burn injury (Difede et al., 2002).

2.3.7 The course of PTSD

Information about the course of PTSD has been derived from epidemiological studies (Kessler et al, 1995) that have asked respondents how many weeks, months or years after onset of symptoms they continued to have symptoms at least a few times per week. Kessler and colleagues (1995) used these retrospective reports to create 'survival curves' or models of the course of PTSD symptoms following exposure to a traumatic event. Their findings suggest that symptoms decreased most substantially in the first 12 months following the event and continued to decline over the following six years. Approximately 40% of people had ongoing PTSD that did not remit even after many years.

Higher rates of unremitting PTSD have been found in other populations. A study of Australian Vietnam veterans found that half those who reported having a diagnosis of PTSD at some point in their lifetime still had the disorder decades later (O'Toole et al.,

1996). Similar rates of chronic PTSD have been found in fire fighters after a major bushfire, where 56% of those who had the disorder following the fire still had it four years later (McFarlane & Papay, 1992). Data from several studies suggest that people who meet PTSD criteria at around six months post trauma are likely (in the absence of effective treatment) to show a chronic course with symptoms lasting for many decades (Kessler et al., 1995; Solomon, 1989).

PTSD is less likely to follow a chronic course with effective treatment. On the basis of several studies it is reasonable to assume that around one-third will make a good recovery following effective treatment, one-third will do moderately well and one-third are unlikely to benefit.

2.3.8 Economic burden of PTSD

Following a literature review of the population prevalence and societal cost of PTSD, Kessler (2000) concluded that, as a highly prevalent and impairing condition that is frequently associated with psychiatric comorbidity and broader societal costs including work impairment and reduced life course opportunities (educational attainment, teenage childbearing, marital instability and earning capacity), PTSD is a high burden disorder. Similarly, Khouzam et al (2005) noted that PTSD is often a chronic disorder that impairs functioning in many, if not all, areas of life with consequences extending beyond the individual to impact on family members and society as a whole.

One index of the societal costs of PTSD is the elevated rate of medical visits and other health service use amongst people with PTSD, compared to similar groups without PTSD. Populations studied include treatment seeking combat veterans (Calhoun et al., 2002), US Vietnam veterans (Schnurr et al., 2000), Australian Vietnam veterans (Marshall et al., 2000), female health organisation members (Walker et al., 2003), psychiatric outpatients (Switzer et al., 1999) and motor vehicle accident survivors (Chan et al., 2003). As yet there is no research that clearly identifies whether these increased health care costs are a direct result of the PTSD or are indirectly accounted for by the poor physical health commonly associated with PTSD (O'Donnell et al., 2005).

In terms of direct treatment costs, Issakidis et al (2004) found that PTSD treatment has higher per case per year costs than any of the other anxiety disorders (\$1,224 compared to \$1,188 for panic/agoraphobia, \$1,011 for social phobia and \$795 for generalised anxiety disorder). According to this study, individuals with PTSD constitute one third of people treated for an anxiety disorder, but their treatment including mental health, general health and pharmaceutical services, accounts for 40% of the total cost of treatment for all anxiety disorders. In Australia in the 1997/8 financial year, this amounted to \$158.2 million.

Unfortunately, there is evidence that current treatment practices for PTSD are not cost-effective. The Australian National Survey of Mental Health and Wellbeing (Issakidis et al 2004) has found that PTSD is under treated in Australia, and when it is treated, optimal care is not always provided. Data from the survey suggest that only 40% of the respondents with PTSD were in current contact with health services for their condition. Of those, 64% had received some component of an evidence-based intervention - medication and/or CBT - but the pattern of care was not optimal given

the current evidence. Current treatment practices, when compared to an optimal treatment regime derived from the literature, reveal a greater emphasis on GP prescribed medication and less emphasis on psychological interventions from psychologists and psychiatrists. The authors argued that this optimal care regime would be no more expensive but would result in increased efficacy of care and improved population cost-effectiveness as measured by a decrease in *years lived with disability* (Issakidis et al, 2004).

In addition to direct health care costs, PTSD has additional indirect costs through work impairment. Kessler and Frank (1997) found that PTSD was associated with an average of 3.6 lost working days per month, a rate similar to that found with depression. Given the morbidity and cost of this disorder, prompt recognition and treatment for PTSD are important public health issues (Khouzam et al., 2005).

2.3.9 Posttraumatic mental health disorders: Key differences between ASD and PTSD

There is significant overlap in the diagnostic criteria for the two posttraumatic mental health conditions, ASD and PTSD, described above. The key distinguishing feature between the two disorders is the duration of symptoms required for the diagnosis to be made. ASD is diagnosed between 2 days and one month following the traumatic event while PTSD requires that the symptoms be present for at least one month following the traumatic event. Acute PTSD is diagnosed if symptoms have persisted for between 1 and 3 months; chronic PTSD is diagnosed if symptoms have persisted for 3 months or more. In terms of symptom constellation, the diagnoses differ only in emphasis; ASD requires a number of dissociative symptoms not included in PTSD while PTSD places greater emphasis on avoidance symptoms.

2.4 Screening, Assessment and Diagnosis

People with ASD and PTSD will not necessarily present to their doctor or mental health professional with expressed concern about a traumatic experience in the first instance. They may present with any of a range of problems including mood disorders, anger, relationship problems, poor sleep, sexual dysfunction or physical health complaints such as headaches, gastrointestinal problems, rheumatic pains, and skin disorders. Their traumatic experience may not even be mentioned. This problem arises, in part, due to the avoidance of people with this condition which prevents them speaking about it or seeking assistance. It also needs to be acknowledged that there remains a social stigma attached to mental health problems and the fear of discrimination may be a barrier to some people reporting their symptoms. Furthermore, there is stigma attached to some forms of traumatic experience such as sexual assault which may discourage the individual from disclosing the experience. The practitioner needs to be sensitive to these issues when screening for PTSD and consider this when selecting of cut-off scores in the self-report instruments. This problem emphasises the importance of empirically establishing the optimal cut-offs in different populations.

In seeking to understand the origins of presenting problems, the practitioner should routinely enquire about any experience of stressful or traumatic events, recently or in the past. If a traumatic experience is suspected, the practitioner may utilise a

traumatic events checklist. If the person endorses any events on the checklist, then it is recommended a brief PTSD screening tool be administered.

There is a range of PTSD screening measures currently in use (see Brewin, 2005, for a recent review). These include the SPAN (Meltzer-Brody et al., 2004: 4 items); the BPTSD-6 (Fullerton et al., 2000), DRPST (Chou et al., 2003: 7 items) and a four question measure published in the US Veterans Affairs / Department of Defense PTSD treatment guideline document (US VA/DoD, 2004). There is probably little to choose between the various measures;. The following is an example of a screening measure (Breslau et al., 1999) that has been empirically validated.

1. *Do you avoid being reminded of the experience by staying away from certain places, people or activities?*
2. *Have you lost interest in activities that were once important or enjoyable?*
3. *Have you begun to feel more distant or isolated from other people?*
4. *Do you find it hard to feel love or affection for other people?*
5. *Have you begun to feel that there is no point in planning for the future?*
6. *Have you had more trouble than usual falling or staying asleep?*
7. *Do you become jumpy or easily startled by ordinary noise or movements?*

Research into this scale has established that, among trauma exposed individuals, 71% of people who score positively on 4 or more items have a diagnosis of PTSD and 98% of people who score less than 4 do not have a diagnosis of PTSD. On this basis, it can be said that if 4 or more questions are answered positively, a PTSD diagnosis is likely. This level of diagnostic accuracy is equal or superior to the more lengthy measures.

The section above is predicated on the notion of people presenting to the practitioner for care and the implementation of screening in this context. It is also important to acknowledge that there are populations who may be identified as higher risk on the basis of their exposure to a major disaster, occupational role such as emergency service and military populations or other population wide exposure such as refugees for whom screening may be delivered on a more systematic basis. This has implications for service planning. Screening high-risk populations is a way of identifying those who are at risk and targeting the resources available to those who are going to benefit from the provision of an evidence-based intervention. Of critical importance to obtaining evidence-based care is the existence of an adequate pool of trained and experienced clinicians within the community. Currently there are a number of locations where individuals with posttraumatic stress disorder have significant difficulties accessing evidence-based care for these reasons.

2.4.1.1 Recommendations

2.4.1.1.1 *For people presenting to primary care services with repeated non-specific physical health problems it is recommended that the primary care practitioner consider asking whether the person has experienced a traumatic event and describe some examples of such events. (GPP)*

2.4.1.1.2 Service planning should consider the application of screening of individuals at high-risk for PTSD after major disasters or incidents. (GPP)

2.4.1.1.3 Programs responsible for the management of refugees should consider the application of culturally appropriate screening for refugees and asylum seekers at high-risk for developing PTSD (GPP)

2.4.1.1.4 Screening should be undertaken in the context of a service system that includes adequate provision of services for those who require care. (GPP).

2.4.2 Comprehensive assessment of PTSD

PTSD is often associated with diffuse and broad patterns of symptoms and impairments, and clinical presentations vary according to the unique characteristics and circumstances of the individual. As such, comprehensive assessment processes are necessary. Comprehensive assessment includes details of the person's personal history including, but not limited to, trauma history. With regard to trauma history, pretrauma history (encourage disclosure of any prior traumatic experience through routine enquiry), the traumatic event itself, their pretrauma, current and past psychosocial functioning (past psychosocial functioning is particularly important where trauma has involved early sexual or physical abuse), the presence and course of PTSD symptoms, and any comorbid problems (including substance use) should all be considered. Particular attention should also be paid to physical health issues. This may include issues related to injury arising from the traumatic incident to health behaviour change following the incident, to concurrent or developing physical health problems and potential medications prescribed for any physical health issues. Broader quality of life indicators such as physical health, marital and family situation and occupational, legal and financial status should also be assessed. For instance, good social support is associated with recovery (Brewin et al., 2000; Ozer et al., 2003) and, therefore, the person's support network should be examined. Attention should be directed towards key issues to consider in formulating treatment plans, including prior mental health problems especially depression (Ozer et al., 2003), prior treatment experience and pretrauma coping strategies. The comprehensive assessment should include assessment of risk of self harm, suicide and harm to others. PTSD sufferers who are suicidal or homicidal need to be closely monitored. Attention should also be paid in the assessment, to the person's resilience factors and strengths.

It is important to note that comprehensive assessment should not be confined to the initial period of care but should be an ongoing process. Throughout treatment, the person's wellbeing and progress should be monitored and reassessed in an ongoing way. This becomes particularly critical where treatment does not appear to be helping the person to recover. In these circumstances the practitioner should thoroughly reassess and address co-existing psychosocial problems and more thoroughly assess personality.

2.4.2.1 Recommendations:

2.4.2.1.1 A thorough assessment is required, covering PTSD and related diagnoses, quality of life and psychosocial functioning, trauma history, general psychiatric status (noting extent of comorbidity), physical health,

substance use, marital and family situation and vocational and social status. (GPP)

2.4.2.1.2 *Assessment should include assessment of strengths and resilience (GPP)*

2.4.2.1.3 *Assessment and intervention must be considered in the context of the time that has elapsed since the traumatic event occurred. Assessment needs to recognise that whereas the majority of people will display distress in the initial weeks after trauma exposure, most of these reactions will remit within the following three months. (GPP)*

2.4.2.1.4 *Assessment and monitoring should be undertaken throughout treatment. When adequate progress in treatment is not being made, the practitioner should revisit the case formulation, reassess potential treatment obstacles and implement appropriate strategies (GPP)*

2.4.3 Diagnosis

In most clinical settings, an unstructured interview comprises the primary assessment strategy. However because PTSD can be grounds for compensation there may be a need for objective assessment that will stand up to more rigorous scrutiny. Regardless of the context, the clinician must maintain a balance between providing empathic support to a distressed person while obtaining reliable and objective information. For a comprehensive overview of assessment issues in PTSD see Simon (1995) and Wilson & Keane (1997).

There is currently no agreed *gold standard* with which to make a comprehensive diagnostic assessment for PTSD. Rather, clinicians should adopt a multifaceted approach incorporating information from a variety of sources. In clinical settings, this may comprise unstructured psychiatric interviews (to collect the information detailed in the previous paragraph), structured clinical interviews, self-report inventories, and (where possible) the report of significant others in the person's life. In research contexts, the addition of psychophysiological measures which assess sympathetic nervous system activity through measures such as heart rate, blood pressure and perspiration, may provide an extra degree of objectivity, which is rarely practical in clinical settings.

2.4.4 Differential diagnosis

It is important to remember that PTSD is not the only mental health consequence of exposure to traumatic events. Other common diagnoses for consideration as potential differential diagnoses include depression, other anxiety disorders such as panic disorder, generalised anxiety disorder and specific phobias, substance abuse/dependence and adjustment disorders. Consideration should also be given to the diagnosis of complicated grief (formerly known as traumatic grief), following bereavement, which has received increasing demand for inclusion as separate diagnostic entity in DSM (see Lichtenthal et al., 2004, for a review). Proposed criteria for CG (Horowitz et al., 1997; Prigerson et al., 1999) contain some similarities to PTSD in regard to symptoms such as intrusive thoughts and memories of the deceased and avoidance of reminders of the loss. Importantly however, complicated grief is also defined by grief-specific symptoms such as yearning and searching for the deceased, which differentiate it from PTSD.

Survivors of prolonged or repeated traumatic events (e.g. childhood sexual abuse, torture) are more likely to experience a number of the associated features of PTSD. There is substantial symptom overlap between this more complex PTSD presentation and Borderline Personality Disorder, and so careful assessment is required to differentiate between these two diagnoses.

2.4.4.1 Recommendations

2.4.4.1.1 Assessment should cover the broad range of potential posttraumatic mental health problems beyond PTSD (GPP)

2.4.5 “Recovered memories”

A recovered memory is thought to be the recollection of a memory that has been unavailable to deliberate recall for some period of time. This is distinct from incomplete or fragmented memories that may be associated with PTSD. The issue of recovered memories has most commonly arisen in the area of childhood abuse. It is controversial, and has attracted debate in both the professional and public arenas. While it is possible that trauma memories can be both forgotten and then remembered, and that “false memories” can be suggested and remembered as true, the former is arguably rare. Therapy that attempts to recover otherwise forgotten memories of childhood abuse as the basis for relieving emotional distress has been criticised for lacking a sound theoretical basis, failing to consider the fallibility of memory and using techniques such as suggestion that increase memory distortion and confabulation. In the absence of corroboration, it is not possible to unequivocally determine the validity of recovered memories.

Risk associated with the concept of recovered memory can be minimised when clinicians are trained to professional standards, conduct full assessments at the start of treatment, adopt a neutral stance towards a history of abuse avoiding preconceived beliefs about factors that may or may not be causing the presenting problems, and avoid use of techniques that increase suggestibility and memory distortion. In the absence of corroboration of new memories of childhood abuse, treatment should enable the person to arrive at their own conclusions with some understanding of memory processes, and to adapt to uncertainty when it persists.

2.4.6 Symptom exaggeration and malingering

PTSD is the only mental health condition with experience of a traumatic event as part of the diagnosis. Issues of financial compensation can therefore arise with PTSD, arguably more than for any other disorder. Studies investigating whether compensation seeking affects assessment processes have had mixed results and so any relationship between financial incentives and symptom reporting in PTSD is presently unclear. It is important however, to consider the possibility of symptom exaggeration and malingering in the assessment of PTSD.

The possibility of symptom exaggeration should be carefully considered in any of the following circumstances: the person reports all 17 PTSD symptoms; the person emphasises reexperiencing, (rather than avoidance and numbing) symptoms; or the person does not report sexual dysfunction or sleep disturbance. In order to assist in

clarification of this issue, clinicians should not be satisfied with a simple “yes/no” responses to questions, but should request further elaboration of reported symptoms (e.g., “tell me about the last time you experienced that – what was it like?”). During the interview the clinician should remain alert for PTSD symptoms that are directly observable (e.g., hypervigilance and flattened affect) and to any contradictions in the person’s reports (e.g., complete inability to work but retention of an active social life).

It needs to be emphasised that the issue of symptom exaggeration and malingering primarily arises in the context of litigation, compensation claims and contested cases rather than in the course of routine clinical practice. Even in these settings, the practitioner must retain and convey empathy for the person to avoid the risk of compounding suffering by being interviewed in an interrogatory fashion.

There are of course factors other than financial gain that can contribute to prolonged symptoms. Secondary gain in social, family or occupational settings may exert a powerful influence on the individual’s sick role and ongoing disability, of which they are unaware.

2.4.7 Assessment instruments

Diagnostic instruments for PTSD include both structured clinical interviews and self-report measures.

2.4.7.1 Structured clinical interviews

Structured clinical interviews provide the optimal strategy for making a reliable clinical diagnosis and an indication of symptom severity. For a competent, well-trained clinician, these measures combine a standardised and objective instrument with an element of clinical judgment. The questions directly address PTSD symptoms and an objective scale determines whether each is sufficiently severe to meet criteria.

The Clinician Administered PTSD Scale (CAPS: Blake et al., 1995; Weathers et al., 2001) is a psychometrically robust instrument designed to overcome many of the limitations of other structured PTSD interviews. Each symptom is assessed for intensity and frequency and, where possible, is behaviourally defined. While the CAPS is highly recommended in research settings, it is a little complex for use in routine clinical practice. Several other well validated structured PTSD interviews, which are briefer and simpler to administer, are appropriate in this context (see Weiss, 1997, for a review). Two that are strongly recommended include the PTSD Symptom Scale Interview (PSS-I: Foa et al., 1993) and the Structured Interview for PTSD (SIP: Davidson et al., 1997).

2.4.7.2 Self-Report Measures

There are a variety of general and population-specific self-report measures available to assess PTSD symptoms and a number of comprehensive reviews of measures are available (e.g. Norris & Riad, 1997; Solomon et al., 1996). The best scales are psychometrically robust and relatively non-intrusive. While these measures provide a valid assessment of the person’s own perception of his/her symptoms without influence from the interviewer, their weakness lies in the potential for symptom exaggeration or minimisation. They are also limited in their diagnostic accuracy as they pick up general feelings of distress more reliably than specific symptoms. Accordingly, it is not appropriate to rely on self-report measures as the only (or even

the primary) diagnostic tool. Rather, they provide a useful screening device prior to more intensive interview procedures, or to assess symptom change as a function of treatment through repeated administration (Forbes et al., 2001).

Several established scales have been in use for decades and continue to be popular among clinicians and researchers (e.g. the Impact of Events Scale, Horowitz et al., 1979). However the diagnostic criteria have evolved in recent years and it is recommended that newer scales that are consistent with the current diagnostic criteria be used where possible. One example is the PTSD Checklist (PCL: Weathers et al., 1993) which assesses the 17 DSM-IV PTSD symptoms, with each rated on a five-point scale from “not at all” to “extremely”. The scale takes only five minutes to complete and possesses excellent psychometric qualities (Blanchard et al., 1996; Forbes et al., 2001). A score of 50 is recommended as the diagnostic cutoff. Separate forms are available for military (M) and civilians (C) stressors. The self-report version of the PTSD Symptom Scale (PSS) (PSS-SR: Falsetti et al., 1993) is similar to the PCL, while the Davidson Trauma Scale (DTS: Zlotnick et al., 1996) allows for both frequency and intensity ratings. In the final analysis, there is probably little to choose between these scales; any would be a useful addition for clinicians and researchers alike. It is worth noting however that the PCL is the only scale available in the public domain.

In addition to symptom measures, a broader quality of life instrument that measures progress in recovery and rehabilitation would be of value. One of the most commonly used quality of life measures is the short form of the WHOQOL, the WHOQOL Bref (WHOGroup 1998).

Although there has been increased interest in resilience, there is not yet sufficient data from which to identify an optimal or recommended measure at this point.

2.4.7.3 Recommendations

2.4.7.3.1 It is recommended that practitioners be guided in their assessment of PTSD, comorbidity and quality of life by the available validated self-report and structured clinical interview measures (GPP)

2.4.7.3.2 It is recommended that practitioners also use self-report measures to support their assessments of treatment outcomes over time. (GPP)

2.5 Intervention Planning

2.5.1 Factors influencing treatment outcome

There is a range of factors that have been found to potentially influence treatment outcome that should be considered when planning interventions. These factors include comorbid conditions, development of a working or therapeutic alliance, and treatment expectancy. In terms of influence of comorbidity on treatment response, the data are mixed and inconsistent. Several studies identify features such as depression (van Minnen et al., 2002), generalised anxiety disorder (TARRIER et al., 2000), borderline personality disorder (Feeny et al., 2002; Forbes et al., 2002), anger (Foa et al., 1995; Forbes et al., 2005; Forbes et al., 2003), alcohol use disorder (Perconte & Griger,

1991; Steindl et al., 2003), social alienation (Ehlers et al., 1998; Forbes et al., 2002), and emotional dysregulation (Cloitre et al., 2002) as negatively influencing outcome. On the other hand, a number of studies have failed to find these outcomes, suggesting that the influence of comorbidity on outcome may be sample specific (Van Minnen et al., 2002) or that more specific predictive components of these factors have not yet been identified.

The establishment of a good therapeutic alliance has been found to improve the outcome of PTSD treatment (Cloitre et al., 2002; Cloitre et al., 2004). This is consistent with findings for a range of other anxiety and mood disorders (Hatcher & Barends, 1996). Unfortunately, for people who have experienced a severe interpersonal trauma such as torture or childhood sexual abuse, the establishment of a trusting therapeutic relationship can often be particularly difficult. In most cases this difficulty will be overcome if the practitioner is able to convey genuine empathy and warmth towards the person.

There is also evidence that a person's expectation of the outcome of their treatment is positively related to actual outcomes. This effect of treatment expectancy has been found with Vietnam veterans with PTSD (Collins & Hyer, 1986), and others with PTSD, generalised anxiety disorder (Borkovec & Costello, 1993; Devilly & Borkovec, 2000) and social phobia (Chambless et al., 1997).

Interestingly, the evidence suggests that demographic variables such as age, marital status, employment and level of education are unrelated to treatment outcome (Ehlers et al., 1998; Foa et al., 1991; Munley et al., 1994). While female gender may be predictive of PTSD development, findings suggest either that females respond better to treatment (TARRIER et al., 2000) or no significant gender differences in outcome (Jaycox et al., 1998; Marks et al., 1998). Other predictors such as education, IQ and marital status have also been found to be unrelated to outcome

It is often speculated that outcomes are compromised in people seeking compensation for PTSD, however few studies have investigated this issue. DeViva and Bloem (2003) did not find differences in PTSD treatment outcomes between veterans seeking compensation and those who were not, although neither group showed significant posttreatment improvement. Fontana and Rosenheck (1998) also found that compensation seeking did not affect PTSD treatment outcomes for veterans undergoing outpatient treatment or short term inpatient programs. They did however find that compensation seeking was associated with worse treatment outcomes for veterans undergoing long term inpatient programs that automatically trigger increased benefits.

2.5.1.1 Recommendations (Please not also recommendations regarding PTSD and comorbidity in section 4.1.11.5)

2.5.1.1.1 Mental health practitioners are advised to note the presence and severity of comorbidities in their assessments, with a view to considering their implications for treatment planning. (GPP)

2.5.1.1.2 *The development of a robust therapeutic alliance should be regarded as the necessary basis for undertaking specific psychological interventions and may require extra time for people who have experienced prolonged and/or repeated traumatic exposure (GPP)*

2.5.1.1.3 *Mental health practitioners should provide a clear rationale for treatment and promote realistic and hopeful outcome expectancy. (GPP)*

2.5.2 Treatment goals

In general terms the goals of treatment of PTSD include reduction in PTSD symptoms and achieving optimal psychosocial functioning. While much of the evidence-based literature focuses on the goal of symptom reduction, the practitioner should not lose sight of the broader wellbeing and quality of life issues. In all cases, the goals of treatment should be established collaboratively with the person, guided by best practice recommendations and a comprehensive assessment of the individual as outlined above. In terms of symptom focused treatment, prominent anxiety, anger and guilt all have varying implications for treatment. For some, especially those who have been subjected to protracted child sexual abuse or torture, clinical interventions often need to focus initially on symptoms of dissociation, impulsivity, emotional lability, somatisation and interpersonal difficulties (Foa et al., 2000).

Optimal recovery from PTSD requires a focus on wellbeing and rehabilitation from the outset. Immediate needs for practical and social support should be assessed. The family and broader system of care should be engaged early and provided with information about PTSD as well as being involved in the collaborative care and recovery plan as far as is possible. Attention should be paid to vocational rehabilitation needs from the outset, which may include supporting the individual's capacity to stay at work.

While the treatment of all adults with PTSD should have a rehabilitation focus, for those with chronic PTSD, improvements in psychosocial functioning may be the primary goal over and above reduction of PTSD symptoms.

2.5.2.1 Recommendations

2.5.2.1.1 *The practitioner should assess immediate needs for practical and social support and provide education and referrals accordingly (GPP)*

2.5.2.1.2 *Appropriate goals of treatment should be tailored to the unique circumstances and overall mental health care needs of the individual and established in collaboration with the person (GPP)*

2.5.2.1.3 *From the outset, there should be a collaborative focus on recovery and rehabilitation between the person and practitioners and, where appropriate, family members (GPP)*

2.5.3 Cultural and linguistic diversity

Australian adults with PTSD come from diverse ethnic and cultural backgrounds, with English a second language for many. Services should be made as accessible as possible with information available in a number of different languages and distributed

through general practitioners and health centres that provide primary care services to various ethnic and cultural groups. Further, interpreters should be available as required. Several issues for consideration when working with interpreters are included in Section 7.2 Refugees and Asylum Seekers. When working with an individual from a non-English speaking background, the practitioner should familiarise themselves with the person's cultural background and liaise with population-specific health care providers as necessary to understand cultural expressions of distress and support the appropriate applications of the interventions described in these guidelines.

2.5.3.1 Recommendations

2.5.3.1.1 Recommended treatments for PTSD should be available to all Australians regardless of cultural and linguistic background (GPP)

2.5.4 The impact of PTSD on family

The impact of PTSD can extend beyond the individual directly affected, to those around them – family and close friends. As such, the practitioner should consider the support and treatment needs of those close to the person with PTSD as well as the person's own needs. In involving family members, the person's confidentiality must be respected and the family members' clinical needs considered. In exceptional circumstances, where there are issues of risk of harm to self or others, family involvement may need to occur without the person's consent.

Family members can be affected both directly and indirectly by the person's PTSD symptoms, and may even develop emotional difficulties of their own, as a result. The impact of PTSD on the individual can often lead to him or her becoming more difficult to get along with, for instance becoming more irritable or angry, withdrawing from family involvement, or drinking to excess. Additional problems such as being unable to cope at work may emerge, leading to financial pressures for the family. Family members may adjust their own lives in an attempt to support the family member with PTSD or to conceal difficulties from those outside the family.

Over time, family members may develop emotional problems of their own. In some cases, these may mirror the problems of the person with PTSD, for example, adopting similar views of the world as a dangerous place and resultant fear and avoidant behaviours. In other cases, emotional problems of family members may be in response to living with the person with PTSD, for example, developing feelings of helplessness and hopelessness if the PTSD sufferer's condition remains untreated and unchanged over time, or turning to alcohol to avoid having to face the problems at home.

2.5.4.1 Recommendations

2.5.4.1.1 Wherever possible family members should be included in assessment processes, education and treatment planning, and their own needs for care considered alongside the needs of the person with PTSD (GPP).

2.5.5 General professional issues

This guideline document makes recommendations about treatment for people with ASD and PTSD on the assumption that treatment is being provided by appropriately

qualified and professionally supported practitioners. In effect this means that individual practitioners should not deliver interventions that are beyond their level of expertise given available training and support.

It needs to be recognised that various practitioners will contribute to the care of the individual with PTSD in different ways. In most cases the specialist symptom focused interventions will be undertaken by psychiatrists, psychologists and other mental health practitioners specifically trained in recommended treatments, while occupational therapists, rehabilitation counsellors and social workers are more likely to address family, social and occupational recovery and rehabilitation issues. Ideally, the general practitioner will have an existing relationship with the individual that allows them to provide holistic care and support to the person and family over time. Where a number of practitioners are involved in care, the general practitioner is well placed to assume overall management of care, making appropriate referrals and coordinating the contribution of other practitioners. The individual, their family and carers also play a critical role in support and recovery. Effective collaboration between relevant people is important for optimal care of the person with PTSD.

Unfortunately, this ideal circumstance is not always possible, most notably in rural and remote parts of Australia where a visiting nurse or general practitioner may be the sole health professional in the region. In these circumstances the responsibility for care of people with ASD and PTSD may largely rest with these primary care practitioners. It needs to be recognised that these practitioners are unlikely to have the time or training to undertake the full range of recommended psychological and psychosocial rehabilitation interventions for ASD and PTSD. Their role is more likely to involve screening, assessment and general psychological interventions such as psychoeducation and arousal management as well as overall mental health care. Where the PTSD sufferer is using self help materials (e.g. web-based treatment) the primary care practitioner may also offer support and monitoring. Wherever possible the person should be referred to an appropriately trained mental health practitioner for time limited specialist psychological treatment and to provide ongoing consultation to the primary care practitioner. To address psychosocial rehabilitation needs the primary care practitioner should ideally consult with a psychosocial rehabilitation specialist in planning interventions. In their care of people with ASD and PTSD primary care practitioners should be supported with provision of education and training material that can be accessed remotely, for example via the internet.

All practitioners in the field of posttraumatic mental health need to be aware of the potential adverse impacts of the work on themselves. Health professionals can be at risk of stress or adverse psychological reactions if they do not receive sufficient training and support. Responsibility for self-care should be shared between the individual practitioner and where appropriate their employer organisation. With evidence that isolation is a risk factor for developing stress related problems, the needs of practitioners working in isolated rural and remote communities again warrant special consideration. For these practitioners routine training and support needs may need to be addressed remotely for example via the internet and teleconferencing. General practitioner *Balint Groups* that offer peer support to practitioners who are geographically isolated in their work, operate in some areas of Australia (Benson & Magraith, 2005).

2.5.5.1 Recommendations

- 2.5.5.1.1** *Primary care practitioners, especially in rural and remote areas, who assume responsibility for the care of people with ASD and PTSD in the absence of specialist providers should be supported with accessible education and training (GPP)*
- 2.5.5.1.2** *In their self-care, practitioners should pay particular attention to skill and competency development and maintenance including regular supervision, establishing and maintaining appropriate emotional boundaries with PTSD sufferers, and effective self-care including maintaining a balanced and healthy lifestyle and responding early to signs of stress (GPP).*
- 2.5.5.1.3** *For those practitioners who work in an organisational context, broader policies and practices should support individual practitioners in these self-care measures. (GPP)*

3 Interventions

There is a range of psychological and pharmacological interventions currently used in the treatment of people with ASD and PTSD. Of course in routine clinical practice these interventions do not occur in isolation but in the context of a trusting therapeutic relationship and in many cases, broader mental health care for a range of associated posttraumatic mental health issues.

The systematic evidence review underpinning the development of these guidelines investigated the range of current treatments used for people with PTSD, people with ASD and “treatment for all” following exposure to a traumatic event. In this section, each of the treatments specified in the research questions will be described. **Please note that the interventions described in this section are not necessarily recommended treatments for ASD and PTSD.**

3.1 Psychological interventions

3.1.1 Trauma-focused CBT

CBT is a short term, structured psychological intervention that aims to address the emotional, cognitive and behavioural sequelae of exposure to traumatic events. CBT strategies are derived from learning and behavioural theories. They include preparatory work in the form of psychoeducation and arousal management along with exposure techniques and cognitive therapies.

Exposure therapy has long been established as an effective treatment for a range of anxiety disorders. The key objective of exposure therapy is to help the person confront the object of their anxieties. A fundamental principle underlying the process of exposure is that of *habituation*, the notion that if people can be kept in contact with the anxiety provoking stimulus for long enough, their anxiety will inevitably reduce. This may occur within an exposure session or across a series of sessions. In the case of PTSD, this means confronting the memory of their traumatic experiences in a controlled and safe environment (imaginal exposure), as well as confronting trauma-related avoided situations through *in vivo* exposure to external situations. Exposure therapy, beginning with Foa’s Prolonged Exposure (PE) for PTSD, has become the cornerstone of psychological treatment of PTSD.

Beck introduced cognitive therapy (CT) into the treatment literature in the 1970s, as a treatment for depression. Since then it has been successfully used in the treatment of a range of other emotional disorders including anxiety disorders and to some extent the psychoses and personality disorders (see Beck, 2005, for an overview). In the treatment of PTSD, cognitive therapy helps the individual to identify, challenge and modify any biased and distorted thoughts and memories of their traumatic experience as well as any subsequent maladaptive or unhelpful beliefs about themselves and the world they may have developed.

Resick’s Cognitive Processing Therapy (CPT) has been developed for sexual assault victims with PTSD. The therapy combines a small component of exposure to the

traumatic memory, with systematic cognitive work that addresses themes of safety, trust, power/control, esteem, and intimacy.

3.1.2 Eye movement desensitization Reprocessing (EMDR)

EMDR is based on the assumption that during a traumatic event, overwhelming emotions or dissociative processes may interfere with information processing, and lead to the experience being stored in an unprocessed way disconnected from existing memory networks. In EMDR the person is asked to focus on trauma-related imagery, negative thoughts, and body sensations while simultaneously moving their eyes back and forth following the movement of the therapist's fingers across their field of vision for 20-30 seconds or more. This process may be repeated many times. It is proposed that this *dual attention* facilitates the processing of the traumatic memory into existing knowledge networks, although the precise mechanism involved is not known.

It is important to note that EMD/ and then EMDR over time has increasingly included more treatment components that would be considered core CBT interventions. These include cognitive interweaving (cognitive therapy); imaginal templating (rehearsal of mastery or coping responses to anticipated stressors) and standard in vivo exposure. Combined with its initial inclusion of imaginal focus on traumatic images, EMDR now includes most of the core elements of standard trauma focused CBT. In addition, the protocol has shifted from a single session treatment to a twelve session protocol with the above elements included, comparable in length to standard trauma focused CBT.

Given the above, there is a case for considering EMDR, as reflected in its current protocol, as a variant of trauma focused CBT with a novel component, rather than as a separate treatment. However, for consistency with other international guidelines and given the view of the developer of the initial EMDR techniques that it is atheoretical, for the purposes of these guidelines EMDR will be considered as a separate intervention.

3.1.3 Brief psychodynamic psychotherapy

Psychodynamic therapy is a method of treatment that encourages the individual to use the supportive relationship with a therapist and the transference that occurs within that relationship, to verbalise and reflect upon their experiences. This process allows unconsciously held memories, thoughts and emotions to be brought into conscious awareness, which in turn allows the cognitive, emotional and social aspects of experience to be integrated into a meaning structure that helps the person to accept and adapt to their experiences. Brief models of psychodynamic psychotherapy have been developed for the treatment of PTSD following recent traumatic events. Brief psychodynamic therapy involves a specific trauma focus whereby the individual is encouraged to put their experience into words and examine the meaning that the event and surrounding circumstances holds for them, and thereby integrate the experience.

3.1.4 Stress management

Stress management interventions cover a broad range of cognitive, behavioural and physiological techniques aimed at reducing levels of arousal and modifying lifestyle factors that contribute to an individual's level of stress or anxiety. The application of stress management to PTSD aims to reduce arousal symptoms and address the impact of anxiety and avoidance symptoms on the individual's lifestyle. Core components of

stress management used in PTSD include relaxation training, controlled breathing (to counter hyperventilation), adaptive *coping statements* for use when confronting feared or avoided situations, and *thought stopping* distraction techniques.

3.1.5 Supportive counselling/therapy

Supportive counselling is characterised by the development of a therapeutic relationship that focuses on aspects of a person's current life situation looking to address and solve current issues or problems. In PTSD supportive counselling addresses problems arising from posttraumatic psychopathology as well as general circumstances. It aims to help the individual better understand and help themselves through the application of practical problem solving and coping strategies. The level of therapist direction and advice varies in supportive counselling.

3.1.6 Narrative exposure therapy (NET)

NET is a standardised short term intervention adapted from exposure therapy for survivors of torture and war exposed to numerous traumatic experiences. In NET the person is asked to construct a complete narrative of their life, focussing in detail on the traumatic events and elaborating on the associated thoughts and emotions. It is proposed that NET works in two ways: promoting habituation to traumatic memories through exposure, and reconstructing the individual's autobiographic memory.

3.1.7 Hypnosis/Hypnotherapy

Hypnotherapy is the therapeutic application of hypnosis to various mental health problems. Hypnosis involves a form of dissociation in that a state of heightened mental focus and suggestibility is induced, that allows the individual to better control their symptoms. Hypnosis is thought to be of particular value for people with ASD and PTSD because of the maladaptive dissociation involved in some of the symptoms. Hypnosis is used in PTSD in addressing traumatic memories as well as increasing control over hyperarousal symptoms.

3.1.8 Interapy

Interapy is an internet-mediated therapy. The therapist and PTSD sufferer communicate via a computer, which is designed to treat posttraumatic stress symptoms and pathological grief, but not a full PTSD diagnosis. Lange et al. (2003b) suggest that this approach is particularly useful for people living in remote areas, for those who are physically disabled and have restricted mobility, or who are unwilling to seek face-to-face therapy due to anxiety or fear of stigmatisation. Treatment includes psychoeducation, exposure and cognitive reappraisal, all of which involve structured writing assignments that are submitted to the therapist for feedback.

3.1.9 Imagery rehearsal

Imagery rehearsal therapy involves the person planning a change to the imagery of the traumatic memory or dream in a way that increases their sense of mastery or control, and then rehearsing the changed imagery in their imagination.

3.1.10 Group therapy

Group therapies for PTSD include supportive, psychodynamic and cognitive behavioural approaches with common features being homogenous group membership; acknowledgement and validation of the traumatic experience; normalisation of

traumatic responses; use of the presence of other individuals with similar experiences to overcome beliefs that the therapist cannot be helpful as they have not experienced the specific trauma; and a nonjudgemental approach toward behaviour required for survival during the traumatic event. Foy et al. (2000)

3.1.11 Debriefing

The terms *psychological debriefing* and *critical incident stress debriefing* (CISD) are often used interchangeably. The former describes a class of interventions delivered immediately following trauma (usually within 3 days) that aim to relieve stress in an attempt to mediate or avoid long term psychopathology. Psychological debriefing operates on the principles of ventilation/catharsis, normalisation of distress, and psychoeducation regarding presumed symptoms. CISD, on the other hand, is a specific form of debriefing developed in the 1980's (Mitchell, 1983, et seq.). It centers predominantly around group based interventions for secondary victims such as emergency service personnel, rather than primary victims. While generally group based it also advocates individual (or 'one-on-one') interventions as an acceptable and expected variant. It relies heavily on processes of reconstruction of the traumatic event, ventilation, and normalisation and includes a structured education component. More recently CISD has been amalgamated within a framework of self help activities and structured organisational processes, called *critical incident stress management* (CISM: Everly & Mitchell, 1995).

Other models of debriefing have been proposed that emerge from the crisis intervention literature. For example, Raphael's (1986) model of group debriefing is less structured and outlines a range of topics that may be useful for discussion. These include personally experienced disaster stressors, such as death encounter, survivor conflict and loss dislocation; positive and negative feelings, victims and their problems and the special nature of disaster work and personal feelings. .

3.1.12 Psychological First Aid

Psychological First Aid seeks to reduce distress and provide basic needs following a traumatic event, such as comfort, information, support and immediate practical and emotional (National Child Traumatic Stress Network and National Centre for PTSD, 2006)}. There are eight core components of Psychological First Aid. These involve initiating contact and engaging with an affected person in a non-intrusive, compassionate and helpful manner; providing immediate and ongoing safety and both physical and emotional comfort; if necessary, stabilising survivors who are overwhelmed and distraught; gathering information to determine immediate needs and concerns and to tailor Psychological First Aid interventions; providing practical assistance in helping the survivor address immediate needs and concerns; connecting the survivor with social supports by helping to structure opportunities for brief or ongoing contacts with primary support persons and/or community helping services; providing information on coping, including education about stress reactions and coping (often in a written format) and linking the survivor with collaborative services and providing information about those that may be needed in the future. Thus Psychological First Aid is designed to enhance an individuals natural resilience and coping in the face of trauma.

3.2 Pharmacological interventions

Pharmacological treatments (medications) used in PTSD are intended to ameliorate symptoms and as a result improve function. A wide range of medications have been examined and used in clinical practice to treat PTSD. The different classes of psychotropic (affecting a person's mental state) agents have been assessed in most detail.

Antidepressant medications can be categorised as either older or more recent, in terms of when they began to be used in clinical practice. The class of antidepressants is usually named according to their presumed mode of action or their chemical structure.

There are two classes of older antidepressant medicines: *tricyclic antidepressants* (TCAs) and *monoamine oxidase inhibitors* (MAOIs). There are numerous types of newer antidepressants, with most belonging to the class of *selective serotonin reuptake inhibitors* (SSRIs). The other classes are: *Serotonin-noradrenaline reuptake inhibitor* (SNRI); *Selective noradrenaline reuptake inhibitor* (NRI); *Noradrenaline-dopamine reuptake inhibitor* (NDRI); *Reversible inhibitor of MAO-A* (RIMA); *Noradrenergic and specific serotonergic antidepressant* (NaSSA) – alpha 2 antagonist.

Other psychotropic medications that may be used to treat PTSD and related symptoms include *hypnosedative agents* that reduce anxiety and insomnia (*benzodiazepines*, other sleeping tablets), *atypical antipsychotic medications*, *mood stabilisers* and *anticonvulsants*. Medications that are not traditionally considered to be psychotropic have also been borrowed from other areas of medicine to target specific PTSD symptoms. The most commonly used of these are medications that alter adrenergic function. These include *beta-blockers* and *alpha-adrenergic agents*. Another example of non-psychotropic medication that has been used to treat PTSD symptoms is the older *antihistamine* medicines.

3.3 Physical therapies

3.3.1 Medical

3.3.1.1 Electroconvulsive therapy

Electroconvulsive therapy (ECT) involves the induction of a modified seizure, under general anaesthetic by passing electricity through the brain. This treatment is mainly used in the treatment of severe depression (Helsley et al., 1999).

3.3.1.2 Repeated transcranial magnetic stimulation

Repeated transcranial magnetic stimulation (rTMS) by an electromagnetic coil pulsing high intensity current, is a non-invasive technique for stimulating cortical neurons that may assist in reducing the symptoms of various conditions, including PTSD (Grisaru et al., 1998).

3.3.2 Exercise

Various forms of exercise, both aerobic and anaerobic, have general benefits for physical and mental health. Many programs of mental health treatment include structured exercise and evidence exists that exercise is beneficial for depression and anxiety. Consequently there may be both direct and indirect benefits from exercise in the treatment of PTSD.

3.3.3 Alternative therapies

The list of alternative therapies included in the literature search in relation to PTSD have been described as touch, energy and “power” therapies and include: acupuncture, Reiki, craniosacral therapy, Tapas acupressure technique, visual-kinesthetic dissociation, osteopathy, therapeutic touch, thought field therapy, emotion freedom techniques, and traumatic incident reduction.

3.4 Psychosocial rehabilitation

Traditionally, psychosocial rehabilitation interventions are used to facilitate independent living, socialisation, and effective life management in people who have chronic mental health conditions including PTSD (Weinstein & Hughes, 2000). Psychosocial interventions help an individual compensate for the negative effects of disability by reducing some of the problems associated with PTSD, such as lack of self-care/independent living skills, homelessness, high-risk behaviours, interactions with family or friends who do not understand PTSD, social inactivity, unemployment, and other barriers to receiving various forms of treatment/rehabilitation (Department of Veterans Affairs/Department of Defence, 2004). Components of psychosocial rehabilitation include social skills training and activities, job skills training, housing support, vocational rehabilitation, case management, and family support (Weinstein & Hughes, 2000).

Psychosocial rehabilitation often occurs alongside other treatments but rather than aiming to reduce symptoms these interventions are designed to promote community integration and improved functioning.

There is increasing recognition that rehabilitation interventions that promote optimal vocational, family and social functioning should routinely begin in the earliest phase of care rather than being reserved for chronic conditions. For an individual with PTSD, this would entail early psychoeducation of the individual and family members, maximising existing social supports or creating new ones, and providing vocational support to enable the individual to maintain their optimal work/study performance.

4 Evidence review and treatment recommendations for adults with PTSD

4.1 Interventions for adults with PTSD

4.1.1 Psychological interventions

4.1.1.1 Research questions and PICO

Box 1 Single psychological interventions for adults with PTSD: Research question/s and study selection criteria

Research Question	
3. For adults with PTSD do psychological interventions improve outcomes compared to no intervention?	
4. For adults with PTSD, does any psychological intervention confer any advantage over other psychological interventions?	
Selection criteria	Inclusion criteria
Population	Adults with PTSD
Intervention	Psychological intervention (e.g., trauma-focused CBT, stress management therapy, EMDR, narrative exposure therapy, supportive counselling, interapy)
Comparator	3. No intervention 4. Other psychological intervention
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2004-8/2005*
Language	English

These were psychological questions 1 and 2 in the NICE review, with a search period up to 2004.

4.1.1.2 Studies included in previous reviews: NICE (2005)

The NICE review team conducted systematic research for RCTs of each of the five therapy groupings outlined above (trauma-focused CBT, EMDR, stress management, group CBT and other therapies) that compared these treatments against waiting list or usual care or against another psychological treatment. (Full details of the search strategy for this and other reviews of the guideline are given in Appendix 6 of the NICE guidelines. Information about each study along with an assessment of methodological quality is given in Appendix 14 of the NICE guidelines, which also contains a list of excluded studies with reasons for exclusions.) The following studies were identified by the NICE Guideline Development Group as meeting the inclusion criteria.

- 24 studies compared trauma-focused CBT with waiting list or other psychological interventions (Blanchard et al., 2003; Brom et al., 1989; Bryant et al., 2003a; Cloutre et al., 2002; Cooper & Clum, 1989; Devilly & Spence, 1999; Echeburua et al., 1997; Ehlers et al., 2005; Fecteau & Nicki, 1999; Foa et al., 1999; Foa et al.,

1991; Gersons et al., 2000; Ironson et al., 2002; Keane et al., 1989; Kubany et al., 2003; Kubany et al., 2004; Lee et al., 2002b; Marks et al., 1998; Paunovic & Ost, 2001; Peniston & Kulkosky, 1991; Power et al., 2002; Resick et al., 2002; Taylor et al., 2003; Vaughan et al., 1994)

- 11 studies compared EMDR with waiting list or other psychological interventions (Carlson et al., 1998; Devilly & Spence, 1999; Ironson et al., 2002; Jensen, 1994; Lee et al., 2002b; Marcus et al., 1997; Power et al., 2002; Rothbaum, 1997; Scheck et al., 1998; Taylor et al., 2003; Vaughan et al., 1994).
- 7 studies compared stress management with waiting list or other psychological interventions (Carlson et al., 1998; Echeburua et al., 1997; Foa et al., 1999; Foa et al., 1991; Marks et al., 1998; Taylor et al., 2003; Vaughan et al., 1994)
- 6 studies compared other therapies (supportive therapy, psychodynamic therapies, hypnotherapy) with waiting list or other psychological interventions (Blanchard et al., 2003; Brom et al., 1989; Bryant et al., 2003a; Foa et al., 1991; Scheck et al., 1998)
- 4 studies compared group CBT with waiting list or other psychological interventions (Classen et al., 2001; Krakow et al., 2001; Schnurr et al., 2003; Zlotnick et al., 1997).

4.1.1.3 Studies included in the current review of psychological treatments (2004-2005)

The review team conducted systematic research for RCTs published from 2004 to 2005, of the same five therapy groupings outlined above (trauma-focused CBT, EMDR, stress management, group CBT and other therapies) that compared these treatments against waiting list or usual care or against another psychological treatment. The following studies were identified by the NHMRC Guideline Development Group as meeting the inclusion criteria.

- 4 additional studies that compared trauma-focused CBT with waiting list were identified (Basoglu et al., 2005; Lindauer et al., 2005; McDonagh et al., 2005; Rothbaum et al., 2005).
- 1 additional study that compared trauma-focused CBT with other psychological intervention was (Blanchard et al., 2004). This was a follow-up to Blanchard (2003) identified in the NICE review.
- 2 additional studies that compared EMDR with waiting list or other psychological interventions (Marcus et al., 2004; Rothbaum et al., 2005) were identified. NB: Marcus et al., (2004) was a follow-up to Marcus et al., (1997) identified in the NICE review.
- 1 additional study that compared stress management with waiting list or other psychological interventions was identified (McDonagh et al., 2005).

- No additional studies that compared other therapies with waiting list or other psychological interventions were identified.

4.1.1.4 Treatment comparisons (waitlist/usual care or alternate treatment)

4.1.1.4.1 Trauma-focused CBT versus waitlist

Previous evidence: NICE Guidelines evidence statements

There is evidence favouring trauma-focused CBT over waiting list on reducing the likelihood of having a PTSD diagnosis after treatment (k=14; n=716; RR=0.47, 95% CI 0.37 to 0.59). I

There is evidence favouring trauma-focused CBT over waiting list on reducing the severity of PTSD symptoms (self-report measures) (k=8; n=388; SMD=-1.7, 95% CI -2.21 to -1.18). I

There is evidence favouring trauma-focused CBT over waiting list on reducing the severity of PTSD symptoms (clinician-rated measures) (k=13; n=609; SMD=-1.36, 95% CI -1.88 to -0.84). I

There is limited evidence favouring trauma-focused CBT over waiting list on reducing depression symptoms (k=13; n=585; SMD=-1.2, 95% CI -1.65 to -0.75). I

There is limited evidence favouring trauma-focused CBT over waiting list on reducing anxiety symptoms (self-report measures) (k=10; n=375; SMD=-0.94; 95% CI -1.16 to -0.72). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and waitlist/usual-care on reducing the likelihood of leaving treatment early for any reason (k = 14; n = 814; RR = 1.47; 95% CI, 1.07 to 2.02). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and waitlist/usual-care on improving quality of life (k = 5; n = 233; SMD = -0.35; 95% CI, -1.27 to 0.56). I

Further evidence identified in the current review (2004-2005)

There were six randomised controlled trials that compared trauma-focused CBT with waitlist. Two of these studies were included in the systematic review by NICE (Ehlers et al., 2005; Kubany et al., 2004) and the other four were identified only in the current review (Basoglu et al., 2005; Lindauer et al., 2005; McDonagh et al., 2005; Rothbaum et al., 2005). All six of the included studies compared a form of individual cognitive behavioural therapy against a waitlist or no-treatment condition. Two studies assessed the effectiveness of a single session of cognitive behavioural therapy (Basoglu et al., 2005; Lindauer et al., 2005) while the other four studies assessed a series of 4-14 individual treatment sessions at weekly or twice weekly intervals (Ehlers et al., 2005; Kubany et al., 2004; McDonagh et al., 2005; Rothbaum et al., 2005).

Posttraumatic Stress

All six trials in the current guidelines analysed PTSD severity or PTSD diagnosis posttreatment. These trials (varying in quality) were conducted in the United States, Turkey, the Netherlands, and the United Kingdom. The PTSD populations in these

trials included women with partner abuse-related PTSD; earthquake victims; women with sexual abuse history; and people experiencing PTSD as a consequence of a single traumatic event in adulthood. Three of these six trials used intention-to-treat analyses (Ehlers et al., 2005; Kubany et al., 2004; McDonagh et al., 2005), and of these only McDonagh et al., (2005) was found as new evidence. Kubany et al., (2004) and Ehlers et al., (2005) were previously included in the NICE guidelines however the NICE reported completer data from Kubany et al., (2004) while this review has included the intention-to-treat data.

The study by Basoglu et al., (2005) was described in the NICE guidelines as an example of the wide range of settings that cognitive behavioural therapies are used.

Results obtained from a combination of *completer data* and *intention to treat data* concerning posttraumatic stress symptoms are provided in Table 5. For all these trials, cognitive behavioural therapy was found to be consistently clinically and statistically significantly superior to a waitlist condition.

Table 5 Posttraumatic stress symptoms

Study	Level and Quality	Population	Effectiveness				Difference ¥ Effect size[95% CI]
			CBT		Waitlist/ no-treatment		
			Pre	Post	Pre	Post	
(Kubany, 2004) United States previously included in NICE§	Level II (RCT)	125 women with partner abuse-related PTSD	<i>Clinician-Administered PTSD Scale (CAPS; 0-136)</i>				Mann Whitney U=0.85 p<0.001 (two-tailed) SMD -1.46 [95% CI -1.86 to -1.07]
	Assignment: c		74.4±19.9	33.3±32.8	78.0±20.5	74.1±21.9	
	Selection bias: c						
	Blinding: c						
	Assessment: a						
	ITT: Yes						
(Basoglu, 2005) Turkey	Level II (RCT)	59 earthquake victims with PTSD	67.8±16.5	44.4±25.0	60.5±14.1	54.7±21.4	F(1,57)=14.0 p<0.001 SMD -0.44 [95% CI -0.97 to 0.08]
	Assignment: a						
	Selection bias: c						
	Blinding: b						
	Assessment: a						
	ITT: No						
(McDonagh, 2005) United States	Level II (RCT)	Women with PTSD secondary to Child Sexual Abuse	<i>ITT</i>	<i>ITT</i>	<i>ITT</i>	<i>ITT</i>	NS NS ITT SMD -0.50 [95% CI -1.06 to 0.06]
	Assignment: c		69.9±16.8	53.1±28.8	72.0±17.6	65.5±18.6	
	Selection bias: c		<i>Completer</i>	<i>Completer</i>	<i>Completer</i>	<i>Completer</i>	
	Blinding: b		67.1±18.4	38.5±27.7	70.0±16.9	65.5±17.0	
	Assessment: a						
	ITT: Yes						
(Ehlers, 2005) United Kingdom previously included in NICE	Level II (RCT)	28 people with PTSD, linked to single event in adulthood	<i>frequency</i>	<i>frequency</i>	<i>frequency</i>	<i>frequency</i>	<i>frequency</i> p<0.0005 ^a <i>intensity</i> p<0.0005 ^a <i>Posttraumatic Diagnostic Scale (PDS)</i> <i>original</i> p<0.0005 ^a SMD -2.18 [95% CI -3.12 to -1.24] <i>distress</i> p<0.0005 ^a
	Assignment: c		42.0±8.5	16.0±15.3	31.6±8.4	35.5±11.4	
	Selection bias: a		<i>intensity</i>	<i>intensity</i>	<i>intensity</i>	<i>intensity</i>	
	Blinding: b		36.5±9.4	13.7±13.4	29.0±8.5	30.9±9.6	
	Assessment: a						
	ITT: Yes		<i>original</i>	<i>original</i>	<i>original</i>	<i>original</i>	
			32.4±6.5	10.3±8.9	31.2±6.3	29.8±8.4	
			<i>distress</i>	<i>distress</i>	<i>distress</i>	<i>distress</i>	
	33.8±7.1	9.7±10.1	34.4±7.1	30.5±9.3			
(Lindaur, 2005) The Netherlands	Level II (RCT)	24 patients with PTSD (DSM-IV criteria) referred to outpatient clinic	<i>Structured Interview for PTSD (SI-PTSD)</i>				χ ² (1, N=24)=5.74 p<0.05 RR 0.22 [95% CI 0.06 to 0.82] p=0.004
	Assignment: a		12/12	2/12	12/12	9/12	
	Selection bias: b		(100%)	(16.7%)	(100%)	(75%)	
	Blinding: b						
	Assessment: a	Depression=					
	ITT: No	25%					
		<i>waitlist group</i>					
		(n=12)					
		Depression=0%					
(Rothbaum) United States	Level II (RCT)	60 adult rape victims ^b No sig. diffs between groups	<i>Structured Clinical Interview for DSM-IV (SCID)</i>				NR ^c RR 0.06 [95% CI 0.008 to 0.38]
	Assignment: c		20/20	1/20	20/20	18/20	
	Selection bias: c		(100%)	(5%)	(100%)	(90%)	
	Blinding: b						
	Assessment: a						
	ITT: No						

CAPS=Clinician Administered PTSD Scale; ^agroup differences posttreatment, univariate test; BEP=brief eclectic psychotherapy; SI-PTSD=Structured Interview for PTSD; NS=not stated; ¥=results of author's analysis. RR=risk ratio; § completer data from NICE reevaluated as intention-to-treat analysis, SMD=standardised mean difference; SCID=Structured Clinical Interview for DSM-IV; ^b74 women were randomised to treatment, but only completer data were analysed, due to similar dropout rates and demographics between groups; ^cunable to give exact results, as analyses provided combined EMDR and Prolonged Exposure treatment groups together in their comparison with the Waitlist group

Depression

All six recent randomised controlled trials provided data on the impact of CBT on depressive symptoms in PTSD sufferers (Table 6). Where statistical testing was conducted, results indicate that CBT was associated with significantly reduced depression in populations that were predominantly female and aged in their late thirties to forties. The one study where CBT had no effect on depression symptoms appears to be confounded by a higher rate of depression in the active treatment group.

Findings from three of these studies (Ehlers et al., 2005; Kubany et al., 2004; McDonagh et al., 2005) were obtained from intention to treat analyses while the remaining studies used completer data (Basoglu et al., 2005; Lindauer et al., 2005; Rothbaum et al., 2005). These latter studies potentially present more biased results, although Rothbaum (2005) reported that intention-to-treat analyses were conducted and provided no significant differences to completer-data.

Table 6 Depression

Study	Level and Quality	Population	Effectiveness				Difference ¥ Effect size [95 % CI]
			CBT		Waitlist/ no-treatment		
			Pre	Post	Pre	Post	
(Kubany et al., 2004) United States previously included in NICES	Level II (RCT)	125 women with partner abuse-related PTSD	<i>Beck Depression Inventory (BDI)</i>				Mann Whitney U=0.83 p<0.001 (two-tailed) SMD -0.28 [95% CI -0.63 to -0.0]
	Assignment: c Selection bias: c Blinding: c Assessment: a ITT: Yes		26.9±10.1	12.0±14.2	27.4±11.0	15.5±10.5	
(Rothbaum et al.) United States	Level II (RCT)	60 adult rape victims ^a No sig. diffs between groups	16.7±8.2	4.7±5.0	24.1±10.5	22.2±10.6	NR ^b SMD -2.08 [95% CI -2.78 to -1.38] 6 months SMD -2.08 [95% CI -2.78 to -1.38]
	Assignment: c Selection bias: c Blinding: b Assessment: a ITT: No			6 months 4.4±5.1			
(Basoglu et al., 2005) Turkey	Level II (RCT)	59 earthquake victims with PTSD	22.0±9.8	15.1±11.4	18.6±8.8	16.1±9.5	F(1, 57)=4.8 p<0.05 SMD -0.10 [95% CI -0.61 to 0.42]
	Assignment: a Selection bias: c Blinding: b Assessment: a ITT: No						
(McDonagh et al., 2005) United States	Level II (RCT)	Women with PTSD secondary to Child Sexual Abuse <i>CBT group n=29</i> <i>Waitlist group n=23</i>	<i>ITT</i>	<i>ITT</i>	<i>ITT</i>	<i>ITT</i>	NS NS SMD -0.51 [95% CI -1.07 to 0.05]
	Assignment: c Selection bias: c Blinding: b Assessment: a ITT: Yes		18.9±9.6 <i>Completers</i> 15.7±7.0	12.9±12.5 <i>Completers</i> 7.5±7.9	20.9±7.8 <i>Completers</i> 21.2±8.1	19.0±11.3 <i>Completers</i> 20.1±12.1	
(Ehlers et al., 2005) previously included in NICE	Level II (RCT)	28 people with PTSD, linked to single event in adulthood	23.7±9.0	10.6±8.6	23.2±8.0	19.3±7.2	p=0.003 ^c SMD -1.10 [95% CI -1.89 to -0.30]
	Assignment: c Selection bias: a Blinding: b Assessment: a ITT: Yes						
(Lindauer et al., 2005)	Level II (RCT)	24 patients with PTSD (DSM-IV criteria) referred to outpatient clinic <i>BEP group (n=12)</i> Depression=25%	<i>Hospital Anxiety and Depression Scale – Depression (HADS-D)</i>				F(1,22)=2.85 not significant SMD -0.18 [95% CI -0.98 to 0.63]
	Assignment: a Selection bias: b Blinding: b Assessment: a ITT: No		11.8±4.3	8.0±6.7	9.0±3.5	9.1±5.7	

waitlist group
(n=12)
Depression=0
%

[§] completer data from NICE reevaluated as intention-to-treat analysis [¶]74 women were randomised to treatment, but only completer data were analysed, due to similar dropout rates and demographics between groups; [‡]unable to give exact results, as analyses provided combined EMDR and Prolonged Exposure treatment groups together in their comparison with the Waitlist group; [†]Univariate comparison between groups posttreatment; BEP=brief eclectic psychotherapy; NS=not stated; ¥ Author's reported value statistical analysis; SMD=standardised mean difference.

Anxiety

Four of the trials assessed the effectiveness of CBT on anxiety-related symptoms and found various degrees of improvement compared to waitlist controls (Table 7).

Two of these studies used intention to treat analysis (Ehlers et al., 2005, ITT; McDonagh et al., 2005) one of which used both intention to treat and completer data. On the other hand, results obtained from Lindauer (2005) and Rothbaum (2005) were based on completer data.

Table 7 Anxiety

Study	Level and Quality	Population	Effectiveness				Difference ¥ Effect size [95 % CI]
			CBT		Waitlist/ no-treatment		
			Pre	Post	Pre	Post	
(McDonah, 2005)	Level II (RCT)	Women with PTSD secondary to Child Sexual Abuse <i>CBT group</i> n=29 <i>Waitlist group</i> n=23	<i>Spielberger State-Trait Anxiety Inventory</i>				
	Assignment: c		ITT	ITT	ITT	ITT	
	Selection bias: c		53.5±10.4	46.2±13.9	54.6±9.6	51.5±9.7	NR
	Blinding: b		<i>Completer</i>	<i>Complete</i>	<i>Completer</i>	<i>Completer</i>	
	Assessment: a		49.8±11.0	r	56.2±9.5	52.7±10.1	NR
ITT: Yes		39.4±11.9			SMD -0.43 [95% CI -0.99 to 0.12]		
Rothbuam	Level II (RCT)	60 adult rape victims ^a No sig. diffs between groups	<i>Spielberger State-Trait Anxiety Inventory- State</i>				
	Assignment: c		43.3±12.6	30.0±10.4	46.6±13.5	49.0±13.7	NR ^b
	Selection bias: c			6 months			SMD -1.54 [95% CI -2.18 to -0.89]
	Blinding: b			29.2±8.8			6 months
	Assessment: a						SMD -1.69 [95% CI -2.35 to -1.03]
	ITT: No						
			<i>Spielberger State-Trait Anxiety Inventory- Trait</i>				
			48.7±8.6	35.6±9.9	53.4±13.1	54.0±13.0	NR ^b
				6 months			SMD -1.57 [95% CI -2.21 to -0.92]
				34.2±7.5			6 months SMD -1.84 [95% CI -2.5 to -1.16]
(Ehlers, 2005) previousl y included in NICE	Level II (RCT)	28 people with PTSD, linked to single event in adulthood	<i>Beck Anxiety Inventory (BAI)</i>				
	Assignment: c		24.1±1.1	8.2±10.8	19.2±7.2	21.2±11.2	p<0.0005 ^c
	Selection bias: a						SMD -1.18 [95% CI -1.98 to -0.38]
	Blinding: b						
Assessment: a							
ITT: Yes							
(Lindaur, 2005)	Level II (RCT)	24 patients with PTSD (DSM-IV criteria) referred to outpatient clinic <i>BEP group (n=12)</i> Depression=25% <i>waitlist group (n=12)</i> Depression=0%	<i>Hospital Anxiety and Depression Scale- Anxiety (HADS-A)</i>				
	Assignment: a		13.1±3.2	8.1±4.8	11.3±3.3	12.0±4.7	F(1,22)=5.07 p<0.05
	Selection bias: b						SMD -0.82 [95% CI -1.65 to 0.01]
	Blinding: b						
	Assessment: a						
ITT: No							

^a74 women were randomised to treatment, but only completer data were analysed, due to similar dropout rates and demographics between groups; ^bunable to give exact results, as analyses provided combined EMDR and Prolonged Exposure treatment groups together in their comparison with the Waitlist group; ^cUnivariate comparison between groups posttreatment; BEP=brief eclectic psychotherapy; NR=not reported; ¥ Author's reported value for statistical analysis; SMD=standardised mean difference.

Functional improvement

Statistically significant improvements in functioning were noted in people receiving CBT, compared to waitlist controls in the two trials reporting on this outcome (see Table 8).

These results were obtained from a study that used intention to treat analysis (Ehlers et al., 2005) and two using completer data (Basoglu et al., 2005; Rothbaum, 2005 #24607).

Table 8 Functioning

Study	Level and Quality	Population	Effectiveness				Difference ¥ Effect size [95% CI]
			CBT		Waitlist/ no-treatment		
			Pre	Post	Pre	Post	
(Basoglu, 2005) Turkey	Level II (RCT)	59 earthquake victims with PTSD	<i>Work and Social Adjustment (WSA; 0-8)</i>				F(1, 57)=4.0 p<0.05 SMD -0.144 [95% CI -0.66 to 0.37]
	Assignment: a		3.9 ±1.9	2.4 ±2.4	3.2 ±1.9	2.7 ±1.6	
	Selection bias: c						
	Blinding: b						
	Assessment: a						
	ITT: No						
(Ehlers, 2005)	Level II (RCT)	28 people with PTSD, linked to single event in adulthood	<i>Disability, self-report, Sheehan scale</i>				p<0.0005 ^a SMD -1.43 [95% CI -2.26 to -0.6]
	Assignment: c		7.6±1.9	3.0±2.6	6.7±1.9	6.3±1.8	
	Selection bias: a						
	Blinding: b						
	Assessment: a						
	ITT: Yes						
			<i>Clinician Administered PTSD Scale (CAPS)</i>				
			3.1±0.6	1.4±1.1	2.4±0.6	2.5±0.7	p<0.0005 ^a SMD -1.16 [95% CI -1.96 to -0.36]
Rothbaum	Level II (RCT)	60 adult rape victims ^b	<i>Good end state functioning^c</i>				NR NA
	Assignment: c		-	10/20	-	0%	
	Selection bias: c			50%			
	Blinding: b			6 months (35.3%)			
	Assessment: a						
	ITT: No						

^aUnivariate comparison between groups posttreatment; ¥ Author's reported value for statistical analysis; SMD=standardised mean difference;

^b74 women were randomised to treatment, but only completer data were analysed, due to similar dropout rates and demographics between groups; ^cGood end state functioning was defined as ≥50% decrease on Clinician-Administered PTSD scale from pretreatment, a score of ≤10 on Beck Depression Inventory, and a score of ≤40 on Spielberger State-Trait Anxiety Inventory

Quality of life

One average quality trial assessed the effect of CBT on quality of life, as measured by the Quality of Life Inventory (QOLI) (McDonagh et al., 2005). Cognitive behavioural therapy improved quality of life scores more than the waitlist condition, but the clinical importance of the benefit is unclear (Table 9). This study conducted intention to treat analyses as well as results from completer data (McDonagh et al., 2005).

Table 9 Quality of life

Study	Level and Quality	Population	Effectiveness				Difference ¥ Effect size [95 % CI]
			CBT		Waitlist/ no-treatment		
			Pre	Post	Pre	Post	
(McDonagh, 2005)	Level II (RCT)	Women with PTSD secondary to Child Sexual Abuse CBT group n=29 Waitlist group n=23	<i>Quality of Life Inventory (QOLI)</i>				
	Assignment: c		ITT	ITT	ITT	ITT	
	Selection bias: c		36.1±15.9	39.5±17.0	36.8±13.2	37.2±14.7	NR
	Blinding: b		Completer	Completer	Completer	Completer	
	Assessment: a		43.3±14.8	47.1±13.9	36.0±12.6	34.7±14.3	NR
ITT: Yes					SMD -0.14 [95% CI -0.69 to 0.40]		

NR=not reported; ¥ Author's reported value for statistical analysis; SMD=standardised mean difference

Current review evidence statements

There is limited relevant and applicable evidence favouring CBT over waitlist/usual care for PTSD symptom severity (k=3; n=205; SMD=-1.32, 95% CI -2.15 to -0.49). I

There is relevant and applicable evidence suggesting that there is unlikely to be a clinically important difference between CBT versus waitlist/usual care for depression (k=3; n=205; SMD=-0.44, 95% CI -0.72 to -0.16).

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between CBT and waitlist/usual care for anxiety (k=2; n=80; SMD=-0.67, 95% CI -1.13 to -0.22).

There is limited relevant and applicable evidence favouring CBT over waitlist/usual care on improving functional improvement (k=1; n=28; SMD -1.43; 95% CI, -2.26 to -0.6). II

There is relevant and applicable evidence suggesting that there is unlikely to be a clinically important difference between CBT and waitlist on improving quality of life (k=1; n=52; SMD=-0.14, 95% CI -0.69 to 0.40). II

Updated evidence statements on the combined evidence from previous and current reviews

There is relevant and applicable evidence favouring trauma-focused CBT over waitlist/ usual care on reducing the severity of PTSD symptoms (k=14, n=654; SMD=-1.21; 95%CI, -1.62,-0.80). I

There is limited relevant and applicable evidence favouring trauma-focused CBT over waitlist/usual care on reducing depression symptoms (k=14, n=637; SMD=-0.96; 95%CI, -1.32, -0.59). I

There is relevant and applicable limited evidence favouring trauma-focused CBT over waitlist/ usual care on reducing anxiety symptoms (k=11, n=420; SMD=-0.89; 95%CI, -1.09, -0.68). I

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between trauma-focused CBT and waitlist/usual care on improving quality of life (k=6, n=278; SMD=-0.76; 95%CI, -1.25, -0.20). I

4.1.1.4.2 EMDR versus waitlist

Previous evidence: NICE Guidelines evidence statements

There is limited evidence favouring EMDR over waiting list on reducing the likelihood of having a PTSD diagnosis after treatment (k=5; n=169; RR= 0.51; 95% CI 0.28 to 0.95). I

There is limited evidence favouring EMDR over waiting list on reducing the severity of PTSD symptoms (self-report measures) (k=4; n=116; SMD=-1.1; 95% CI -2.42 to 0.23). I

There is evidence favouring EMDR over waiting list on reducing the severity of PTSD symptoms (clinician-rated measures) (k=4; n=122; SMD=-1.54, 95% CI, -1.96 to -1.12). I

There is evidence favouring EMDR over waiting list on reducing depression symptoms (k=4; n=120; SMD=-1.67, 95% CI -2.1 to -1.25). I

There is limited evidence favouring EMDR over waiting list on reducing anxiety symptoms (k=4; n=116; SMD=-1.18, 95% CI -1.58 to -0.78). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and waitlist/usual-care on reducing the likelihood of leaving treatment early for any reason (k = 5; n =168; RR = 1.28; 95% CI, 0.64 to 2.56). I

There is limited evidence favouring EMDR over waitlist/usual-care on improving quality of life (k = 1; n = 51; SMD = -1.36; 95% CI, -1.97 to -0.74). I

Further evidence identified in the current review

One new poor-to-average quality trial (Rothbaum et al., 2005) was identified which compared the effectiveness of Eye movement desensitization and Reprocessing (EMDR) vs waitlist for female rape victims with PTSD. *Completer data* were confounded by the fact that the EMDR participants had higher baseline levels of PTSD symptoms, depression, dissociation and trait anxiety than waitlist controls.

Despite the discrepancy in baseline differences, the EMDR group had consistently better outcomes at follow-up than the waitlist group (See Table 10).

Table 10 Effectiveness of EMDR versus waitlist for treating PTSD

Study	Level and Quality	Population	Outcome	Effectiveness				Difference ¥ Effect size [95% CI]
				EMDR		Waitlist		
				Pre	Post	Pre	Post	
(Rothbaum)	Level II (RCT) Assignment: c Selection bias: c Blinding: b Assessment: a ITT: No	60 adult rape victims ^a Patients in EMDR condition had significantly more PTSD symptoms, anxiety and depression than those in the waitlist condition	PTSD diagnosis (SCID-IV)	20/20 (100%)	5/20 (25%) <i>6 months</i> (26.3%)	20/20 (100%)	18/20 (90%)	significantly fewer in EMDR group ^b RR 0.28 [95% CI 0.13 to 0.60]
			Dissociation (DES-II)	18.7±12.7	8.1±8.0 <i>6 months</i> 8.9±9.1	12.5±10.2	12.4±8.5	NR SMD -0.51 [95% CI -1.09 to 0.06] <i>6 months</i> SMD -0.39 [95% CI -0.96 to 0.18]
			Anxiety (State)	51.1±11.1	32.6±11.6	46.6±13.5	49.0±13.7	NR SMD -1.27 [95% CI -1.89 to -0.65]
			Anxiety (Trait)	56.8±11.0	41.1±14.5	53.4±13.1	54.0±13.0	NR SMD -0.92 [95% CI -1.52 to -0.33]
			Depression (BDI)	26.0±7.1	10.7±11.5	24.1±10.5	22.2±10.6	NR SMD -1.02 [95% CI -1.63 to -0.42]
			Good end state functioning ^c	-	10/20 (50%) <i>6 months</i> (35.3%)	-	0%	NR NA

^a74 women were randomised to treatment, but only completer data were analysed, due to similar dropout rates and demographics between groups; SCID=Structured Clinical Interview of DSM-IV, Non-Patient Version; ^bunable to give exact results, as analyses provided combined EMDR and Prolonged exposure treatment groups together in their comparison with the Waitlist group ^cGood end state functioning was defined as ≥50% decrease on Clinician-Administered PTSD scale from pretreatment, a score of ≤10 on Beck Depression Inventory, and a score of ≤40 on Spielberger State-Trait Anxiety Inventory; NR=not reported; NA=not applicable; ¥ Author's reported value for statistical analysis; SMD=standardised mean difference.

Current review evidence statements

There is relevant and applicable evidence favouring EMDR over waitlist on reducing the likelihood of having a PTSD diagnosis (SCID) after treatment (k=1, n = 40; RR = 0.28; 95% CI, 0.13 to 0.60). II

The relevant and applicable evidence is inconclusive and so it is not possible to

determine whether there is a clinically important difference between EMDR and waitlist/usual-care on reducing dissociation (DES-II) after treatment (k = 1; n = 40; SMD = -0.51; 95% CI, -1.09 to 0.06). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between EMDR and waitlist/usual-care on reducing dissociation at six months (k = 1; n = 39; SMD = -0.39; 95% CI, -0.96 to 0.18). II

There is limited relevant and applicable evidence favouring EMDR over waitlist/usual-care on reducing anxiety (state) symptoms (k = 1; n = 40; SMD = -1.27; 95% CI, -1.89 to -0.65). II

There is limited relevant and applicable evidence favouring EMDR over waitlist/usual-care on reducing anxiety (trait) symptoms (k = 1; n = 40; SMD = -0.92; 95% CI, -1.52 to -0.33). II

There is limited relevant and applicable evidence favouring EMDR over waitlist/usual care on reducing depression symptoms (k=1, n=40; SMD= -1.02; 95% CI, -1.63 to -0.42). II

Updated evidence statements on the combined evidence from previous and current reviews

There is relevant and applicable evidence favouring EMDR over waitlist/usual care on reducing depression symptoms (k=6, n=156; SMD=-1.53; 95%CI -1.88, -1.17). I

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between EMDR and waitlist/usual care on having a PTSD diagnosis after treatment (k=6, n=209; RR=-0.74; 95%CI, 0.64, 0.86). I

4.1.1.4.3 Stress management versus waitlist

Previous evidence: NICE Guidelines evidence statements

There is limited evidence favouring stress management therapy over waiting list on reducing the likelihood of having a PTSD diagnosis after treatment (k=4; n=121; RR=0.64, 95% CI 0.47 to 0.87). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between stress management therapy and waiting list on reducing the severity of PTSD symptoms (self-report measures) (k=1; n=24; SMD=0.33, 95% CI -0.47 to 1.14). I

There is limited evidence favouring stress management therapy over waiting list on reducing the severity of PTSD symptoms (clinician-rated measures) (k=3; n=86; SMD=-1.14, 95% CI -1.62 to -0.67). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between stress management therapy and waiting list on reducing depression symptoms (k=4; n=109; SMD=-0.73, 95% CI -1.12 to -0.33). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between stress management therapy and waiting list

on reducing anxiety symptoms ($k=3$; $n=82$; $SMD=-0.77$, 95% CI -1.23 to -0.32). *I*

There is limited evidence favouring waitlist/usual-care over stress management therapy on reducing the likelihood of leaving treatment early for any reason ($k = 4$; $n = 121$; $RR = 2.19$; 95% CI, 0.71 to 6.73). *I*

There is limited evidence favouring stress management therapy over waitlist/usual-care on improving quality of life ($k = 1$; $n = 34$; $SMD = -0.98$; 95% CI, -1.7 to -0.26). *I*

Further evidence identified in the current review

One poor-to-average quality trial assessed the effectiveness of a present-centred therapy compared with a waitlist group in a population of women with PTSD secondary to childhood sexual trauma (McDonagh et al., 2005). The therapy included psychoeducation about PTSD and the effects of childhood sexual abuse, and focused on current problem solving skills and coping strategies without focusing on the trauma. For all outcome measures, excepting quality of life, posttreatment scores were reduced in the present-centred therapy group, compared to the waitlist controls. However, in general the active treatment group had slightly lower baseline scores for these outcomes and so it is unclear whether the differences between the groups were in some part due to treatment differences as opposed to preexisting inequalities as it is not stated whether statistical adjustment for baseline differences was conducted in this trial. This study reported on both *intention to treat (ITT)* and *completer data* (see Table 11) although only *ITT* is included in the evidence statements.

Table 11 Effectiveness of Present-Centred Therapy vs Waitlist for treating PTSD

Study	Level and Quality	Population	Outcome	Effectiveness				Difference‡
				Present-centred therapy		Waitlist		
				Pre	Post	Pre	Post	Effect size [95% CI]
(McDonah, 2005) United States	Level II (RCT) Assignment: c Selection bias: c Blinding: b Assessment: a ITT: Yes	Women with PTSD secondary to Child Sexual Abuse <i>PCT group</i> n=22 <i>Waitlist group</i> n=23	<i>ITT</i> CAPS	(n=22)		(n=23)		NR
				67.7±14.2	47.2±22.4	72.0±17.6	65.5±18.6	ES=0.89
								SMD -0.89 [95% CI -1.51 to -0.28]
			BDI	17.0±7.7	10.8±9.5	20.9±7.8	19.0±11.3	NR
								SMD -0.78 [95% CI -1.39 to -0.18]
								NR
			STAI	54.5±9.2	46.4±12.2	54.6±9.6	51.5±9.7	NR
								SMD -0.46 [95% CI -1.06 to 0.13]
								NR
			QOLI	35.2±15.3	39.0±12.6	36.8±13.2	37.2±14.7	NR
				SMD -0.13 [95% CI -0.71 to 0.46]				
				NR				
<i>Completer</i>				(n=20)	(n=20)			
CAPS	67.5±15.1	44.9±22.1	70.0±16.9	62.5±17.0	NR			
					ES=0.89			
BDI	17.7±8.2	10.4±10.2	21.2±8.1	20.1±12.1	NR			

CBT=cognitive behavioural therapy; PCT=present-centred therapy; ITT=intent-to-treat; CAPS=Clinician Administered PTSD Scale; BDI=Beck Depression Inventory; STAI=Spielberger State-Trait Anxiety Inventory; QOLI=Quality of Life Inventory; ES=Effect size (Cohen's d); NR=not reported; ‡ Author's reported value for statistical analysis; SMD=standardised mean difference.

Current review evidence statements

There is limited applicable evidence favouring present-centred therapy over waitlist on reducing the severity of PTSD symptoms (CAPS) (k=1; n=45; SMD= -0.89; 95% CI, -1.51 to -0.28). II

The applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between present-centred therapy and waitlist on reducing depression symptoms (BDI) (k=1; n=45; SMD -0.78; 95% CI, -1.39 to -0.18). II

The applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between present-centred therapy and waitlist on reducing anxiety symptoms (STAI) (k=1; n=45; SMD -0.46; 95% CI, -1.06 to 0.13). II

There is applicable evidence suggesting that there is unlikely to be a clinically important difference between present-centred therapy and waitlist on improving quality of life (QOLI) (k=1; n=45; SMD -0.13; 95% CI, -0.71 to 0.46). II

The generalisability of the evidence is limited as the study population included only women with PTSD secondary to Child Sexual Abuse

Updated evidence statements on the combined evidence from previous and current review

There is relevant and applicable limited evidence favouring stress management therapy over waitlist/ usual care on reducing the severity of PTSD symptoms (k=4, n=111; SMD=-1.07; 95%CI, -1.45, -0.70). I

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between stress management therapy and waitlist/ usual care on reducing depression symptoms (k=5, n=154; SMD=-0.76; 95%CI, -1.09, -0.43). I

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between stress management therapy and waitlist/ usual care on reducing anxiety symptoms (k=4, n=127; SMD=-0.67; 95%CI, -1.04, -0.31). I

There is relevant and applicable evidence suggesting that there is unlikely to be a clinically important difference between stress management therapy and waitlist/ usual care on improving quality of life (k=2, n=79; SMD=-0.42; 95%CI -1.53, -0.70). I

4.1.1.4.4 Other therapies versus waitlist

Previous evidence: NICE Guidelines evidence statements

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between other therapies and waiting list on reducing the likelihood of having a PTSD diagnosis after treatment (k=2; n=85; RR=0.79, 95% CI 0.53 to 1.18). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between other therapies and waiting list on reducing the severity of PTSD symptoms (self-report measures) (k=2; n=132; SMD=-0.61, 95% CI -0.98 to -0.24). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between other therapies and waiting list on reducing the severity of PTSD symptoms (clinician-rated measures) (k=2; n=72; SMD=-0.43, 95% CI -0.9 to 0.04). I

There is evidence suggesting there is unlikely to be a clinically important difference between other therapies and waiting list on reducing depression symptoms (k=2; n=72; SMD=-0.25, 95% CI -0.71 to 0.22). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between other therapies and waiting list on reducing anxiety symptoms (k=3; n=153; SMD=-0.48, 95% CI -0.82 to -0.14). I

There is limited evidence favouring waitlist/usual-care over other therapies on reducing the likelihood of leaving treatment early for any reason (k = 3; n = 166; RR = 3.82; 95% CI, 1.19 to 12.29). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between other therapies and waitlist/usual care on improving quality of life (k = 1; n = 51; SMD = -0.33; 95% CI, -0.88 to 0.23). I

Further evidence identified in the current review

No new studies were identified comparing other therapies to waitlist.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.1.4.5 Group CBT versus waitlist

Previous evidence: NICE Guidelines evidence statements

The full range of outcome measures was not provided in the three studies of group CBT.

There is limited evidence favouring group CBT over waiting list on reducing the likelihood of having a PTSD diagnosis after treatment (k=1; n=48; RR=0.56, 95% CI 0.31 to 1.01). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between group CBT and waiting list/usual care on reducing the severity of PTSD symptoms (self-report measures) (k=2; n=71; SMD=-0.71, 95% CI -1.2 to -0.22). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between group CBT and waitlist/usual-care on reducing the severity of PTSD symptoms (clinician) (k = 1; n = 97; SMD = -0.72; 95% CI, -1.14 to -0.31). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between group CBT and waitlist/usual-care on reducing the likelihood of leaving treatment early for any reason (k = 3; n = 271; RR = 1; 95% CI, 0.64 to 1.56). I

Further evidence identified in the current review

No new studies were identified comparing group CBT to waitlist.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.1.4.6 Interapy versus waitlist

Previous evidence: NICE Guidelines evidence statements

There is evidence favouring interapy over waitlist on reducing severity of PTSD symptoms as measured by self-report IES at endpoint ($k = 1$; $n = 101$; $SMD = -1.32$; 95% CI, -1.77 to -0.86). I

There is evidence favouring interapy over waitlist on reducing depression symptoms as measured by self-report SCL-90 at endpoint ($k = 1$; $n = 101$; $SMD = -1.06$; 95% CI, -1.51 to -0.62). I

There is limited evidence favouring interapy over waitlist on reducing anxiety symptoms as measured by self-report SCL-90 at endpoint ($k = 1$; $n = 101$; $SMD = -0.81$; 95% CI, -1.24 to -0.37). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between interapy and waitlist on reducing the likelihood of leaving the study prior to endpoint for any reason ($k = 1$; $n = 184$; $RR = 0.9$; 95% CI, 0.65 to 1.25). I

Further evidence identified in the current review

No new studies were identified comparing interapy to waitlist.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

COMPARING INTERVENTION AGAINST INTERVENTION

Although many of the included studies compared active treatments against waiting list, there were fewer studies available for direct comparisons of each of the active treatments against one another. Each treatment is considered in the same order as in the preceding section (trauma-focused CBT, EMDR, stress management and other therapies). The comparisons are therefore set out in the following order:

- trauma-focused CBT versus EMDR
-
- trauma-focused CBT versus stress management
-
- trauma-focused CBT versus other therapies
-
- trauma-focused CBT (exposure) versus trauma-focused CBT (cognitive therapy)
-
- EMDR versus stress management therapies
-
- EMDR versus other therapies
-
- stress management therapies versus other therapies
-
- group CBT (trauma-focused) versus group CBT (non trauma-focused)
-
- narrative exposure therapy versus supportive therapy
-
- narrative exposure therapy versus psychoeducation
-
- psychoeducation versus supportive therapy

Where available, three outcome measures are reported for each comparison: a self-report measure of the severity of PTSD symptoms (or where this is not reported, the clinician-rated measure), likelihood of having a PTSD diagnosis, and leaving treatment early.

4.1.1.4.7 Trauma-focused CBT versus EMDR

Previous evidence: NICE Guidelines evidence statements

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and trauma-focused CBT on reducing the likelihood of having a PTSD diagnosis after treatment (k=6; n=220; RR=1.03, 95% CI 0.64 to 1.66). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and trauma-focused CBT on reducing the severity of PTSD symptoms (self-report) (k=6; n=166; SMD=-0.31, 95% CI -0.62 to 0). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and trauma-focused CBT on reducing the likelihood of leaving treatment early for any reason (k=7; n=240; RR=0.83, 95% CI 0.54 to 1.27). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and trauma-focused CBT on reducing the severity of clinician-rated PTSD symptoms (k = 5; n = 147; SMD = -0.06; 95% CI, -0.68 to 0.55). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and trauma-focused CBT on reducing the severity of PTSD symptoms (clinician-rated) at follow-up (3months) (k = 3; n = 76; SMD = -0.19; 95% CI, -0.97 to 0.58). I

There is evidence suggesting there is unlikely to be a clinically important difference between EMDR and trauma-focused CBT on reducing the severity of self-report PTSD symptoms at follow-up (3 months) (k = 5; n = 111; SMD = -0.01; 95% CI, -0.39 to 0.37). I

There is limited evidence favouring EMDR over trauma-focused CBT on reducing self-report depression symptoms (k = 6; n = 166; SMD = -0.5; 95% CI, -1.04 to 0.04). I

There is evidence suggesting there is unlikely to be a clinically important difference between EMDR and trauma-focused CBT on reducing self-report depression symptoms at follow-up (2-5 months) (k = 5; n = 111; SMD = -0.09; 95% CI, -0.47 to 0.29). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and trauma-focused CBT on reducing self-report anxiety symptoms (k = 3; n = 96; SMD = -0.3; 95% CI, - 0.71 to 0.11). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and trauma-focused CBT on reducing self-report anxiety symptoms at follow-up (2-5 months) (k = 2; n =48; SMD = 0.24; 95% CI, -0.33 to 0.81). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and trauma-focused CBT on improving quality of life (k = 2; n = 71; SMD = -0.12; 95% CI, -1.2 to 0.95). I

Further evidence identified in the current review

One trial was identified that compared Eye movement desensitisation and reprocessing (EMDR) to prolonged exposure (Rothbaum et al., 2005). Results from *completer data* indicate that for most outcomes EMDR was not beneficial compared to prolonged exposure. Avoidance scores were significantly lower in the EMDR group than the prolonged exposure group posttreatment, but this difference was no longer statistically significant at 6 months. Prolonged exposure was more effective than EMDR at achieving good End state functioning and depression at 6 months. Baseline scores were consistently lower in the prolonged exposure group than the EMDR group, so differences between groups may be due to sample characteristics rather than treatment effects. The results are flawed by the use of completer data only, and EMDR had a higher dropout rate than prolonged exposure, so any conclusions made on the comparative effectiveness of the treatments should be made with caution.

Table 12 Effectiveness of EMDR vs Prolonged exposure for treating PTSD

Study	Level and Quality	Population	Outcome	Effectiveness				Difference ¥ Effect size [95 % CI]
				EMDR		Prolonged exposure		
				Pre	Post	Pre	Post	
(Rothbaum)	Level II (RCT) Assignment: c Selection bias: c Blinding: b Assessment: a ITT: Yes	60 adult rape victims ^a EMDR group had sig. more severe PTSD symptoms	PTSD diagnosis SCID	20/20 (100%)	5/20 (25%) <i>6 months</i> (26.3%)	20/20 (100%)	1/20 (5%) <i>6 months</i> (5.6%)	$\chi^2(n=1)=2.58$ $p=0.108$ <i>6 months</i> $p=0.185^b$ RR 5.0 [95% CI 0.64-39.0] $p=0.08$
		Total score improvement ^c	n/a	n/a	n/a	n/a	$F(1,57)=0.3$ $p=0.608$ ES=0.005	
		Symptom cluster change ^d	n/a	n/a	n/a	n/a	$F(1,57)=0.3$ $p=0.608$ ES=0.005	
		Dissociation(D ES-II)	18.7±12.7	8.1±8.0 <i>6 months</i> 8.9±9.1	10.1±5.5	4.8±4.7 <i>6 months</i> 3.5±2.6	$F(1,56)=4.1$ $p<0.05$ $F(2,33)=2.2$ Not significant SMD -0.50 [95% CI -1.07 to 0.08] <i>6 months</i> SMD -0.79 [95% CI -1.38 to -0.21]	
		Anxiety (State)	51.1±11.1	32.6±11.6	43.3±12.6	30.0±10.4	Not significant SMD -0.23 [95% CI -0.80 to 0.34]	
		Anxiety (Trait)	56.8±11.0	41.1±14.5	48.7±8.6	35.6±9.9	Not significant SMD -0.44 [95% CI -1.00 to 0.14]	
		Depression (BDI)	30.0±7.1	10.7±11.5 <i>6 months</i> 10.5±10.9	16.7±8.2	4.7±5.0 <i>6 months</i> 4.4±5.1	$F(1,57)=1.2$ Not significant $F(2,34)=0.6$ Not significant SMD -0.67 [95% CI -1.25 to -0.08] <i>6 months</i> SMD -0.71 [95% CI -1.29 to -0.12]	
		Good end state functioning ^e	-	10/20 (50%) <i>6 months</i> (35.3%)	-	14/20 (70%) <i>6 months</i> (78%)	Not significant ^b <i>6 months</i> $p=0.017^b$	

RR 0.71
[95% CI 0.42 to
1.21]

Dropout rates	20%	13%	NS NC
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EMDR=Eye Movement Desensitisation and Reprocessing; ^a74 women were randomised to treatment, but only completer data was analysed, due to similar dropout rates and demographics between groups; ^bFishers exact test; ^cTotal score improvement=PTSD frequency and intensity total symptom scores measured by CAPS, PSS and IES; ^dSymptoms cluster=PTSD intrusion, avoidance, hyperarousal symptoms as measured by CAPS, PSS, and IES; ^eGood end state functioning was defined as $\geq 50\%$ decrease on CAPS from pretreatment, a score of ≤ 10 on BDI, and a score of ≤ 40 on STAI-S; ES=effect size; n/a=not available; NS=not stated; NC=not calculated due to not count data reported; ¥ Author's reported value for statistical analysis; SMD=standardised mean difference; RR=risk ratio.

Current review evidence statements

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between EMDR and prolonged exposure on reducing the severity of symptoms (SCID) (k=1; n=40; RR 5.0; 95% CI, 0.64 to 39.0). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between EMDR and prolonged exposure on reducing dissociation posttreatment (DES-II) (k=1; n=40; SMD -0.50; 95% CI, -1.07 to 0.08). II

There is relevant and applicable evidence favouring prolonged exposure over EMDR on reducing dissociation (DES-II) at six months (k=1; n=37; SMD -0.79 (95% CI -1.38 to -0.21). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between EMDR and prolonged exposure on reducing anxiety symptoms (state) (k=1; n=40; SMD -0.23; 95% CI, -0.80 to 0.34). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between EMDR and prolonged exposure on reducing anxiety symptoms (trait) (k=1; n=40; SMD -0.44; 95% CI, -1.00 to 0.14). II

There is limited relevant and applicable evidence favouring prolonged exposure over EMDR on reducing depression symptoms posttreatment (BDI) (k=1; n=40; SMD -0.67 (95% CI -1.25 to -0.08). II

There is limited relevant and applicable evidence favouring prolonged exposure on reducing depression symptoms (BDI) at six months (k=1; n=37; SMD -0.71; 95% CI, -1.29 to -0.12). II

There is limited relevant and applicable evidence favouring prolonged exposure over EMDR on good end state functioning (k=1; n=40; RR 0.71(95% CI 0.42 to 1.21). II

Updated evidence statements on the combined evidence from previous and current reviews

There is relevant and applicable evidence suggesting that there is unlikely to be a clinically important difference between EMDR and trauma-focused CBT on reducing depression symptoms (k=7, n=206; SMD= -0.34; 95%CI, -0.94, 0.256). I

There is relevant and applicable evidence suggesting that there is unlikely to be a clinically important difference between EMDR and trauma-focused CBT on reducing depression symptoms at 2-6 months (k=6, n=151; SMD=0.02; 95%CI, -0.50, 0.55). I

There is relevant and applicable evidence suggesting that there is unlikely to be a clinically important difference between EMDR and trauma-focused CBT on reducing anxiety symptoms (k=4, n=136; SMD= -0.15; 95%CI, -0.49, 0.19). I

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between EMDR and trauma-focused CBT on reducing the likelihood of leaving treatment early for any reason (k=8, n=280; RR=0.87; 95%CI, 0.57, 1.32). I

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between EMDR and trauma-focused CBT on reducing the likelihood of having a PTSD diagnosis after treatment (k=7, n=260; RR=1.11; 95%CI, 0.68, 1.81). I

4.1.1.4.8 Trauma focused CBT versus stress management

Previous evidence: NICE Guidelines evidence statements

There is limited evidence favouring trauma-focused CBT over stress management therapy on reducing the likelihood of having a PTSD diagnosis after treatment (k=6; n=284; RR=0.78, 95% CI 0.61 to 0.99). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and stress management therapy on reducing the severity of PTSD symptoms (self-report measures) (k=3; n=127; SMD=-0.37, 95% CI -0.74 to 0.01). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and stress management therapy on reducing the likelihood of leaving treatment early for any reason (k=6; n=284; RR=1.17, 95% CI 0.69 to 2). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and stress management therapy on reducing the severity of clinician-rated PTSD symptoms (k = 6; n = 239; SMD = -0.27; 95% CI, -0.71 to 0.16). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and stress management therapy on reducing the severity of clinician-rated PTSD symptoms at follow-up (2-5 months) (k = 5; n = 127; SMD = -0.48; 95% CI, -0.84 to -0.12). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and stress management therapy on reducing the severity of self-report PTSD symptoms at follow-up (2-5 months) (k = 2; n = 54; SMD = -0.44; 95% CI, -0.99 to 0.1). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and stress management therapy on reducing depression symptoms (k = 5; n = 161; SMD = -0.25; 95% CI, -0.57 to 0.08). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and stress management

therapy on reducing depression symptoms(self-report) at follow-up (2-5 months) (k = 5; n = 147; SMD = -0.28; 95% CI, -0.62 to 0.06). I

There is evidence suggesting there is unlikely to be a clinically important difference between trauma-focused CBT and stress management therapy on reducing anxiety symptoms (k = 4; n = 127; SMD = -0.12; 95% CI, -0.49 to 0.26). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and stress management therapy on reducing anxiety symptoms at follow-up (2-5 months) (k = 4; n = 117; SMD = -0.19; 95% CI, -0.58 to 0.20). I

There is limited evidence favouring trauma-focused CBT over stress management therapy on improving quality of life (k = 1; n = 20; SMD = -0.67; 95% CI, -1.58 to 0.23). I

There is evidence favouring trauma-focused CBT over stress management therapy on improving quality of life at follow-up (3 months) (k = 1; n = 20; SMD = -3.07; 95% CI, -4.45 to -1.69). I

Further evidence identified in the current review

One randomised controlled trial compared trauma-focused CBT with interventions that may be defined as stress management (McDonagh et al., 2005). McDonagh et al., 2005 #23588} used ‘present centred therapy’ in comparison with CBT in a population of women with PTSD secondary to childhood sexual abuse. McDonagh et al., (2005) used both intention to treat and completer data.

Table 13 Effectiveness of Cognitive Behavioural Therapy vs Present Centred Therapy for PTSD

Study	Level and Quality	Population	Outcome	Effectiveness				Difference ¥ Effect size [95 % CI]
				CBT		Present-centred therapy		
				Pre	Post	Pre	Post	
(McDonah, 2005) United States	Level II (RCT) Assignment: c Selection bias: c Blinding: b Assessment: a ITT: Yes	Women with PTSD secondary to Child Sexual Abuse	<i>ITT</i>					
			CAPS	69.9±16.8	53.1±28.8	67.7±14.2	47.2±22.4	NS
								SMD -0.22 [95% CI -0.78 to 0.35]
			BDI	18.9±9.6	12.9±12.5	17.0±7.7	10.8±9.5	NS
								SMD -0.18 [95% CI -0.74 to 0.37]
			STAI	53.5±10.4	46.2±13.9	54.5±9.2	46.4±12.2	NS
								SMD -0.02 [95% CI -0.57 to 0.54]
			QOLI	36.1±15.9	39.5±17.0	35.2±15.3	39.0±12.6	NS
								SMD -0.03 [95% CI -0.59 to 0.52]
					<i>Completer</i>			
		CAPS	67.1±18.4	38.5±27.7	67.5±15.1	44.9±22.1	NS	
		BDI	15.7±7.0	7.5±7.9	17.7±8.2	10.4±10.2	NR	

CBT=cognitive behavioural therapy; PCT=present-centred therapy; ITT=intent-to-treat; CAPS=Clinician Administered PTSD Scale; BDI=Beck Depression Inventory; STAI=Spielberger State-Trait Anxiety Inventory; QOLI=Quality of Life Inventory; *PTSD diagnosis determined by CAPS; NR=not stated; ¥ Author's reported value for statistical analysis; SMD=standardised mean difference; NS=not significant.

Current review evidence statements

The applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between CBT and present-centred therapy on reducing the severity of PTSD symptoms (k=1; n=51; SMD -0.22; 95% CI, -0.78 to 0.35). II

The applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between CBT and present-centred therapy on reducing depression symptoms (k=1; n=51; SMD -0.18; 95% CI, -0.74 to 0.37). II

The applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between CBT and present-centred therapy on reducing anxiety symptoms (k=1; n=51; SMD -0.02; 95% CI, -0.57 to 0.54). II

The applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between CBT and present-centred therapy on improving quality of life (k=1; n=51; SMD -0.03; 95% CI, -0.59 to 0.52). II

The generalisability of the evidence is limited as the study population included

only women with PTSD secondary to Child Sexual Abuse

Updated evidence statements on the combined evidence from previous and current reviews

There is relevant and applicable evidence suggesting that there is unlikely to be a clinically important difference between trauma-focused CBT and stress management therapy on reducing the severity of PTSD symptoms (k=7, n=290; SMD=-0.20; 95%CI, -0.60, 0.20). I

There is relevant and applicable evidence suggesting that there is unlikely to be a clinically important difference between trauma-focused CBT and stress management therapy on reducing depression symptoms (k=6, n=212; SMD= -0.14; 95%CI, -0.42, 0.14). I

There is relevant and applicable evidence suggesting that there is unlikely to be a clinically important difference between trauma-focused CBT and stress management therapy on reducing anxiety symptoms (k=5, n=178; SMD= -0.09; 95%CI, -0.40, 0.22). I

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between trauma-focused CBT and stress management therapy on improving quality of life (k=2, n=71; SMD= -0.22; 95%CI, -0.69, 0.26). I

4.1.1.4.9 Trauma focused CBT versus other therapies

Previous evidence: NICE Guidelines evidence statements

There is limited evidence favouring trauma-focused CBT over other therapies on reducing the likelihood of having a PTSD diagnosis after treatment (k=5; n=286; RR=0.71, 95% CI 0.56 to 0.89). I

There is limited evidence favouring trauma-focused CBT over other therapies on reducing the severity of PTSD symptoms (self-report measures) (k=3; n=176; SMD=-1.18, 95% CI -2.32 to -0.03). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and other therapies on reducing the likelihood of leaving treatment early for any reason (k=5; n=290; RR=1.14, 95% CI 0.68 to 1.9). I

There is limited evidence favouring trauma-focused CBT over other therapies on reducing the severity of clinician-rated PTSD symptoms (k = 3; n = 120; SMD = -0.81; 95% CI, -1.19 to -0.42). I

There is limited evidence favouring trauma-focused CBT over other therapies on reducing the severity of clinician-rated PTSD symptoms at follow-up (3months) (k = 2; n = 70; SMD = -0.65; 95% CI, -1.13 to -0.16). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and other therapies on reducing the severity of self-report PTSD symptoms at follow-up (2-5 months) (k = 2; n = 131; SMD = -0.28; 95% CI, -1.04 to 0.48). I

There is limited evidence favouring trauma-focused CBT over other therapies on reducing depression symptoms (k = 3; n = 120; SMD = -0.65; 95% CI, -1.03 to -0.28). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and other therapies on reducing anxiety symptoms (k = 4; n = 197; SMD = -0.47; 95% CI, -1.11 to 0.17). I

There is limited evidence favouring trauma-focused CBT over other therapies on reducing depression symptoms (2-5 months) (k = 2; n = 72; SMD = -0.53; 95% CI, -1 to -0.05). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and other therapies on reducing anxiety symptoms at follow-up (2-5 months) (k = 3; n = 149; SMD = -0.27; 95% CI, -0.6 to 0.07). I

There is evidence favouring trauma-focused CBT over other therapies on reducing the severity of clinician-rated PTSD symptoms at follow-up (6-9 months) (k = 1; n = 45; SMD = -1.85; 95% CI, -2.59 to -1.11). I

There is evidence favouring trauma-focused CBT over other therapies on reducing the severity of self-report PTSD symptoms at follow-up (6-9 months) (k = 1; n = 45; SMD = -1.72; 95% CI, -2.45 to -1). I

There is limited evidence favouring trauma-focused CBT over other therapies on reducing depression symptoms at follow-up (6-9 months) (k = 1; n = 45; SMD = -1.08; 95% CI, -1.74 to -0.42). I

There is evidence favouring trauma-focused CBT over other therapies on reducing anxiety symptoms at follow-up (6-9 months) (k = 1; n = 45; SMD = -1.18; 95% CI, -1.85 to -0.51). I

I

Further evidence identified in the current review

One poor quality trial was included (Blanchard et al., 2004) that was an update of a randomised controlled trial that was included in the NICE systematic review, comparing CBT to supportive psychotherapy in motor vehicle accident survivors with PTSD (Blanchard et al., 2003). Follow-up was 91 percent after one year and 75 percent after two years. These experimenters only used data from *people that had completed the study*.

Supportive therapy included psychoeducation regarding PTSD in an effort to reassure participants that their reactions were normal. A history of coping strategies was kept, but no cognitive restructuring occurred, and no relaxation techniques were suggested (Blanchard et al., 2004).

Comparisons between the pretreatment and posttreatment time for the Clinician Administered PTSD scale have not been made, as they were included in the previous paper (showing superiority of CBT over supportive psychotherapy; these comparisons were included in the previous NICE guidelines). The comparative benefits of CBT were also found on the PTSD checklist, the Impact of Events Scale, the Beck Depression Inventory, and the Spielberger State-Trait inventory.

Table 14 Effectiveness of Cognitive Behavioural Therapy vs Supportive Psychotherapy for PTSD

Study	Level and Quality	Population	Outcome	Effectiveness				Difference ¥ Effect size [95% CI]	
				CBT (n=28)		Supportive psychotherapy (n=24)			
				Pre	Post	Pre	Post		
(Blanchard, 2004) Update on (Blanchard, 2003) United States	Level II (RCT) Assignment: c Selection bias: c Blinding: c Assessment: a ITT: No	52/57 motor vehicle accident survivors 24 months 39 participants	CAPS	64.4±24.0	23.2±26.1	66.3±26.9	40.9±25.9	Condition main effect F[1,50]= 4.65 ^a p=0.036 SMD -0.67 [95% CI -1.23 to -0.11]	
					<i>3 months</i>		<i>3 months</i>	<i>3 months</i>	
					21.9±24.9		40.0±30.3	SMD -0.65 [95% CI -1.21 to -0.09]	
						<i>12 months</i>		<i>12 months</i>	<i>12 months</i>
					21.3±28.4		35.5±27.5	SMD -0.50 [95% CI -1.05 to 0.05]	
						<i>24 months</i>		<i>24 months</i>	<i>24 months</i>
					20.1±25.0		29.7±24.5	SMD -0.38 [95% CI -0.93 to 0.17]	
			PTSD checklist	52.1±12.3	31.8±14.0	56.3±14.4	44.2±13.9	NS SMD -0.88 [95% CI -1.45 to -0.31]	
					<i>3 months</i>	<i>3 months</i>	<i>3 months</i>		
					33.1±13.1	41.6±14.3	SMD -0.61 [95% CI -1.17 to -0.06]		
						<i>12 months</i>	<i>12 months</i>	<i>12 months</i>	
					35.0±14.5	39.2±14.9	SMD -0.28 [95% CI -0.83 to 0.27]		
						<i>24 months</i>	<i>24 months</i>	<i>24 months</i>	
					30.6±14.3	40.1±13.5	SMD -0.67 [95% CI -1.23 to -0.11]		
			Impact of Events Scale	38.1±13.7	13.1±15.3	40.5±20.4	27.1±18.9	NS SMD -0.81 [95% CI -1.38 to -0.24]	
					<i>3 months</i>	<i>3 months</i>	<i>3 months</i>		
					12.6±13.5	24.3±19.6	SMD -0.70 [95% CI -1.26 to -0.13]		
						<i>12 months</i>	<i>12 months</i>	<i>12 months</i>	
					14.2±17.5	19.2±17.5	SMD -0.28 [95% CI -0.83 to 0.27]		
						<i>24 months</i>	<i>24 months</i>	<i>24 months</i>	
					9.9±12.1	22.1±19.0	SMD -0.78 [95% CI -1.33 to -0.20]		

Beck Depression Inventory	22.8±11.4	11.8±12.6	27.0±11.8	20.4±12.3	NS
					SMD -0.68 [95% CI -1.24 to -0.12]
		<i>3 months</i>		<i>3 months</i>	<i>3 months</i>
		12.6±12.8		18.8±13.4	SMD -0.47 [95% CI -1.02 to 0.09]
		<i>12 months</i>		<i>12 months</i>	<i>12 months</i>
		13.8±14.2		18.8±11.9	SMD -0.37 [95% CI -0.92 to 0.18]
		<i>24 months</i>		<i>24 months</i>	<i>24 months</i>
		11.8±14.2		17.4±15.0	SMD -0.38 [95% CI -0.93 to 0.17]
STAI-State	53.9±13.7	39.5±13.1	57.8±11.9	51.3±12.4	F[1,50]=8.90 ^a p=0.004 ES=0.151
					SMD -0.91 [95% CI -1.48 to -0.34]
		<i>3 months</i>		<i>3 months</i>	<i>3 months</i>
		42.9±14.8		50.9±14.6	SMD -0.54 [95% CI -1.09 to 0.02]
		<i>12 months</i>		<i>12 months</i>	<i>12 months</i>
		38.0±12.3		50.0±12.7	SMD -0.95 [95% CI -1.52 to -0.37]
		<i>24 months</i>		<i>24 months</i>	<i>24 months</i>
		37.1±14.8		45.9±16.7	SMD -0.55 [95% CI -1.11 to 0.003]
STAI-Trait	53.8±13.7	41.4±15.3	56.4±10.1	52.3±11.6	F[1,50]=3.98 ^a p=0.050 ES=0.074
					SMD -0.78 [95% CI -1.35 to -0.22]
		<i>3 months</i>		<i>3 months</i>	<i>3 months</i>
		41.6±14.7		49.1±10.9	SMD -0.56 [95% CI -1.12 to -0.008]
		<i>12 months</i>		<i>12 months</i>	<i>12 months</i>
		42.2±15.8		49.4±12.9	SMD -0.49 [95% CI -1.04 to 0.07]
		<i>24 months</i>		<i>24 months</i>	<i>24 months</i>
		38.5±15.8		46.8±17.0	SMD -0.50 [95% CI -1.05 to 0.05]

CBT=cognitive behaviour therapy; CAPS=Clinician Administered PTSD Scale; STAI=Speilberger State-Trait Inventory; ^aUnivariate ANOVAs performed to assess main effect of treatment condition at 3 and 12 months follow-up; ES=effect size; ¥ Author's reported value for statistical analysis; SMD=standardised mean difference.

Current review evidence statements

There is limited relevant and applicable evidence favouring CBT over supportive psychotherapy on reducing severity of PTSD symptoms (CAPS) at 12 months (k=1; n=52; SMD -0.50; 95% CI, -1.05 to 0.05). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between CBT and supportive psychotherapy on reducing the severity of PTSD symptoms (CAPS) at 24 months (k=1; n=39; SMD -0.38; 95% CI, -0.93 to 0.17). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between CBT and supportive psychotherapy on reducing the severity of PTSD symptoms (PTSD checklist) at 12 months (k=1; n=52; SMD -0.28 (95% CI -0.83 to 0.27). II

There is limited relevant and applicable evidence favouring CBT over supportive psychotherapy on reducing severity of PTSD symptoms (PTSD checklist) at 24 months (k=1; n=39; SMD -0.67; 95% CI, -1.23 to -0.11). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between CBT and supportive psychotherapy on improving an impact of events scale score at 12 months (k=1; n=52; SMD -0.28; 95% CI -0.83 to 0.27). II

There is limited relevant and applicable evidence favouring CBT over supportive psychotherapy on improving an impact of events scale score at 24 months (k=1; n=39; SMD -0.78; 95% CI, -1.33 to -0.20). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between CBT and supportive psychotherapy on reducing depression symptoms at 12 months (k=1; n=52; SMD -0.37; 95% CI, -0.92 to 0.18). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between CBT and supportive psychotherapy on reducing depression symptoms at 24 months (k=1; n=39; SMD -0.38; 95% CI, -0.93 to 0.17). II

There is limited relevant and applicable evidence favouring CBT over supportive psychotherapy on reducing anxiety symptoms (STAI-state) at 12 months (k=1; n=52; SMD -0.95; 95% CI, -1.52 to -0.37). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between CBT and supportive psychotherapy on reducing anxiety symptoms (STAI-state) at 24 months (k=1; n=39; SMD -0.55; 95% CI, -1.11 to 0.003). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between CBT and supportive psychotherapy on reducing anxiety symptoms (STAI-trait) at 12 months (k=1; n=52; SMD -0.49; 95% CI, -1.04 to 0.07). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between CBT and supportive psychotherapy on reducing anxiety symptoms (STAI-trait) at 24 months (k=1; n=39; SMD -0.50; 95% CI, -1.05 to 0.05). II

Updated evidence statements on the combined evidence from previous and current reviews

As stated above the new evidence available for the current review only included follow-up data (12 and 24 months) on a previously reported study. Therefore there is no new combined evidence statement.

4.1.1.4.10 Trauma focused CBT (exposure) versus trauma focused CBT (cognitive therapy)

Previous evidence: NICE Guidelines evidence statements

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of posttreatment PTSD symptoms using clinician measure CAPS (k = 1; n = 62; SMD = -0.09; 95% CI, -0.59 to 0.41). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of PTSD symptoms at 6 month follow-up using clinician measure CAPS (k = 1; n = 56; SMD = 0.08; 95% CI, -0.45 to 0.6). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of PTSD symptoms at 12 month follow-up using clinician measure CAPS (k = 1; n = 54; SMD = -0.28; 95% CI, -0.81 to 0.26). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of posttreatment PTSD symptoms using self-report IES avoidance subscale (k = 1; n = 62; SMD = -0.48; 95% CI, -0.99 to 0.02). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of PTSD symptoms at 6 month follow-up using self-report IES avoidance subscale (k = 1; n = 56; SMD = -0.06; 95% CI, -0.58 to 0.47). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of PTSD symptoms at 12 month follow-up using self-report IES avoidance subscale (k = 1; n = 54; SMD = -0.24; 95% CI, -0.77 to 0.3). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of posttreatment PTSD

symptoms using self-report IES intrusions subscale ($k = 1$; $n = 62$; $SMD = -0.15$; 95% CI, -0.65 to 0.35). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of PTSD symptoms at 6 month follow-up using self-report IES intrusions subscale ($k = 1$; $n = 56$; $SMD = -0.19$; 95% CI, -0.71 to 0.34). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of PTSD symptoms at 12 month follow-up using self-report IES intrusions subscale ($k = 1$; $n = 54$; $SMD = -0.32$; 95% CI, -0.86 to 0.22). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of posttreatment depression symptoms using self-report BDI ($k = 1$; $n = 62$; $SMD = -0.13$; 95% CI, -0.62 to 0.37). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of depression symptoms at 6 month follow-up using self-report BDI ($k = 1$; $n = 56$; $SMD = -0.04$; 95% CI, -0.56 to 0.49). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of depression symptoms at 12 month follow-up using self-report BDI ($k = 1$; $n = 54$; $SMD = -0.05$; 95% CI, -0.58 to 0.49). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of posttreatment anxiety symptoms using self-report BAI ($k = 1$; $n = 62$; $SMD = -0.02$; 95% CI, -0.52 to 0.48). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of anxiety symptoms at 6 month follow-up using self-report BAI ($k = 1$; $n = 56$; $SMD = 0.19$; 95% CI, -0.34 to 0.71). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the severity of anxiety symptoms at 12 month follow-up using self-report BAI ($k = 1$; $n = 54$; $SMD = -0.07$; 95% CI, -0.6 to 0.47). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT (exposure) and trauma-focused CBT (cognitive therapy) on reducing the likelihood of having a posttreatment PTSD diagnosis ($k = 1$; $n = 72$; $RR = 0.83$; 95% CI, 0.55 to 1.24). I

There is limited evidence favouring trauma-focused CBT (cognitive therapy) over trauma-focused CBT (exposure) on reducing the likelihood of leaving the study prior to end of treatment for any reason (k = 1; n = 72; RR = 1.59; 95% CI, 0.49 to 5.15). I

Further evidence identified in the current review

No new studies were identified comparing trauma-focused CBT (exposure) to trauma-focused CBT (cognitive therapy)

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.1.4.11 EMDR versus stress management

Previous evidence: NICE Guidelines evidence statements

There is limited evidence favouring EMDR over stress management on reducing the likelihood of having a PTSD diagnosis after treatment (k=3; n=84; RR=0.69, 95% CI 0.46 to 1.04). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and stress management therapy on reducing the severity of PTSD symptoms (self-report measures) (k=3; n=75; SMD=-0.4, 95% CI -0.86 to 0.06). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and stress management therapy on reducing the likelihood of leaving treatment early for any reason (k=3; n=84; RR=1.03, 95% CI 0.37 to 2.88).

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and stress management therapy on reducing the severity of clinician-rated PTSD symptoms (k = 2; n = 53; SMD = -0.35; 95% CI, -0.9 to 0.19). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and stress management therapy on reducing the severity of clinician-rated PTSD symptoms at follow-up (2-5 months) (k = 3; n = 71; SMD = -0.59; 95% CI, -1.08 to -0.09). I

There is limited evidence favouring EMDR over stress management therapy on reducing the severity of self-report PTSD symptoms at follow-up (2-5 months) (k = 3; n = 75; SMD = -0.51; 95% CI, -0.98 to -0.05). I

There is limited evidence favouring EMDR over stress management therapy on reducing depression symptoms (k = 3; n = 75; SMD = -0.67; 95% CI, -1.14 to -0.2). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between EMDR and stress management therapy on

reducing depression symptoms at follow-up (2-5 months) (k = 3; n = 75; SMD = -0.23; 95% CI, -0.7 to 0.23). I

There is limited evidence favouring EMDR over stress management therapy on reducing anxiety symptoms (k = 2; n = 45; SMD = -0.75; 95% CI, -1.36 to -0.13). I

Further evidence identified in the current review

No new studies were identified comparing EMDR to stress management therapies.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.1.4.12 EMDR versus other therapies

Previous evidence: NICE Guidelines evidence statements

There is limited evidence favouring EMDR over other therapies on reducing the likelihood of having a PTSD diagnosis after treatment (k=1; n=67; RR=0.4, 95% CI 0.19 to 0.84). I

There is limited evidence favouring EMDR over other therapies on reducing the severity of PTSD symptoms (self-report measures) (k=2; n=124; SMD=-0.84, 95% CI -1.21 to -0.47). I

There is limited evidence favouring other therapies over EMDR on reducing the likelihood of leaving treatment early for any reason (k=2; n=127; RR=1.48, 95% CI 0.26 to 8.54). I

There is limited evidence favouring EMDR over other therapies on reducing depression symptoms (k = 2; n = 127; SMD = -0.67; 95% CI, -1.03 to -0.32). I

There is limited evidence favouring EMDR over other therapies on reducing anxiety symptoms (k = 2; n = 126; SMD = -0.72; 95% CI, -1.08 to -0.36). I

Further evidence identified in the current review

One study by Marcus et al., (2004) provided follow-up information on a trial that compared the effectiveness of EMDR vs standard care for treating a group of people with PTSD in a Health Maintenance Organisation (HMO) setting. Standard care was dependent on clinician's preference, and was a combination of individual psychotherapy, with the possible addition of medication or group therapy. The results of the initial study indicated that EMDR was superior to standard care at reducing PTSD symptoms on all outcome measures. The follow-up paper found that these differences were still maintained at 3 and 6 months posttreatment. The systematic review by NICE defined the standard care provided in the original study by Marcus et al., (1997) as 'Other therapies'. Results of this average quality trial suggest that EMDR had statistically significant and clinically important benefits on several outcome measures for PTSD sufferers *who completed treatment*, compared to standard care.

Table 15 Effectiveness of EMDR vs standard care for treating PTSD

Study	Level and Quality	Population	Outcome	EMDR		Standard care		Difference ¥ Effect size [95 % CI]
				Post	Follow-up	Post	Follow-up	
(Marcus, 2004) update of Marcus (1997) United States	Level II (RCT) Assignment: b Selection bias: c Blinding: c Assessment: a	53 women 14 men	Impact of Events Scale (IES)	17.9±16.5	3 months	35.0±20.2	3 months	t(42)=-3.87
				12.3±33.0	6 months	33.0±20.8	6 months	p<0.001
				11.5±14.6	6 months	27.6±21.1	6 months	t(34)=-2.73
								p=0.010
								3 months
								SMD -0.74
								[95% CI -1.23 to -0.24]
								6 months
								SMD -0.88
								[95% CI -1.38 to -0.38]
			Modified PTSD Scale (MPTSD)	24.5±21.3	3 months	44.3±30.0	3 months	t(42)=-3.40
				17.3±21.1	6 months	42.2±27.2	6 months	p=0.002
				16.0±17.8	6 months	43.5±35.1	6 months	t(34)=3.12
								p=0.004
								3 months
								SMD -1.01
								[95% CI -1.52 to -0.50]
								6 months
								SMD -0.98
								[95% CI -1.49 to -0.47]
			Beck Depression Inventory (BDI)	8.4±8.3	3 months	15.3±12.9	3 months	t(42)=-1.90
				8.1±10.4	6 months	14.4±11.4	6 months	p=0.002
				6.9±8.8	6 months	17.9±16.1	6 months	t(34)=-2.66
								p=0.012
								3 months
								SMD -0.57
								[95% CI -1.06 to -0.08]
								6 months
								SMD -1.43
								[95% CI -1.97 to -0.89]
			Spielberger State-Trait Anxiety (STAI)-Trait	38.1±11.2	3 months	47.8±13.4	3 months	t(42)=-2.35
				34.7±13.7	6 months	44.1±12.3	6 months	p=0.023
				33.6±11.6	6 months	46.8±16.2	6 months	t(34)=-2.85
								p=0.007
								3 months
								SMD -0.71
								[95% CI -1.21 to -0.22]
								6 months
								SMD -0.93
								[95% CI -1.43 to -0.42]
			Spielberger State-Trait Anxiety (STAI)-State	38.0±15.2	3 months	45.6±14.8	3 months	Not significant
				34.8±14.3	6 months	41.1±14.6	6 months	t(34)=-2.50
				31.7±12.1	6 months	43.7±16.8	6 months	p=0.017
								SMD- 0.43
								[95% CI, -0.92 to 0.05]

6 months
SMD - 0.8
[95% CI, -
1.31 to 0.31]

¥ Author's reported value for statistical analysis; SMD=standardised mean difference.

Current review evidence statements

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between EMDR and standard care on improving an impact of events scale score at three months (k=1; n=44; SMD -0.74; 95% CI, -1.23 to -0.24). II

There is limited relevant and applicable evidence favouring EMDR over standard care on improving an impact of events scale score at six months (k=1; n=36; SMD -0.88; 95% CI, -1.38 to -0.38). II

There is limited relevant and applicable evidence favouring EMDR over standard care on improving a modified PTSD scale score at three months (k=1; n=44; SMD -1.01; 95% CI, -1.52 to -0.50). II

There is limited relevant and applicable evidence favouring EMDR over standard care on improving a modified PTSD scale score at six months (k=1; n=36; SMD -0.98; 95% CI, -1.49 to -0.47). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between EMDR and standard care on reducing depression symptoms (BDI) at three months (k=1; n=44; SMD -0.57; 95% CI, -1.06 to -0.08). II

There is relevant and applicable evidence favouring EMDR over standard care on reducing depression symptoms at six months (k=1; n=36; SMD -1.43; 95% CI, -1.97 to -0.89). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between EMDR and standard care on reducing anxiety (trait) symptoms at three months (k=1; n=44; SMD -0.71; 95% CI, -1.21 to -0.22). II

There is limited relevant and applicable evidence favouring EMDR over standard care on reducing anxiety (trait) symptoms at six months (k=1; n=36; SMD -0.93; 95% CI, -1.43 to -0.42). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between EMDR and standard care on reducing anxiety (state) symptoms at three months (k=1; n=44; SMD -0.43; 95% CI, -0.92 to 0.05). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between EMDR and standard care on reducing anxiety (state) symptoms at six months (k=1; n=36; SMD -0.8; 95% CI, -1.31 to 0.31). II

Updated evidence statements on the combined evidence from previous and current reviews

As stated above the new evidence available for the NHMRC review only included follow-up data on a previously reported study. Therefore there is no new combined evidence statement.

4.1.1.4.13 Stress management versus other therapies

Previous evidence: NICE Guidelines evidence statements

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between stress management therapy and other therapies on reducing the likelihood of having a PTSD diagnosis after treatment (k=1; n=31; RR=0.58, 95% CI 0.3 to 1.11). I

There is limited evidence favouring stress management therapy over other therapies on reducing the severity of PTSD symptoms (clinician-rated measures) (k=1; n=25; SMD=-1.22, 95% CI -2.09 to -0.35). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between stress management therapy and other therapies on reducing the likelihood of leaving treatment early for any reason (k=1; n=31; RR=0.82, 95% CI 0.2 to 3.46). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between stress management therapy and other therapies on reducing anxiety symptoms (k = 1; n = 25; SMD = -0.51; 95% CI, -1.32 to 0.29). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between stress management therapy and other therapies on reducing depression symptoms (k = 1; n = 25; SMD = -0.51; 95% CI, -1.31 to 0.3). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between stress management therapy and other therapies on reducing the severity of clinician-rated PTSD symptoms at follow-up (3 months) (k = 1; n = 18; SMD = -0.38; 95% CI, -1.31 to 0.55). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between stress management therapy and other therapies on reducing anxiety symptoms at follow-up (3 months) (k = 1; n = 18; SMD = -0.68; 95% CI, -1.64 to 0.28). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between stress management therapy and other therapies on reducing depression symptoms at follow-up (3 months) (k = 1; n = 18; SMD = -0.48; 95% CI, -1.42 to 0.46). I

Further evidence identified in the current review

No new studies were identified comparing stress management to other therapies.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.1.4.14 Group CBT (trauma-focused) versus Group CBT (non trauma focused)

Previous evidence: NICE Guidelines evidence statements

There is evidence suggesting there is unlikely to be a clinically important difference between group CBT (trauma-focused) and group CBT (non trauma-focused) on reducing the likelihood of having a PTSD diagnosis after treatment (k=1; n=360; RR=0.98, 95% CI 0.83 to 1.16). I

There is evidence suggesting there is unlikely to be a clinically important difference between group CBT (trauma-focused) and group CBT (non trauma-focused) on reducing the severity of PTSD symptoms (k=1; n=325; SMD=0.12, 95% CI -0.34 to 0.1). I

There is limited evidence suggesting a difference favouring group CBT (non trauma-focused) over group CBT (trauma-focused) on reducing the likelihood of leaving treatment early for any reason (k=1; n=360; RR=1.38, 95% CI 1 to 1.9). I

Further evidence identified in the current review

No new studies were identified comparing group CBT (trauma-focused) to group CBT (non trauma-focused).

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.1.4.15 Narrative exposure therapy versus supportive therapy

Previous evidence: NICE Guidelines evidence statements

There is limited evidence favouring narrative exposure therapy over supportive counselling on reducing the severity of PTSD symptoms at 12 month follow-up as measured by clinician interview CIDI ($k = 1$; $n = 27$; $SMD = -1.22$; 95% CI, -2.05 to -0.38). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between narrative exposure therapy and supportive counselling on reducing the severity of PTSD symptoms posttreatment as measured by assisted self-report PDS ($k = 1$; $n = 28$; $SMD = -0.06$; 95% CI, -0.8 to 0.68). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between narrative exposure therapy and supportive counselling on reducing the severity of PTSD symptoms at 4 month follow-up as measured by assisted self-report PDS ($k = 1$; $n = 28$; $SMD = 0.18$; 95% CI, -0.56 to 0.93). I

There is limited evidence favouring narrative exposure therapy over supportive counselling on reducing the severity of PTSD symptoms at 12 month follow-up as measured by assisted self-report PDS ($k = 1$; $n = 27$; $SMD = -1.06$; 95% CI, -1.88 to -0.25). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between narrative exposure therapy and supportive counselling on increasing posttreatment quality of life as measured by the Medical Outcomes Study Self-Report Form-12 ($k = 1$; $n = 28$; $SMD = -0.15$; 95% CI, -0.89 to 0.6). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between narrative exposure therapy and supportive counselling on increasing quality of life at 4 month follow-up as measured by the Medical Outcomes Study Self-Report Form-12 ($k = 1$; $n = 28$; $SMD = -0.37$; 95% CI, -1.12 to 0.38). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between narrative exposure therapy and supportive counselling on increasing quality of life at 12 month follow-up as measured by the Medical Outcomes Study Self-Report Form-12 ($k = 1$; $n = 27$; $SMD = -0.46$; 95% CI, -1.23 to 0.3). I

There is limited evidence favouring narrative exposure therapy over supportive counselling on reducing the likelihood of having a PTSD diagnosis at 12 month follow-up ($k = 1$; $n = 31$; $RR = 0.48$; 95% CI, 0.26 to 0.88). I

There is limited evidence favouring supportive counselling over narrative exposure therapy on reducing the likelihood of leaving the study early due to any reason ($k = 1$; $n = 31$; $RR = 2.47$; 95% CI, 0.29 to 21.21). I

Further evidence identified in the current review

No new studies were identified comparing narrative exposure therapy to supportive therapy.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.1.4.16 Narrative exposure therapy versus psychoeducation

Previous evidence: NICE Guidelines evidence statements

There is evidence favouring narrative exposure therapy over brief psychoeducation on reducing the severity of PTSD symptoms at 12 month follow-up as measured by clinician interview CIDI (k = 1; n = 25; SMD = -1.46; 95% CI, -2.37 to -0.56). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between narrative exposure therapy and brief psychoeducation on reducing the severity of PTSD symptoms posttreatment as measured by assisted self-report PDS (k = 1; n = 27; SMD = -0.19; 95% CI, -0.95 to 0.57). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between narrative exposure therapy and brief psychoeducation on reducing the severity of PTSD symptoms at 4 month follow-up as measured by assisted self-report PDS (k = 1; n = 27; SMD = -0.43; 95% CI, -1.19 to 0.34). I

There is limited evidence favouring narrative exposure therapy over brief psychoeducation on reducing the severity of PTSD symptoms at 12 month follow-up as measured by assisted self-report PDS (k = 1; n = 25; SMD = -1.27; 95% CI, -2.15 to -0.39). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between narrative exposure therapy and brief psychoeducation on increasing posttreatment quality of life as measured by the Medical Outcomes Study -Report Form-12 (k = 1; n = 27; SMD = -0.15; 95% CI, -0.91 to 0.61). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between narrative exposure therapy and brief psychoeducation on increasing quality of life at 4 month follow-up as measured by the Medical Outcomes Study Self-Report Form-12 (k = 1; n = 27; SMD = -0.08; 95% CI, -0.83 to 0.68). I

There is limited evidence favouring narrative exposure therapy over brief psychoeducation on increasing quality of life at 12 month follow-up as measured by the Medical Outcomes Study Self-Report Form-12 (k = 1; n = 25; SMD = -0.48; 95% CI, -1.28 to 0.32). I

There is limited evidence favouring narrative exposure therapy over brief psychoeducation on reducing the likelihood of having a PTSD diagnosis at 12 month follow-up (k = 1; n = 29; RR = 0.55; 95% CI, 0.29 to 1.06). I

There is limited evidence favouring brief psychoeducation over narrative exposure therapy on reducing the likelihood of leaving the study early due to any reason (k = 1; n = 29; RR = 2.12; 95% CI, 0.25 to 17.98). I

Further evidence identified in the current review

No new studies were identified comparing narrative exposure therapy to psychoeducation.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.1.4.17 Psychoeducation versus supportive therapy

Previous evidence: NICE Guidelines evidence statements

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between supportive counselling and brief psychoeducation on reducing the severity of PTSD symptoms at 12 month follow-up as measured by clinician interview CIDI (k = 1; n = 24; SMD = -0.24; 95% CI, -1.04 to 0.57). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between supportive counselling and brief psychoeducation on reducing the severity of PTSD symptoms posttreatment as measured by assisted self-report PDS (k = 1; n = 25; SMD = -0.13; 95% CI, -0.92 to 0.65). I

There is limited evidence favouring supportive counselling over brief psychoeducation on reducing the severity of PTSD symptoms at 4 month follow-up as measured by assisted self-report PDS (k = 1; n = 25; SMD = -0.55; 95% CI, -1.35 to 0.25). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between supportive counselling and brief psychoeducation on reducing the severity of PTSD symptoms at 12 month follow-up as measured by assisted self-report PDS (k = 1; n = 24; SMD = -0.1; 95% CI, -0.91 to 0.7). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between supportive counselling and brief psychoeducation on increasing posttreatment quality of life as measured by the Medical Outcomes Study -Report Form-12 (k = 1; n = 25; SMD = 0; 95% CI, -0.78 to 0.78). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between supportive counselling and brief psychoeducation on increasing quality of life at 4 month follow-up as measured by the Medical Outcomes Study Self-Report Form-12 (k = 1; n = 25; SMD = 0.28; 95% CI, -0.51 to 1.07). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between supportive counselling and brief psychoeducation on increasing quality of life at 12 month follow-up as measured by the Medical Outcomes Study Self-Report Form-12 ($k = 1$; $n = 24$; $SMD = -0.06$; 95% CI, -0.87 to 0.74). I

The evidence is inconclusive and so it is not possible to determine if there is a psychoeducation on reducing the likelihood of having a PTSD diagnosis at 12 month follow-up ($k = 1$; $n = 26$; $RR = 1.14$; 95% CI, 0.77 to 1.69). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between supportive counselling and brief psychoeducation on reducing the likelihood of leaving the study early due to any reason ($k = 1$; $n = 26$; $RR = 0.86$; 95% CI, 0.06 to 12.28). I

Further evidence identified in the current review

No new studies were identified comparing psychoeducation to supportive therapy.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.1.5 Summary of evidence

Psychological interventions

Overall summary

There are now over 30 well controlled studies examining the effectiveness of psychological treatment for PTSD. While a small number of these studies have been published since the NICE guidelines, those later studies have not altered the findings that trauma focused cognitive behavioural therapy (CBT) and eye movement desensitization and reprocessing (EMDR) are the treatments of choice for PTSD. These treatments were found to be effective in the treatment not only of PTSD symptoms but also comorbid anxiety and depression, as well as achieving improvements in broader quality of life. Trauma focused CBT and EMDR share the two key elements of exposure to the traumatic memory and cognitive processing of the meaning or interpretations of the trauma (termed cognitive restructuring in CBT and cognitive interweaving in EMDR). There is some evidence to suggest that these components are the key ingredients in the effectiveness of these interventions.

Studies examining the effectiveness of non trauma focused interventions of anxiety management (AM) and stress inoculation training (SIT) suggest that these interventions were superior to no-treatment in achieving gains in PTSD symptoms, as well as comorbid anxiety and depression. However, AM and SIT were not as effective as trauma focused CBT or EMDR in reducing the likelihood of having the diagnosis at

posttreatment, or in achieving longer term reductions in PTSD symptoms and comorbidity. Importantly, although not as effective as trauma focused CBT or EMDR when used in isolation, elements of AM and SIT, such as controlled breathing and other coping and symptom management techniques, are often included as part of trauma focused intervention protocols.

Similarly, psychoeducation, when delivered as a “stand alone” treatment, was found to be inferior to trauma-focused exposure-based interventions. However, elements of psychoeducation, such as providing an explanatory model for the sufferer of their symptoms and a rationale for treatment, are regularly included as components of trauma focused CBT interventions. Therefore, while psychoeducation, AM and SIT were not as effective as trauma focused CBT or EMDR as stand alone interventions, elements of these interventions may well have a role as part of a broader trauma focused treatment.

While models of brief trauma-focused psychodynamic therapy have been developed, they have not as yet been sufficiently tested in controlled studies to derive practice recommendations. It may be, given the potential inclusion in such models of engagement with the traumatic memory and addressing the interpretations and meaning of the trauma, (the key components of effective treatments noted above), that such models are efficacious. However, until controlled studies of the intervention are conducted, this remains largely speculative.

Supportive counselling and hypnotherapy have not been found to be effective as “stand alone” interventions when compared to trauma-focused CBT or EMDR.

To varying degrees, the studies cited in this section also include adults with PTSD as a result of prolonged and/or repeated trauma (eg Resick; Foa). One study (Cloitre et al., 2000) specifically provided support for the effectiveness of graded trauma focused CBT for adult survivors of childhood sexual assault. Thus, there is evidence to support the use of trauma focused psychological interventions in adults with PTSD following prolonged and/or repeated trauma. Issues of chronic self harm and suicidal ideation are more likely in this group and, therefore, may warrant special attention or consideration. The adult presenting with these issues may have a comorbid personality disorder that requires management. In such cases, more time and attention to stabilisation and engagement may be required in preparation for trauma-focused therapy, as outlined in Cloitre et al. (2002). In the absence of adequate distress tolerance or emotion regulation skills, the distress associated with trauma focus work may exceed the individual’s coping capacity and become counter productive. In some cases, however, the individual with PTSD may have ongoing suicidality until the traumatic experience is addressed, in which case delay in trauma focus therapy should be avoided.

Although the evidence indicates that trauma-focused CBT and EMDR combined with *in vivo* exposure are important and potent interventions for the treatment of adults with PTSD, their clinical application needs to be carefully considered in each case. The practitioner should note that the clinical efficacy studies upon which the cited evidence is based have generally excluded people with severe comorbid borderline personality disorder, psychotic illness, severe depression and suicide risk or ongoing threat. As such, caution should be exercised, and the use of exposure seriously

questioned, when the traumatised person presents with any of these exclusion criteria. Section 4.1.11 of these guidelines reviews the evidence and provides recommendations for the treatment of adults with PTSD in the context of comorbidity.

Trauma focused CBT and EMDR - a comparison of longer term outcomes

In the development of practice recommendations, the issue of maintenance of treatment gains in the longer term is very important. Given the evidence supporting both trauma focused CBT and EMDR, it is important to examine closely comparative longer term outcomes for these two interventions. Four studies were cited by NICE which compared outcomes for trauma focused CBT and EMDR at three months follow-up. NICE evidence statements indicated that there was unlikely to be a clinically important difference between them. Interestingly, while this is the case when data across the studies is meta-analysed, a closer look at the individual studies reveals divergence on outcomes at follow-up. Two studies (Devilley & Spence, 1999; Taylor et al., 2003) demonstrate superiority of exposure, with EMDR showing some return to baseline at follow-up. The other two studies (Ironson et al., 2002; Lee et al., 2002b) demonstrate superiority of EMDR over exposure in certain outcome variables at follow-up. Subsequent evidence statements drawn from the current review based on Rothbaum et al., (2005), identified superior outcomes in depression, dissociation and end state functioning at six months, in the exposure condition, compared to EMDR.

In attempting to understand this divergence at follow-up for the purposes of developing practice recommendations, two issues are worth noting. Firstly, one of the two studies favouring EMDR in terms of longer term outcomes (Ironson et al., 2002) added *in vivo* exposure to the EMDR condition. Importantly, the trauma focused CBT studies also all included *in vivo* exposure. Secondly, as stated in the descriptions of treatments in Chapter 3, a number of core CBT interventions have been added to EMDR and reflected in its progressive protocols, including cognitive interweaving (cognitive therapy), then future templating (modelling and imaginal rehearsal of coping and mastery responses to anticipated future stressors) and most recently references to, although no explicit procedures for, *in vivo* exposure (Shapiro, 1999). Therefore, the use of more recent elaborated EMDR protocols that incorporate these elements, including *in vivo* exposure (considered either as part of, or in addition to, EMDR), may be important for achieving longer term outcomes and explaining some of the divergence in existing studies.

Although the precise mechanisms involved in EMDR are not known, there is increasing evidence from dismantling studies that the eye movements themselves are unlikely to be an active ingredient in EMDR's effectiveness (Foley & Spates, 1995; Renfrey & Spates, 1994; Sanderson & Carpenter, 1992) These studies have demonstrated comparable outcomes when eye movements have been replaced with alternate novel techniques such as fixing attention to a single point of light on a screen or a stationary raised hand. Given the above, there is a case for considering EMDR, based on the most recent protocols, as a variant of trauma focused CBT with the inclusion of a novel component, rather than as a separate treatment. However, this would be contrary to the position argued by the developers of EMDR who do not classify it as a CBT intervention. For this reason, and for consistency with other international guidelines, these guidelines will continue to treat EMDR as a separate intervention, but the inclusion and potential contribution of CBT components is noted.

Length and number of sessions

While length and number of sessions for both CBT and EMDR have not been empirically tested as independent variables in their own right, the recommendations in these guidelines draw on the length and number of sessions reported in the controlled studies and on expert consensus. They are also consistent with recommendations in the NICE guidelines. In relation to EMDR and trauma-focused CBT, at this point there is no consistent evidence suggesting that fewer treatment sessions are required for one treatment over the other. As such, there is no basis for recommending one treatment over the other on cost-effectiveness grounds.

4.1.1.6 Recommendations

Clinical Recommendations

- 4.1.1.6.1** *Adults with PTSD should be provided with trauma focused interventions (trauma focused CBT or eye movement desensitization and reprocessing in addition to in vivo exposure). (A)*
- 4.1.1.6.2** *As available evidence does not support the importance of eye movements per se in EMDR, it is recommended that practitioners who use EMDR be aware that treatment gains are more likely to be due to the engagement with the traumatic memory, cognitive processing and rehearsal of coping and mastery responses (GPP)*
- 4.1.1.6.3** *Where symptoms have not responded to one form of first line trauma-focused interventions (trauma focused CBT or EMDR in addition to in vivo exposure), health practitioners may consider the alternative form of trauma-focused interventions. GPP*
- 4.1.1.6.4** *Non trauma-focused interventions such as supportive counselling and relaxation should not be provided to adults with PTSD in preference to trauma-focused interventions. (B)*
- 4.1.1.6.5** *Where symptoms have not responded to a range of trauma focused interventions, evidence-based non trauma focused interventions (such as stress management) and/or pharmacotherapy (see section 3.1.3.6) should be considered. (C)*
- 4.1.1.6.6** *Sessions that involve imaginal exposure require 90 minutes to ensure that therapy is adequate in those sessions. (C)*
- 4.1.1.6.7** *Following diagnosis, assessment and treatment planning, eight to 12 sessions of trauma focused treatment is usually sufficient. (D)*
- 4.1.1.6.8** *For PTSD sufferers with several problems arising from multiple traumatic events, traumatic bereavement or where PTSD is chronic and associated with significant disability and comorbidity, further sessions using specific treatments to address those problems may be required. (GPP)*

4.1.1.6.9 *Where adults have developed PTSD and associated features following exposure to prolonged and/or repeated traumatic events, more time to establish a trusting therapeutic alliance, more attention to teaching emotional regulation skills and a more gradual approach to exposure therapy may be required. (GPP)*

4.1.2 Single versus multiple psychological interventions

4.1.2.1 Research questions and PICO

Box 2 Multiple psychological interventions compared to single interventions for adults with PTSD: Research question and study selection criteria

Research Question	
16. For adults with PTSD, is a single intervention more effective than multiple interventions?	
Selection criteria	Inclusion criteria
Population	Adults with PTSD
Intervention	Single psychological or pharmacological intervention or psychosocial rehabilitation strategy
Comparator (1)	Combined psychological interventions, combined pharmacological interventions, combined psychosocial interventions or combined psychological, pharmacological or psychosocial interventions
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Comparator (2)	Combined psychological intervention and psychosocial rehabilitation (e.g., teaching self-care and independent living skills techniques, providing supported housing, marital/family skills training, social skills training, anger management, vocational rehabilitation and case management) or combined pharmacological intervention and psychosocial rehabilitation
Outcome	Primary outcome: resolution of symptoms of PTSD, social and occupational function, quality of life Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2002-8/2005*
Language	English

This was question number 10 in the VA/DoD review, with a search period up to 2002.

4.1.2.2 Studies included in previous reviews: VA/DoD (2004)

Four studies that compared combined psychological interventions with single psychological interventions were identified in the VA/DoD review (Cooper & Clum, 1989; Foa et al., 1999; Glynn et al., 1999).

4.1.2.3 Studies included in the current review of combined psychological treatments (2002-2005)

One randomised controlled trial was identified for the current review that assessed the effectiveness of the combination of two psychological treatments for PTSD against one of these alone (Bryant et al., 2003a). Bryant et al., (2003a) assessed the value of adding cognitive restructuring to 8 weeks of exposure.

4.1.2.4 Treatment comparisons

4.1.2.4.1 Stress Inoculation Therapy (SIT) combined with Prolonged exposure (PE) versus SIT or PE alone

Previous evidence: VA/DoD summary statement

(NOTE: The VA/DoD review did not provide evidence statements in the form of the NICE review)

One high quality randomised trial (Foa et al., 1999) showed poorer outcomes with a combination of Stress Inoculation therapy (SIT) than with exposure therapy alone. Number Needed to Treat for Harm (NNT_H) ranged from 4 to 5 for the various outcomes measured. No significant differences were found between the combination and SIT used alone.

Further evidence identified in the current review

No new studies were identified comparing SIT and PE with either intervention alone.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.2.4.2 Exposure therapy combined with cognitive restructuring versus exposure therapy or CR alone

Previous evidence: VA/DoD summary statement

A [second] randomised trial of good quality (Marks et al., 1998) showed poorer outcomes with a combination of exposure and cognitive restructuring when compared with cognitive restructuring alone. NNT_H ranged from 5 to 8 for the various outcomes measured.

Further evidence identified in the current review

Bryant et al., (2003a) found limited benefit with the addition of cognitive restructuring to exposure therapy.

Table 16 Effectiveness of exposure therapy vs exposure therapy plus cognitive restructuring

Study	Level and Quality	Population	Outcome	Exposure therapy (n=20)		Cognitive restructuring + exposure (n=20)		Difference † Effect size [95 % CI]
				Pre	Post	Pre	Post	
(Bryant, 2005) Australia	Level II (quasi-randomised controlled trial) Assignment: c Selection bias: c Blinding: b Assessment: a	40 civilian trauma victims after nonsexual assault or motor vehicle accident	CAPS-intensity	32.5±8.7	19.2±11.1	32.7±7.5	15.9±13.4	Not significant p<0.05 ^a SMD -0.36 [-0.99-0.26]
						6 months	6 months	
			CAPS-frequency	36.8±9.8	20.6±12.7	36.0±8.7	17.2±15.6	Not significant SMD -0.53 [-1.16-0.10]
					6 months	6 months		
			CAPS-frequency		23.3±12.9	15.7±15.2	Not significant SMD -0.14 [-0.76-0.48]	
					6 months	6 months		
			IES-intrusion	23.9±7.1	17.7±7.3	26.6±7.0	15.1±12.9	Not significant SMD -0.24 [-0.86-0.38]
					6 months	6 months		
			IES-avoidance	26.4±6.7	19.5±13.5	26.4±6.7	16.2±13.5	Not significant SMD -0.24 [-0.86-0.38]
					6 months	6 months		
STAI- State	56.8±11.2	43.1±13.5	54.6±8.2	41.5±14.8	Not significant SMD 0.04 [-0.58-0.66]			
		6 months	6 months					
Beck Depression Inventory	21.7±11.2	17.5±12.8	23.2±10.1	13.9±14.3	Not significant SMD -0.09 [-0.71-0.53]			
		6 months	6 months					
			16.2±12.2	15.0±14.0				

CAPS=Clinician Administered PTSD scale; IES=Impact of Events Scale; STAI=State-Trait Anxiety Inventory; ^a post hoc Tukey's comparison; †=Author's reported value; SMD=standardised mean difference

Current review evidence statements

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between cognitive restructuring in addition to exposure therapy and exposure therapy alone for improvement in clinician administered PTSD intensity score at 6 months (k=1; n=40; SMD=-0.36, 95% CI -0.99 to 0.26). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between cognitive restructuring in addition to exposure therapy and exposure therapy alone for improvement in clinician administered PTSD frequency score at 6 months (k=1; n=40; SMD=-0.53, 95% CI -1.16 to 0.10). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between cognitive restructuring in addition to exposure therapy and exposure therapy alone for improvement in impact of events scale (intrusion) score at 6 months (k=1; n=40; SMD=-0.14, 95% CI -0.76 to 0.48). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between cognitive restructuring in addition to exposure therapy and exposure therapy alone for improvement in impact of events scale (avoidance) score at 6 months (k=1; n=40; SMD=-0.24, 95% CI -0.86 to 0.38). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between cognitive restructuring in addition to exposure therapy and exposure therapy alone for improvement in Stait anxiety index score at 6 months (k=1; n=40; SMD=0.04, 95% CI -0.58 to 0.66). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between cognitive restructuring in addition to exposure therapy and exposure therapy alone for improvement in Beck depression inventory score at 6 months (k=1; n=40; SMD=-0.09, 95% CI -0.71 to 0.53). II

Updated evidence statements on the combined evidence from previous and current reviews

The VA/DoD summary statements are not in a form that can be combined with evidence statements from the current review. Consideration of both bodies of evidence will be reflected in the summary and recommendations.

4.1.2.4.3 Direct therapeutic exposure combined with behavioural family therapy versus direct exposure alone

Previous evidence: VA/DoD summary statement

A low quality RCT (Glynn et al., 1999) revealed that the addition of behavioural family therapy to the treatment of PTSD with direct therapeutic exposure did not improve outcomes.

Further evidence identified in the current review

No new studies were identified comparing direct therapeutic exposure and behavioural family therapy with direct therapeutic exposure alone.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.2.4.4 *Imaginal flooding combined with standard treatment versus standard treatment alone*

Previous evidence: VA/DoD summary statement

A low quality trial (Cooper & Clum, 1989) found improved outcomes when imaginal flooding was added to standard individual and group psychotherapy. The irregular methods and small sample size make these results questionable.

Further evidence identified in the current review

No new studies were identified comparing SIT and PE with either intervention alone.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.2.5 Summary of the evidence

There are now three moderate to high quality trials examining the issue of single versus combined psychological treatment. Two of these studies (Bryant et al., 2005; Marks et al., 1998) examine the combination of cognitive restructuring and exposure compared to cognitive restructuring or exposure alone. The findings of these studies suggest that while exposure and cognitive restructuring are effective interventions, there was no evidence of improved outcomes when they were delivered in combination.

A number of issues need to be considered in relation to these findings. First, it is important to acknowledge that the two treatments are not completely independent - exposure treatments include by their nature some level of cognitive re-processing and cognitive restructuring treatments include some level of engagement with and exposure to the traumatic memory. While the evidence suggests that both treatments are effective in facilitating trauma recovery, studies investigating the benefits of combining treatment have been flawed by reducing the amount of each treatment when provided in combination with another. This, and other methodological issues (for example, experimental power limitations) raised by combination studies mean that at this point recommendations cannot be made about combining these treatments.

In relation to SIT, while this treatment has been identified as an effective treatment for PTSD, although second line to trauma-focused interventions, it does not appear to demonstrate any advantage in combination with exposure in comparison to exposure alone (Foa et al., 1999). However, the limitations described in relation to the combination studies examining cognitive restructuring and exposure also apply here. As such, recommendations cannot be made about combining these treatments.

The range of trauma populations included in the above studies and the interventions provided are generalisable to the PTSD populations in Australia and the Australian healthcare context.

4.1.3 Individual and group psychological interventions

4.1.3.1 Research questions and PICO

Box 3 Individual compared to group therapy for adults with PTSD: research question and study selection criteria

Research Question	
5. Is individual therapy more effective than group therapy for PTSD?	
Selection criteria	Inclusion criteria
Population	Adults with PTSD
Intervention	Individual therapy (e.g., psychodynamic psychotherapy, individual cognitive behavioural therapies, EMDR, narrative exposure therapy, image rehearsal therapy, supportive counselling, hypnosis)
Comparator	Group therapy (e.g., supportive therapy, psychoeducation, psychodynamic therapy, group CBT such as anxiety management, stress inoculation, assertiveness training, prolonged exposure, cognitive restructuring)
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2002-8/2005*
Language	English

This was question number 8 in the VA/DoD review with a search period up to 2002.

Box 4 Combination individual and group therapy: research question and study selection criteria

Research Question	
6. For adults with PTSD, is the combination of individual therapy and group therapy more effective than either alone?	
Selection criteria	Inclusion criteria
Population	Adults with PTSD
Intervention	Individual therapy <u>and</u> group therapy (See Box 18 for examples)
Comparator	Individual therapy <u>or</u> group therapy (See Box 18 for examples)
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	1966-8/2005*
Language	English

A new search (1996-2005) was conducted on this question as it was not addressed in either the NICE or VA/DoD reviews.

4.1.3.2 Studies included in previous reviews: VA/DoD (2004)

Neither of these questions was addressed by the NICE review.

VA/DoD question 8 compared individual and group therapy for PTSD but no studies addressing this question were identified in the review.

The VA/DoD review did not address the question of combination individual and group therapy compared to either individual or group therapy alone.

4.1.3.3 Studies included in the current review

No studies were identified in the current review (2002-2005) that compared individual and group therapy for PTSD.

No studies were identified in the current review (1996-2005) that compared combined individual and group therapy with either individual or group therapy alone.

4.1.3.4 Treatment comparisons

Not applicable as no studies were identified.

4.1.3.5 Summary of evidence

While there were no studies examining the effectiveness of group versus individual therapy there is a small amount of evidence summarised in the NICE guidelines (outlined in sections 3.1.1.4.5.1 and 3.1.1.4.14.1 above) suggesting that group CBT is effective compared to waitlist and that trauma-focused group CBT and non trauma-focused group CBT were equally effective. The range of trauma populations included in the above studies and the interventions provided are generalisable to the PTSD populations in Australia and the Australian healthcare context

The recommendations in these guidelines reflect the weight of evidence supporting the effectiveness of trauma focused CBT when delivered in individual therapy. However, given that there is some evidence supporting group CBT, its potential adjunctive value has been noted in the recommendations, with an appropriately lower level of evidence.

4.1.3.6 Recommendations

4.1.3.6.1 Group CBT (trauma focused or non trauma focused) may be provided as adjunctive to, but should not be considered an alternative to, individual therapy. C

4.1.4 Self-delivered interventions

4.1.4.1 Research questions and PICO

Box 5 Self-delivered interventions: Research question and study selection criteria

Research Question	7. Are established interventions for PTSD effective when self-delivered without face-to-face practitioner support?
Selection criteria	Inclusion criteria
Population	Adults with PTSD
Intervention	Self-delivered psychological intervention without face-to-face practitioner support (e.g., web-based interapy or telephone support)
Comparator	(1) Practitioner delivered psychological intervention (2) No-treatment (e.g., assessment only)
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	1966-8/2005*
Language	English

A new search (1996-2005) was conducted on this question as it was not addressed in either the NICE or VA/DoD reviews.

4.1.4.2 Studies included in previous reviews

This question was not asked in either the NICE or VA/DoD reviews. However, the NICE question on psychological treatments (question 1) identified one study that compared interapy to waitlist (Lange et al., 2003a). Given its relevance to this question the NICE evidence statements have been included below.

4.1.4.3 Studies included in the current review (1996-2005)

There were no studies that met the inclusion criteria comparing self-delivered PTSD treatments with face-to-face therapy. However one study of relevance to this question that investigated self help CBT as an early intervention for adults exposed to trauma (Ehlers et al., 2003) failed to find a difference with waitlist. This study was not included in the review of this question as it was delivered as an early intervention (therefore covered under question 2) and included a 40 minute session with a therapist at the beginning of treatment to explain the self help book and its content (face-to-face contact).

4.1.4.4 Treatment comparisons

4.1.4.4.1 Interapy versus waitlist

Previous evidence: NICE Guidelines evidence statements

There is evidence favouring interapy over waitlist on reducing severity of PTSD symptoms as measured by self-report IES at endpoint ($k = 1$; $n = 101$; $SMD = -1.32$; 95% CI, -1.77 to -0.86). I

There is evidence favouring interapy over waitlist on reducing depression symptoms as measured by self-report SCL-90 at endpoint ($k = 1$; $n = 101$; $SMD = -1.06$; 95% CI, -1.51 to -0.62). I

There is limited evidence favouring interapy over waitlist on reducing anxiety symptoms as measured by self-report SCL-90 at endpoint ($k = 1$; $n = 101$; $SMD = -0.81$; 95% CI, -1.24 to -0.37). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between interapy and waitlist on reducing the likelihood of leaving the study prior to endpoint for any reason ($k = 1$; $n = 184$; $RR = 0.9$; 95% CI, 0.65 to 1.25). I

Further evidence identified in the current review

No further studies that compared interapy with waitlist were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.4.5 Summary of the evidence

Given the substantial body of evidence supporting practitioner delivered trauma-focused CBT interventions, a single study examining and supporting interapy interventions, and a single study failing to support the effectiveness of a CBT self help booklet as an early intervention, these guidelines recommend seeking practitioner facilitated treatment where this is available. Self-delivered options such as interapy may be of some benefit where face-to-face practitioner support is not available. However, there is clearly a need for further research into self-care interventions and practitioner delivered interventions combined with components of self-care. This need is evident across the range from early intervention through to cases of chronic PTSD. In the latter case, the application of existing chronic disease self-management models to PTSD may be investigated. While not an alternative to practitioner delivered interventions, in routine care practitioners are advised to discuss self-care strategies with PTSD sufferers to support recovery and the practitioner delivered interventions.

The studies examining these treatment options are applicable and generalisable to the Australian healthcare context.

The following recommendations are not intended to be used prescriptively but rather as guidelines to assist the practitioner. In each case treatment decisions should be based on recommended treatment combined with the clinical judgement of the practitioner and the person's preferences.

4.1.4.6 Recommendations

4.1.4.6.1 *For adults with PTSD, self-delivered interventions should not be prescribed in place of evidence-based practitioner delivered interventions. (B)*

4.1.4.6.2 *Facilitated although non face-to-face interventions such as interapy may be considered where face-to-face practitioner delivered interventions are not available (D)*

4.1.4.6.3 *Self-delivered interventions may be useful as adjunctive to practitioner delivered interventions (GPP)*

4.1.5 Pharmacological interventions

4.1.5.1 Research questions and PICO

Box 6 Pharmacological interventions for adults with PTSD: Research questions and study selection criteria

Research Questions	
	10. For adults with PTSD, do pharmacological interventions improve outcomes compared with placebo?
	11. For adults with PTSD, does any pharmacological intervention confer any advantage over other pharmacological interventions?
Selection criteria	Inclusion criteria
Population	Adults with PTSD
Intervention	Pharmacological intervention (e.g., SSRIs, other second-generation antidepressants, tricyclic antidepressants, monoamine oxidase inhibitors, benzodiazepines, mood stabilisers, anti-convulsants, and some non-benzodiazepine hypnotics and anti-anxiety medications)
Comparator	10. Placebo 11. Other pharmacological intervention
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2004-8/2005*
Language	English

SSRIs = selective serotonin reuptake inhibitors

These were pharmacological questions 1 and 2 in the NICE review, with a search period up to 2004.

4.1.5.2 Studies included in previous reviews: NICE (2005)

The following studies were identified by the NICE Guideline Development Group as meeting the inclusion criteria. References given in shortened format and summary characteristics of trials are listed in Appendix **.

- 23 studies comparing drug treatments against placebo (Brady et al., 2000; Bryson et al., unpublished-a; Bryson et al., unpublished-b; Butterfield et al., 2001; Connor et al., 1999; Davidson et al., 1990; Davidson et al., Unpublished; Davidson et al., 2001a; Davidson et al., 2001b; Davidson et al., 2003; Davidson, 2004; Eli Lilly, unpublished data; Hertzberg et al., 2000; Katz et al., 1994; Kosten et al., 1991; Marshall et al., 2001; Martenyi et al., 2002a; Martenyi et al., 2002b; Pfizer 588, unpublished data; Pfizer 589, unpublished data; Stein et al., 2002; Tucker et al., 2001; Zohar et al., 2002).
- 1 study compared one pharmacological treatment against another pharmacological treatment (Hamner et al., 2003)

“Study characteristics

In contrast to the reports of psychological interventions, the studies included did not typically provide data on remission of PTSD diagnosis, but instead reported response rate in terms of a percentage decrease in symptoms from baseline score. Response rate data were not used within the meta-analysis because of the inconsistency in reporting (thresholds for reported response rates typically vary from 30% to 50%). This decision was taken because it is known that relatively small differences in mean scores (which are not clinically significant) between two comparison groups can produce statistically significant differences when presented as response rates (Kirsch et al., 2002). Remission rates have the advantage of being clinically determined in advance (diagnosis v. no diagnosis). Recent research in depression suggests that remission is a more reliable indicator of a stable return to normal mood states than response rates (Keller, 2003). The most consistent evidence reported for tolerability was the number of participants leaving the treatment early and this is reported within the review.”

Extracted from NICE (2005, p. 69)

4.1.5.3 Studies included in the current review (2004-2005)

The review team conducted a systematic search for RCTs published from 2004 to 2005 that compared pharmacological treatments against waiting list or usual care or against another pharmacological treatment. The following studies were identified as meeting the inclusion criteria.

- 5 studies comparing drug treatments against placebo (Brady et al., 2005; Davidson et al., 2005a; Davis et al., 2004; Reich et al., 2004; Tucker et al., 2004)
- 2 studies comparing one drug treatment against another (Chung et al., 2004; McRae et al., 2004)

4.1.5.4 Treatment comparisons (placebo or alternate treatment)

4.1.5.4.1 Paroxetine versus placebo

Previous evidence: NICE Guidelines evidence statements

Four studies of paroxetine were identified that met the inclusion criteria (Bryson et al., unpublished-a; Bryson et al., unpublished-b; Marshall et al., 2001; Tucker et al., 2001) and this included one continuation/relapse prevention study. In these trials people with depression were admitted provided PTSD was considered to be the primary diagnosis. All four trials were of mixed-trauma populations.

Acute phase

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between paroxetine and placebo on reducing the severity of PTSD symptoms (CAPS - clinician) ($k = 3$; $n = 1070$; $SMD = -0.42$; 95% $CI, -0.55$ to -0.3). I

There is evidence suggesting there is unlikely to be a clinically important difference between paroxetine and placebo on reducing the severity of PTSD symptoms (DTS - self-report) (k = 3; n = 1065; SMD = -0.37; 95% CI, -0.49 to -0.24). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between paroxetine and placebo on reducing depression symptoms (Montgomery-Asberg Depression Rating Scale -clinician) (k = 3; n = 1069; SMD = -0.34; 95% CI, -0.61 to -0.07). I

There is evidence suggesting there is unlikely to be a clinically important difference between paroxetine and placebo on improving quality of life (k = 3; n = 1039; SMD = -0.27; 95% CI, -0.4 to -0.14). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between paroxetine and placebo on reducing the likelihood of leaving treatment early. (k = 3; n = 1196; RR = 0.95; 95% CI, 0.79 to 1.15). I

Continuation/relapse prevention

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between paroxetine and placebo on reducing the severity of PTSD symptoms (CAPS - clinician) (k = 1; n = 129; SMD = 0.19; 95% CI, -0.15 to 0.54). I

There is evidence suggesting there is unlikely to be a clinically important difference between paroxetine and placebo on reducing the severity of PTSD symptoms (DTS - self-report) (k = 1; n = 127; SMD = 0.06; 95% CI, -0.28 to 0.41). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between paroxetine and placebo on reducing the likelihood of leaving treatment early (k = 1; n = 176; RR = 0.84; 95% CI, 0.51 to 1.38). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between paroxetine and placebo on reducing the likelihood of having a PTSD diagnosis after treatment k = 1; n = 176; RR = 0.81; 95% CI, 0.55 to 1.19). I

Dosage comparison: Paroxetine 20 mg versus paroxetine 40 mg

Acute phase

There is evidence suggesting there is unlikely to be a clinically important difference between paroxetine 20mg and paroxetine 40mg on reducing the severity of PTSD symptoms as measured by clinician measure CAPS (k = 1; n= 365; SMD = -0.06; 95% CI, -0.27 to 0.14). I

There is evidence suggesting there is unlikely to be a clinically important difference between paroxetine 20mg and paroxetine 40mg on reducing the severity of PTSD symptoms as measured by self-report DTS (k = 1; n = 365; SMD = -0.08; 95% CI, -0.29 to 0.12). I

There is evidence suggesting there is unlikely to be a clinically important difference between paroxetine 20mg and paroxetine 40mg on reducing depression symptoms as measured by Montgomery-Asberg Depression Rating Scale (k = 1; n = 365; SMD = -0.08; 95% CI, -0.29 to 0.12). I

There is evidence suggesting there is unlikely to be a clinically important difference between paroxetine 20mg and paroxetine 40mg on increasing quality of life (k = 1; n = 365; SMD = -0.08; 95% CI, -0.28 to 0.13). I

There is evidence suggesting there is unlikely to be a clinically important difference between paroxetine 20mg and paroxetine 40mg on reducing the likelihood of leaving treatment early for any reason (k = 1; n = 375; RR = 0.89; 95% CI, 0.68 to 1.15). I

Further evidence identified in the current review

No new studies that compared paroxetine with placebo were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.5.4.2 Sertraline versus placebo

Previous evidence: NICE Guidelines evidence statements

Six published studies of sertraline were identified by the NICE review as meeting the inclusion criteria (Brady et al., 2000; Davidson et al., Unpublished; Davidson et al., 2001a; Davidson et al., 2001b; Davidson, 2004; Zohar et al., 2002), one of which (Davidson et al., 2001a) was a continuation/relapse prevention study covering the same population as (Davidson et al., 2001b). Four trials were of mixed trauma populations and one was of military veterans. Full data for two large unpublished trials (Pfizer 588, unpublished data; Pfizer 589, unpublished data) held by the manufacturers were unavailable (n=166 for a trial with combat veterans, n=188 for a mixed trauma population trial) despite repeated requests to the manufacturer. In order to incorporate

these substantial trials within the meta-analysis, estimates for missing standard deviation data are included (standard deviations were estimated as the highest standard deviation for each outcome measure as derived from the other published drug trials).

Acute phase

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between sertraline and placebo on reducing the severity of PTSD symptoms as measured by clinician-rated CAPS (k = 6; n = 1123; SMD = -0.26; 95% CI, -0.51 to 0.00). I

There is evidence suggesting there is unlikely to be a clinically important difference between sertraline and placebo on reducing the severity of PTSD symptoms as measured by the self-report Davidson Trauma Scale (k = 5; n = 1091; SMD = -0.18; 95% CI, -0.41 to 0.06). I

There is evidence suggesting there is unlikely to be a clinically important difference between sertraline and placebo on reducing the severity of PTSD symptoms as measured by the self-report Impact of Event Scale (k = 4; n = 739; SMD = -0.06; 95% CI, -0.39 to 0.26). I

There is evidence suggesting there is unlikely to be a clinically important difference between sertraline and placebo on reducing severity of depression symptoms as measured by pooled Hamilton and Montgomery-Asberg depression scale ratings (k = 3; n = 417; SMD = -0.27; 95% CI, -0.46 to -0.07). I

There is evidence suggesting there is unlikely to be a clinically important difference between sertraline and placebo on reducing anxiety symptoms as measured by the clinician-rated Hamilton anxiety scale (k = 1; n = 202; SMD = -0.17; 95% CI, -0.45 to 0.1). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between sertraline and placebo on improving quality of life (k = 2; n = 385; SMD = -0.26; 95% CI, -0.59 to 0.07). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between sertraline and placebo on reducing the likelihood of leaving treatment early for any reason (k = 6; n = 1148; RR = 1.10; 95% CI, 0.90 to 1.33). I

Continuation/relapse prevention

There is evidence suggesting there is unlikely to be a clinically important difference between sertraline and placebo on reducing the likelihood of having a posttreatment

PTSD diagnosis as measured by clinician-rated CAPS (k = 2; n = 747; RR = 0.91; 95% CI, 0.85 to 0.98). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between sertraline and placebo on reducing the severity of PTSD symptoms using clinician-rated CAPS-2 (relapse prevention phase) (k = 1; n = 42; SMD = -0.14; 95% CI, -0.75 to 0.47). I

There is limited evidence favouring sertraline over placebo on reducing the likelihood of leaving treatment early (relapse prevention phase) (k = 1; n = 96; RR = 0.75; 95% CI, 0.52 to 1.08). I

Further evidence identified in the current review

Two trials assessed the effectiveness of sertraline versus a placebo, on reducing PTSD symptoms and depression (Brady et al., 2005). (Tucker et al., 2004). Both trials included people with PTSD secondary to a wide range of traumas.

PTSD symptoms:

Brady et al., (2005), in their good quality trial, found no statistically significant difference between sertraline and placebo in reducing Clinician Administered PTSD Scale (CAPS) scores ($F(2,68)=2.68$, $p=0.08$) *for intention to treat analyses*. On the sub-scales of the CAPS, there was a trend towards significance for lowering amount of intrusion ($F(2,68)=2.49$, $p=0.09$) and hyperarousal symptoms ($F(2,68)=2.85$, $p=0.07$). Tucker et al., (2004) did not assess whether the difference in CAPS change scores was statistically significant.

Depression:

Two trials assessed the effects of sertraline or placebo on depression within PTSD sufferers (Brady et al., 2005; Tucker et al., 2004). Those unwilling to stop their medication prior to either trial were excluded. It was not stated whether any participants were receiving concurrent psychological treatment.

Brady et al., (2005) found that there was no significant difference between sertraline and placebo at reducing depression. Tucker et al., (2004) reported that change in depression was similar for both sertraline and placebo groups even though baseline levels of depression were lower in the former group, however, a statistical comparison was not performed. Furthermore, Tucker et al., (2004) used the data of *program completers* rather than conducting intention to treat analyses.

Table 18 Effectiveness of Sertraline versus placebo for reducing PTSD symptoms

Study	Level and Quality	Population	Sertraline			Placebo			Difference ¥ Effect size [95% CI]
			Pre	Post	Change	Pre	Post	Change	
(Brady, 2005) United States	Level II (RCT)	PTSD patients secondary to civilian trauma <i>Sertraline</i> (n=49) <i>Placebo</i> (n=45)	<i>Clinician Administered PTSD Scale (CAPS)</i>						F(2,68)=2.68 p=0.08 NA
	Assignment: a		60.1	NR	NR	57.6	NR	NR	
	Selection bias: a		±18.1			±20.3			
	Blinding: a								
	Assessment: a								
ITT: yes									
(Tucker, 2004) United States	Level II (RCT)	50 outpatients with PTSD (DSM-IV, CAPS) <i>Sertraline</i> (n=18/23) <i>Placebo</i> (n=7/10)	83.1	32.6	50.5	95.0	41.3	53.7	NR
	Assignment: b		±19.3	±23.9	±18.8	±8.4	±21.2	±22.6	
	Selection bias: d				p<0.0001			p=0.0008	
	Blinding: a								
	Assessment: a								SMD -0.37 [-1.11 to 0.38]
ITT: no									

NR=not reported; ITT=intention to treat; SMD=standardised mean difference; NA=not applicable; ¥=Author's reported value

Table 19 Effectiveness of Sertraline versus placebo for reducing depression in PTSD patients

Study	Level and Quality	Population	Sertraline			Placebo			Difference ¥ SMD [95% CI]
			Pre	Post	Change	Pre	Post	Change	
(Brady, 2005) United States	Level II (RCT)	PTSD patients secondary to civilian trauma <i>Sertraline</i> (n=49) <i>Placebo</i> (n=45)	<i>Hamilton Depression Scale (HAM-D)</i>						p>0.05 NA
	Assignment: a		17.3±7.0	NR	NR	18.7	NR	NR	
	Selection bias: a					±6.5			
	Blinding: a								
	Assessment: a								
ITT: yes									
(Tucker, 2004) United States	Level II (RCT)	50 outpatients with PTSD (DSM-IV, CAPS) <i>Sertraline</i> (n=18/23) <i>Placebo</i> (n=7/10)	<i>Beck Depression Inventory (BDI)</i>						NR SMD -0.58 [-1.34 to 0.17]
	Assignment: b		26.1	11.4	14.7	35.1	20.0	15.1	
	Selection bias: c		±12.1	±12.9	±10.5	±8.7	±17.6	±16.2	
	Blinding: a				p<0.0001			p=0.0481	
	Assessment: a								
ITT: no									

NR=not reported; ITT=intention to treat; NA=not applicable; ¥=Author's reported value; SMD=standardised mean difference

Current review evidence statements

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between Sertraline and placebo on reducing the severity of PTSD symptoms (clinician-rated CAPS) (k = 1; n = 94; SMD = -0.37; 95% CI, -1.11 to 0.38). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between Sertraline and placebo on reducing the severity of depression symptoms (BDI) (k = 1; n = 33; SMD = -0.58; 95% CI, -1.34 to 0.17). II

Updated evidence statements on the combined evidence from previous and current reviews

There is relevant and applicable evidence suggesting that there is unlikely to be a clinically important difference between Sertraline and placebo for reducing the severity of PTSD symptoms (k=7, n=1148, SMD=-0.23 95%CI -0.48, 0.03). I

There is relevant and applicable evidence suggesting that there is unlikely to be a clinically important difference between Sertraline and placebo for reducing the severity of depression symptoms (k=4, n=442, SMD= -0.24 95%CI -0.61, 0.13). I

4.1.5.4.3 Fluoxetine versus placebo

Previous evidence: NICE Guidelines evidence statements

Five studies of fluoxetine met the inclusion criteria (Connor et al., 1999; Eli Lilly, unpublished data; Hertzberg et al., 2000; Martenyi et al., 2002a; Martenyi et al., 2002b), one of which was a continuation/relapse prevention study. The studies were of mixed trauma populations with the exception of one small study (Hertzberg et al., 2000) of male military veterans.

Acute phase

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between fluoxetine and placebo on reducing the severity of PTSD symptoms (CAPS - clinician) (k = 1; n = 301; SMD = -0.28; 95% CI, -0.54 to -0.02). I

There is evidence suggesting there is unlikely to be a clinically important difference between fluoxetine and placebo on reducing the severity of PTSD symptoms (TOP-8 - clinician) (k = 1; n = 411; SMD = -0.02; 95% CI, -0.21 to 0.26). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between fluoxetine and placebo on reducing the severity of PTSD symptoms (DTS - self-report) (k = 3; n = 363; SMD = - 0.41; 95% CI, -0.98 to 0.15). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between fluoxetine and placebo on reducing depression

symptoms (Montgomery-Asberg Depression Rating Scale -clinician) ($k = 1$; $n = 301$; $SMD = -0.45$; 95% CI, -0.71 to -0.18). *I*

*The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between fluoxetine and placebo on reducing depression symptoms (Hamilton - clinician) ($k = 1$; $n = 301$; $SMD = -0.42$; 95% CI, -0.68 to -0.16). *I**

*The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between fluoxetine and placebo on improving quality of life ($k = 2$; $n = 61$; $SMD = -0.62$; 95% CI, -1.13 to -0.1). *I**

*There is limited evidence favouring fluoxetine over placebo on reducing the likelihood of leaving treatment early ($k = 2$; $n = 66$; $RR = 0.6$; 95% CI, 0.28 to 1.3). *I**

Continuation/relapse prevention

*The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between fluoxetine and placebo on reducing the severity of PTSD symptoms (CAPS - clinician) ($k = 1$; $n = 98$; $SMD = -0.28$; 95% CI, -0.68 to 0.12). *I**

*The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between fluoxetine and placebo on reducing the severity of PTSD symptoms (DTS - self-report) ($k = 1$; $n = 98$; $SMD = -0.19$; 95% CI, -0.59 to 0.21). *I**

*There is limited evidence favouring fluoxetine over placebo on reducing the likelihood of leaving treatment early ($k = 1$; $n = 131$; $RR = 0.51$; 95% CI, 0.28 to 0.96). *I**

Further evidence identified in the current review

One trial compared the effects of Fluoxetine versus placebo (Davidson et al., 2005b). Prior to treatment, participants were required to go through a wash-out period of any psychotropic medication they were also receiving.

Twelve month dropout rates were high for both the Fluoxetine and placebo arms of the trial, although twice as high in the placebo arm. Although, the rate of nightmares and insomnia were similar in treatment and placebo groups, people receiving placebo reported more additional symptoms of appetite increase and weight gain. No data were provided on the relative effectiveness of Fluoxetine for the primary outcome of reducing PTSD symptoms.

Table 20 Dropouts and side effects from fluoxetine treatment vs placebo

Study	Level and Quality	Population	Outcome	Fluoxetine	Placebo	Difference ¥ Effect size [95% CI]
(Davidson, 2005) United States	Level II (RCT) Assignment: b Selection bias: c Blinding: a Assessment: a ITT: yes	62 patients with PTSD, between 18-70 <i>Fluoxetine</i> (n=27) <i>Placebo</i> (n=30)	All cause dropouts Side effects	9/27 (33%) nightmares (n=5) insomnia (n=5)	18/30 (66%) nightmares (n=6) insomnia (n=5) akathisia (n=4) heart racing (n=7) headaches (n=7) increased appetite (n=7) weight gain(n=6)	NR RR=0.56 [0.30-1.02] p=0.04 NR NC

NR=not reported; ITT=intention to treat; SMD=standardised mean difference; NA=not applicable; RR=relative risk; NC=not calculated because an event rate cannot be estimated; ¥=Author's reported value

Current review evidence statements

There is limited relevant and applicable evidence favouring fluoxetine over placebo for treatment dropout rate ($k = 1$; $n = 57$; $RR = 0.56$; 95% CI, 0.30 to 1.02). II

Updated evidence statements on the combined evidence from previous and current reviews

There is limited relevant and applicable evidence favouring Fluoxetine over placebo for the likelihood of leaving treatment early ($k=3$, $n=123$, $RR=0.56$, 95%CI 0.35, 0.91). I

4.1.5.4.4 Tricyclic antidepressants versus placebo

Previous evidence: NICE Guidelines evidence statements

Although they are not licensed for PTSD, tricyclic antidepressants have been in use for much longer than the SSRI drugs. The trials of tricyclic antidepressants are of older design and this needs to be borne in mind as these results are considered.

Amitriptyline versus placebo

Acute phase

One trial (in combat veterans) of amitriptyline met the study criteria (Davidson et al., 1990).

There is limited evidence favouring amitriptyline over placebo on reducing the severity of PTSD symptoms (using the total measure of the self-report IES) ($k = 1$; $n = 33$; $SMD = -0.90$; 95% CI, -1.62 to -0.18). I

There is limited evidence favouring amitriptyline over placebo on reducing depression symptoms as measured by the clinician-rated Hamilton scale ($k = 1$; $n = 33$; $SMD = -1.16$; 95% CI, -1.90 to -0.41). I

There is limited evidence favouring amitriptyline over placebo on reducing anxiety symptoms as measured by the clinician-rated Hamilton scale (k = 1; n = 33; SMD = -0.99; 95% CI, -1.72 to -0.26). I

There is limited evidence favouring placebo over amitriptyline on reducing the likelihood of leaving the study early for any reason (k = 1; n = 46; RR = 1.34; 95% CI, 0.52 to 3.49). I

Imipramine versus placebo

Acute phase

One trial in combat veterans of imipramine versus placebo met the inclusion criteria (Kosten et al., 1991)

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between imipramine and placebo on reducing the severity of PTSD symptoms (as measured by self-report IES) (k = 1; n = 41; SMD = -0.24; 95% CI, -0.86 to 0.38). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between imipramine and placebo on reducing depression symptoms as measured by the clinician-rated Hamilton scale (k = 1; n = 41; SMD = -0.22; 95% CI, -0.84 to 0.40). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between imipramine and placebo on reducing anxiety symptoms as measured by the Covi Anxiety Scale (k = 1; n = 41; SMD = -0.46; 95% CI, -1.08 to 0.17). I

There is limited evidence favouring imipramine over placebo on reducing the likelihood of leaving the study early for any reason (k = 1; n = 41; RR = 0.78; 95% CI, 0.47 to 1.30). I

Further evidence identified in the current review

No new studies that compared tricyclic antidepressants with placebo were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.5.4.5 Monoamine Oxidase Inhibitors versus placebo

Previous evidence: NICE Guidelines evidence statements

The use of traditional monoamine oxidase inhibitors (MAOIs) such as phenelzine has been limited by the need to impose dietary restrictions. However, there has been research into this group of drugs in PTSD with trials of phenelzine and brofaromine. Brofaromine is not available in Australia and so will not be discussed further.

Phenelzine versus placebo**Acute phase**

One trial in combat veterans phenelzine versus placebo met the inclusion criteria (Kosten et al., 1991)

There is limited evidence favouring phenelzine over placebo on reducing the severity of PTSD symptoms (as measured by self-report IES) (k = 1; n = 37; SMD = -1.06; 95% CI, -1.75 to -0.36). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between phenelzine and placebo on reducing depression symptoms as measured by the clinician-rated Hamilton scale (k = 1; n = 37; SMD = -0.4; 95% CI, -1.06 to 0.25). I

There is limited evidence favouring phenelzine over placebo on reducing anxiety symptoms as measured by the Covi Anxiety Scale (k = 1; n = 37; SMD = -0.67; 95% CI, -1.34 to -0.01). I

There is evidence favouring phenelzine over placebo on reducing the likelihood of leaving the study early due to any reason (k = 1; n = 37; RR = 0.32; 95% CI, 0.12 to 0.8). I

Further evidence identified in the current review

No new studies that compared monoamine oxidase inhibitors with placebo were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.5.4.6 Mirtizapine versus placebo**Previous evidence: NICE Guidelines evidence statements**

One study of mirtazapine (Davidson et al., 2003) for a mixed trauma population met

the inclusion criteria.

Acute phase

There is evidence favouring mirtazipine over placebo on reducing the severity of PTSD symptoms (Structured Interview for PTSD - clinician) (k = 1; n = 21; SMD = -1.89; 95% CI, -3 to -0.78). I

There is limited evidence favouring mirtazipine over placebo on reducing the severity of PTSD symptoms (DTS - self-report) (k = 1; n = 26; SMD = -0.76; 95% CI, -1.6 to 0.08). I

There is limited evidence favouring mirtazipine over placebo on reducing depression symptoms (HADS-D - self-report) (k = 1; n = 25; SMD = -0.92; 95% CI, -1.81 to -0.04). I

There is limited evidence favouring mirtazipine over placebo on reducing anxiety symptoms (HADS-A - self-report) (k = 1; n = 25; SMD = -0.88; 95% CI, -1.77 to 0). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between mirtazipine and placebo on reducing the likelihood of leaving treatment early (k = 1; n = 29; RR = 0.9; 95% CI, 0.29 to 2.82). I

Further evidence identified in the current review

No new studies that compared mirtazapine with placebo were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.5.4.7 Venlafaxine versus placebo

Previous evidence: NICE Guidelines evidence statements

The U.K. Committee on Safety of Medicines has recently recommended that treatment with venlafaxine should only be initiated by mental health specialists because of concerns about cardiotoxicity and toxicity in overdose (Committee, 2004).

There is one unpublished study of venlafaxine that met the inclusion criteria (Davidson et al., Unpublished); the trauma population was unspecified.

Acute phase

There is evidence suggesting there is unlikely to be a clinically important difference between venlafaxine and placebo on reducing the severity of PTSD symptoms (CAPS - clinician) (k = 1; n = 358; SMD = -0.14; 95% CI, -0.35 to 0.06). I

There is evidence suggesting there is unlikely to be a clinically important difference between venlafaxine and placebo on reducing the severity of PTSD symptoms (DTS - self-report) (k = 1; n = 358; SMD = -0.19; 95% CI, -0.4 to 0.01). I

There is evidence suggesting there is unlikely to be a clinically important difference between venlafaxine and placebo on improving quality of life (Quality of Life Enjoyment and Satisfaction Questionnaire - self-report) (k = 1; n = 352; SMD = 0.2; 95% CI, -0.01 to 0.4). I

There is evidence suggesting there is unlikely to be a clinically important difference between venlafaxine and placebo on improving quality of life (Global Assessment of Functioning - clinician) (k = 1; n = 358; SMD = 0.18; 95% CI, -0.03 to 0.39). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between venlafaxine and placebo on reducing the likelihood of leaving treatment early (k = 1; n = 358; RR = 0.83; 95% CI, 0.62 to 1.12). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between venlafaxine and placebo on reducing the likelihood of having a posttreatment PTSD diagnosis (using clinician measure CAPS) (k = 1; n = 358; SMD = 0.87; 95% CI, 0.77 to 0.98). I

Further evidence identified in the current review

No new studies that compared venlafaxine with placebo were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.5.4.8 Citalopram versus placebo

Previous evidence: NICE Guidelines evidence statements

No studies comparing citalopram with placebo were identified in the NICE review.

Further evidence identified in the current review

One trial assessed the effectiveness of citalopram and placebo on reducing the symptoms of PTSD and depression using completer data (Tucker et al., 2004. Patients were not on any psychotropic medications apart from occasional diphenhydramine for sleep within 2 weeks from baseline {Tucker, 2004 #18315}).

The results of this average quality trial indicated that both citalopram and placebo caused statistically significant reductions in symptoms. However, a comparison between the two groups was not provided.

Table 22 Effectiveness of Citalopram and placebo on PTSD

Study	Level and Quality	Population n	Citalopram (n=19)			Placebo (n=7)			Difference ¥ Effect size [95% CI]
			Pre	Post	Change	Pre	Post	Change	
(Tucker 2004 #69} United States	Level II (RCT)	50	<i>Clinician Administered PTSD Scale (CAPS)</i>						
	Assignment: b	outpatients with PTSD	88.5±10.4	49.8±20.4	38.7±22.1	95.0±8.4	41.3±21.2	53.7±22.6	NA
	Selection bias: d	(DSM-IV, CAPS)			p<0.0001¥			p=0.0008¥	
	Blinding: a								SMD -0.40 [-1.27-0.47]
	Assessment: a	<i>Citalopram</i>							
	ITT: no	<i>m</i>	<i>Beck Depression Inventory (BDI)</i>						
		(n=25)	26.8±10.6	12.9±11.8	13.9±10.4	35.1±8.7	20.0±17.6	15.1±16.2	NR
		<i>Placebo</i>			p<0.0001¥			p=0.0481¥	
		(n=10)							SMD -0.51 [-1.39-0.37]

¥=Author's reported value; SMD= standardised mean difference

Current review evidence statements

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between citalopram and placebo for PTSD symptom severity (k = 1; n =35; SMD = -0.40; 95% CI, -1.27 to 0.47). II

The evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between citalopram and placebo for Beck Depression inventory (k = 1; n =35; SMD = -0.51; 95% CI, -1.39 to 0.37). II

Updated evidence statements on the combined evidence from previous and current reviews

As there was no previous review evidence statements, there are no updated evidence statements.

4.1.5.4.9 Nefazodone versus placebo

One average-to-good quality trial assessed the effect of Nefazodone on PTSD symptoms, compared to placebo (Davis et al., 2004). However Nefazodone has been withdrawn from circulation in Australia and therefore will not be discussed further.

4.1.5.4.10 Olanzapine versus placebo

Previous evidence: NICE Guidelines evidence statements

One trial met the inclusion criteria. This study (Butterfield et al., 2001) was of olanzapine alone versus placebo for a mixed-trauma population (predominantly female rape victims).

Acute phase

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between olanzapine and placebo on reducing the severity of PTSD symptoms (Structured Interview for PTSD & CAPS - clinician) (k = 1; n = 11; SMD = 0.16; 95% CI, -1.07 to 1.39). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between olanzapine and placebo on reducing the severity of PTSD symptoms (DTS - self-report) (k = 1; n = 11; SMD = 0.04; 95% CI, -1.19 to 1.26). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between olanzapine and placebo on improving quality of life (Sheehan Disability Scale - self-report) (k = 1; n = 11; SMD = -0.17; 95% CI, -1.4 to 1.06). I

There is limited evidence favouring placebo over olanzapine on reducing the likelihood of leaving treatment early (k = 1; n = 15; RR = 1.5; 95% CI, 0.2 to 11). I

Further evidence identified in the current review

No new studies that compared olanzapine with placebo were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.5.4.11 Risperidone versus placebo**Previous evidence: NICE Guidelines evidence statements**

No studies were identified in the NICE review that examined risperidone alone versus placebo. One study however examined risperidone as an adjunctive treatment with usual pharmacological treatment (Hamner et al., 2003). This is described in the combined pharmacological section below.

Further evidence identified in the current review

One average quality trial assessed the effectiveness of risperidone as a treatment for participants with PTSD secondary to child sexual abuse (Reich et al., 2004). Nine

participants were taking other psychiatric medications during the study. Five participants randomised to risperidone were also receiving an SSRI (n=1), tricyclic antidepressant (n=1), and benzodiazepines (n=1). Four participants randomised to placebo were on an SSRI (n=2), a tricyclic antidepressant (n=1), a benzodiazepine (n=1) and trazodone (n=1). These medications were kept stable throughout the study (Reich et al., 2004).

Risperidone was found to be statistically significantly better at reducing PTSD symptoms than placebo after 8 weeks of treatment in *people who completed the trial* largely due to a reduction on the intrusion symptoms subscale of the Clinician Administered PTSD Scale.

Table 21 Effectiveness of Risperidone vs placebo

Study	Level and Quality	Population	Outcome	Risperidone (n=12)		Placebo (n=9)		Difference ¥ Effect size [95% CI]
				Pre	Change	Pre	Change	
(Reich, 2004) United States	Level II (RCT) Assignment: c Selection bias: c Blinding: a Assessment: a ITT: No	21 women with PTSD related to child abuse <i>Risperidone</i> <i>Placebo</i>	CAPS-2 total	65.5±13.2	-29.6±31.5	65.6±13.8	-18.6±12.3	z=-2.44 p=0.015 NC

CAPS-2=Clinician Administered PTSD Scale- 1-week version; ITT= intention to treat; NC=not calculated because only change scores reported; ¥=Author's reported value

Current review evidence statements

This study did not provide enough raw data to calculate effect sizes in that it reported mean change scores rather than mean scores. In order to write an evidence statement, standard deviations are needed, and these were not able to be deduced from the information provided.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no previous or current review evidence statements, there are no updated evidence statements.

INTERVENTION COMPARED TO INTERVENTION

4.1.5.4.12 Venlafaxine versus sertraline

Previous evidence: NICE Guidelines evidence statements

There is evidence suggesting there is unlikely to be a clinically important difference between venlafaxine and sertraline on reducing the severity of PTSD symptoms (CAPS - clinician) ($k = 1$; $n = 352$; $SMD = -0.01$; 95% CI, -0.22 to 0.2). I

There is evidence suggesting there is unlikely to be a clinically important difference between venlafaxine and sertraline on reducing the severity of PTSD symptoms (DTS - self-report) ($k = 1$; $n = 352$; $SMD = -0.1$; 95% CI, -0.31 to 0.11). I

There is evidence suggesting there is unlikely to be a clinically important difference between venlafaxine and sertraline on improving quality of life (Q-LES-Q-self-report) ($k = 1$; $n = 352$; $SMD = -0.02$; 95% CI, -0.23 to 0.19). I

There is evidence suggesting there is unlikely to be a clinically important difference between venlafaxine and sertraline on improving quality of life difference between venlafaxine and sertraline on improving quality of life (GAF-Clinician) ($k=1$; $n=352$; $SMD = -0.01$; 95% CI, -0.22 to 0.2). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between venlafaxine and sertraline on reducing the likelihood of leaving treatment early ($k = 1$; $n = 352$; $RR = 0.84$; 95% CI, 0.62 to 1.14). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between venlafaxine and sertraline on reducing the likelihood of having a posttreatment PTSD diagnosis ($k = 1$; $n = 352$; $RR = 0.92$; 95% CI, 0.81 to 1.05). I

Further evidence identified in the current review

No new studies comparing venlafaxine with sertraline were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.5.4.13 Mirtazapine versus Sertraline

Previous evidence: NICE Guidelines evidence statements

No studies that compared mirtazapine with sertraline were identified in the NICE review.

Further evidence identified in the current review

One poor-to-average quality trial by Chung et al., (2004) compared the effectiveness of Mirtazapine with Sertraline in a group of Korean veterans. Prior to the study, participants were required to have a seven day washout period of any medications except for Zopiclone for insomnia. It was not stated whether participants were also receiving psychotherapy for PTSD or not. Participant drop-outs were fairly evenly distributed between the two groups. There were no statistically significant differences in PTSD symptom severity for participants receiving Mirtazapine compared to Sertraline *who completed treatment*. Even though no statistical analyses were performed it appears that dry mouth, constipation and somnolence were more commonly reported by participants receiving Mirtazapine than those taking Sertraline. Conversely, indigestion and heart palpitations were more prevalent in the Sertraline group.

Table 24 Effectiveness of Mirtazapine vs Sertraline

Study	Level and Quality	Population	Outcome	Mirtazapine (n=51)		Sertraline (n=49)		Difference [‡] Effect size [95% CI]
				Pre	Post	Pre	Post	
(Chung, 2004) Korea	Level II (RCT)	113 inpatients and outpatients of Veterans hospital with PTSD and comorbid major depression or dysthymia	CAPS-2 total score	103.2±24.4	-44.8±19.7	88.8±23.9	-33.2±20.4	t=-0.730 p=0.467
	Assignment: c Selection bias: c Blinding: c Assessment: a		HAM-D-17	24.1±7.9	-14.1±7.9	19.8±5.9	-11.7±5.8	t=1.002 p=0.809
		<i>Mirtazapine</i> Major depression=21.6% Dysthymia=72.6%	Side effects	dry mouth (19.6%) constipation (19.6%) somnolence (15.7%) weight gain (2.0%)	indigestion (14.3%) palpitation (6.1%) agitation (2.0%) epigastric soreness (2.0%) sexual dysfunction (2.0%)		NR NC	
		<i>Sertraline</i> Major depression =14.3% Dysthymia=81.6%	Dropouts	7/51 (13.7%)	6/49 (12.2%)		NR RR 0.98 [0.85-1.14] p=0.83	

NR=not reported; NC=not calculated because an event rate cannot be estimated or only change scores reported; ‡=Author's reported value; RR=risk ratio.

Current review evidence statements

There is relevant and applicable evidence suggesting that there is unlikely to be a clinically important difference between Mirtazapine and Sertraline for treatment dropout rate (k = 1; n = 100; RR = 0.98; 95% CI, 0.30 to 1.02). II

Updated evidence statements on the combined evidence from previous and current reviews

As there were no previous review evidence statements, there are no updated evidence statements.

4.1.5.4.14 Nefazadone versus Sertraline

Previous evidence: NICE Guidelines evidence statements

No studies that compared nefazodone with sertraline were identified in the NICE review.

Further evidence identified in the current review

McRae et al., (2004) compared the effectiveness of Nefazodone with Sertraline in an outpatient setting. However, as stated earlier, Nefazadone has been withdrawn from circulation in Australia and therefore will not be discussed further.

Updated evidence statements on the combined evidence from previous and current reviews

As there were no previous review evidence statements, there are no updated evidence statements.

4.1.5.5 Summary of evidence

Since the current guidelines build upon the NICE guidelines, it is appropriate to commence with a review of their approach and recommendations in the area of pharmacotherapy for PTSD. Two cautionary notes are required at the outset.

The NICE guidelines note the difficulty of comparing drug treatment trials with psychological treatment trials. While the latter compare an active treatment with an inert intervention or wait list control condition, pharmacological trials compare the active drug to placebo. Large placebo effects often render the effect size for the drug intervention small or insignificant, despite relatively large pre- to posttreatment changes (in both groups). Currently, there is no adequate trial comparing drug and psychological treatments for PTSD. Indirect methods of comparison are hard to interpret because of the differences in the degree of improvement in the non-active/placebo arms of psychotherapy and pharmacology trials

A second issue to note from the NICE guidelines is that they chose to include unpublished data in their review of pharmacological treatments, but not in their review of psychological treatments. Inclusion of unpublished pharmacological data reduced the overall effect sizes obtained, particularly for sertraline. While the logic of including unpublished data in this case is clear (notably where the reason for not publishing appeared to have been a failure to demonstrate an effect), it could be argued that pharmacological interventions were treated unduly harshly.

Although not specific to the NICE review, it is worth noting that recruitment of participants into pharmacological trials is harder than psychotherapy trials as there tends to be a preferential desire for psychological treatments amongst participants. As a consequence, the comparability of the people in pharmacology trials and psychotherapy trials needs to take account of the potential for pretreatment differences in the participants. Random allocation is critical to removing this potential source of difference.

The NICE guidelines concluded that pharmacotherapy should not be used as a first line treatment for PTSD in preference to a trauma-focused psychological therapy. In clinical practice, the person's choice should also influence the choice of first line psychological versus pharmacological treatment. Further, they found evidence only for paroxetine, mirtazapine, amitriptyline, and phenelzine, using the predetermined effect size of 0.5 (It needs to be recognised that potentially useful gains in a symptom subset, such as irritability, can exist despite small effect sizes on the main endpoint measures).

Since completing our systematic review, the Cochrane Collaboration published their review of the evidence regarding pharmacological treatments in PTSD (Stein et al., 2006); available at <http://tinyurl.com/8tvda>). They found 35 short term RCTs of PTSD (4597 participants) to review, three of which contained a maintenance component; 5 of those were unpublished. Those authors concluded that, while no clear evidence exists to show that any particular class of medication is more effective or better tolerated than any other, the greatest number of trials showing efficacy to date, as well as the

largest, have been with the SSRIs. On the basis of the data, the review recommends the SSRIs as first line agents in the pharmacotherapy of PTSD, and supports their value in long-term treatment.

We found no further studies since the NICE review with regard to pharmacological prevention and early intervention following traumatic exposure. Thus, in line with the NICE recommendations, we do not recommend drug treatments for use either as a preventive intervention non-selectively with traumatised populations or as an early intervention for ASD or related conditions. However, we do recognise the benefits of pharmacological interventions in terms of managing current acute (and chronic) symptoms in certain cases.

With regard to pharmacological treatments for PTSD, we found a small number of studies since the NICE review. Four studies examining SSRI antidepressants (one on citalopram, two on sertraline, one on fluoxetine) failed to provide evidence that these drugs were superior to placebo either in the treatment of PTSD symptoms or in the treatment of depression in the context of PTSD. Importantly, however, relatively large pre- to posttreatment effects were noted in both groups (active and placebo). One trial of nefazadone showed more promising results, particularly in terms of hyperarousal, but is of limited relevance to these guidelines since it has been withdrawn in Australia due to adverse side effects (liver damage). We found two new studies comparing different drug treatments for PTSD. In both cases, no differences were noted between sertraline and mirtazapine or between sertraline and nefazadone.

In interpreting the recommendations in this section, it is important to consider several caveats. First, it is important to note that all agents have the potential for negative effects. As such, adults with PTSD may be reluctant to accept pharmacological treatment or alternatively, side effects may lead to discontinuation. Side effects associated with the SSRI's include headaches, nausea, loss of libido and agitation. The novel antipsychotics, particularly olanzapine is associated with substantial weight gain and a risk of type II diabetes. Hence the initiation and sustained involvement in treatment should not be considered as automatic.

Secondly, the inadequacy of data about the role of medication in conjunction with psychotherapy is a major deficiency. In clinical practice many people receive both CBT and medication, and participants in many psychotherapy trials have been stabilised on medication by the time of their participation. Thirdly, a variety of other agents, including the mood stabilisers, novel antipsychotics, and antihypertensives, have been trialed in open labeled studies, often with promising results. Finally, many people require a combination of medications; there is a paucity of clinical trial data to provide guidance about the effectiveness of different combinations of medication.

Importantly, in interpreting the above cited study findings, the range of trauma populations included in the above studies and the pharmacotherapies provided are generalisable to the PTSD populations in Australia and the Australian healthcare context

In summary, no new evidence has emerged in the last two years to warrant a substantial modification to the NICE recommendations. Notwithstanding the caveats above, we concur with their interpretation of the available evidence that larger clinical

effects are likely to be obtained from trauma-focused psychological treatment than from pharmacological treatment in most sufferers of PTSD. We do not, however, believe that the available evidence warrants a selective recommendation of one SSRI over another in the treatment of PTSD. Rather, we have chosen to recommend the SSRIs generally as the first choice for medication, leaving the final decision regarding the specific drug to the clinician. We note the evidence summarised in the NICE findings regarding mirtazapine, amitriptyline, and phenelzine. With regard to the former, we are not convinced that the current research evidence is sufficient to recommend mirtazapine above other new generation antidepressants as a second line pharmacological treatment. While we recommend that clinicians note the research support for amitriptyline and phenelzine, we recognise that these medications have been used only rarely in routine clinical practice for some time and that they are more difficult to use. Thus, it makes little sense to recommend them as a first choice. The potential interaction of medications prescribed for any physical health issues, with those recommended for PTSD and co-morbid psychological issues, needs to be considered in treatment decisions.

4.1.5.6 Recommendations

Clinical recommendations

- 4.1.5.6.1** *Drug treatments for PTSD should not be used as a routine first line treatment for adults, either by general medical practitioners or by specialist mental health professionals, in preference to a trauma focused psychological therapy (A) (see also Combined psychological and pharmacological treatment Recommendation 3.1.7.6.1)*
- 4.1.5.6.2** *Where medication is considered for the treatment of PTSD in adults, SSRI antidepressants should be the first choice for both general practitioners and mental health specialists (B).*
- 4.1.5.6.3** *Other new generation antidepressants (notably mirtazapine) and the older tricyclic antidepressants should be considered as a second line option. Phenelzine should be considered for use by mental health specialists for people with treatment resistant symptoms (B)*
- 4.1.5.6.4** *Antidepressant medication should be considered for the treatment of PTSD in adults when:*
- a) the sufferer is unwilling to engage in trauma-focused psychological treatment (GPP)*
 - b) the sufferer is not sufficiently stable to commence trauma-focused psychological treatment (as a result, for example, of being actively suicidal or homicidal, or of severe ongoing life stress such as domestic violence) (GPP)*
 - c) the sufferer has not gained significant benefit from trauma-focused psychological treatment (GPP)*

- d) the sufferer is experiencing a high level of dissociative symptoms that are likely to be significantly exacerbated by trauma-focused therapy (GPP)*
- 4.1.5.6.5 Where a decision has been made to commence pharmacotherapy, the person's mental state should be regularly monitored with a view to commencing adjunctive psychological treatment if/when appropriate. In the interim, supportive psychotherapy with a substantial psychoeducational component should be offered. (GPP)*
- 4.1.5.6.6 Where significant sleep disturbance or excessive distress does not settle in response to reassurance, simple psychological first aid, or other non-drug intervention, cautious use of hypnotic medication may be appropriate in the short term. If the sleep disturbance is of more than one month duration and medication is likely to be of benefit in the management of the person's PTSD, a suitable antidepressant should be considered. The risk of tolerance and dependence are relative contraindications to the use of hypnotics for more than one month except if their use is intermittent (GPP)*
- 4.1.5.6.7 Antidepressant medication (see 2 above) should be considered as an adjunct to psychological treatment in adults where core PTSD symptoms are of sufficient severity to significantly interfere with the sufferers ability to benefit from psychological treatment (GPP)*
- 4.1.5.6.8 Where conditions comorbid with the PTSD (e.g., depression, other anxiety conditions) are of sufficient severity to significantly interfere with the sufferers ability to benefit from psychological treatment, or where a more rapid relief of symptoms is likely to offer significant clinical benefit, drug treatments that have a demonstrable evidence-base for the treatment of that condition should be considered (GPP)*
- 4.1.5.6.9 Where symptoms have not responded adequately to pharmacotherapy, consideration should be given to:*
- a) increasing the dosage within approved limits (GPP)*
 - b) switching to an alternative antidepressant medication (GPP)*
 - c) adding risperidone or olanzapine as an adjunctive medication (GPP)*
 - d) reconsidering the potential for psychological intervention (GPP)*
- 4.1.5.6.10 When an adult sufferer with PTSD has responded to drug treatment, it should be continued for at least 12 months before gradual withdrawal (B)*
- 4.1.5.6.11 Best practice prescribing procedures should be adopted when using drug treatments for PTSD in adults, including provision of information prior to commencement, monitoring and management of side effects, monitoring of suicide risk, and appropriate discontinuation and withdrawal practices (GPP)*

4.1.5.6.12 Adult PTSD sufferers receiving pharmacotherapy should be seen at least weekly if there is a significant risk of suicide; if there is no significant risk of suicide, fortnightly contact is recommended initially, dropping to less frequent after 3 months if the response is good. The role of the clinician in providing information and support is an important component of the management. (GPP)

Research Recommendations

4.1.5.6.13 We concur with the NICE recommendations that the conduct of a large, well controlled randomised trial comparing pharmacological with trauma-focused psychological treatment across different trauma populations.

4.1.5.6.14 We also recommend further exploration of the potential benefits of combination (pharmacological and trauma-focused psychological) treatments in trials that adequately address both sides of the equation (i.e., drug vs. drug + psychological is not sufficient; the design must include a trauma-focused psychological treatment alone as it represents the current first line treatment)

4.1.6 Combined pharmacological interventions

4.1.6.1 Research questions and PICO

Box 7 Multiple pharmacological interventions compared to single pharmacological interventions for adults with PTSD: Research question and study selection criteria

Research Question	
16. For adults with PTSD, is a single intervention more effective than multiple interventions?	
Selection criteria	Inclusion criteria
Population	Adults with PTSD
Intervention	Single psychological or pharmacological intervention or psychosocial rehabilitation strategy
Comparator (1)	Combined psychological interventions, combined pharmacological interventions, combined psychosocial interventions or combined psychological, pharmacological or psychosocial interventions
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Comparator (2)	Combined psychological intervention and psychosocial rehabilitation (e.g., teaching self-care and independent living skills techniques, providing supported housing, marital/family skills training, social skills training, anger management, vocational rehabilitation and case management) or combined pharmacological intervention and psychosocial rehabilitation
Outcome	Primary outcome: resolution of symptoms of PTSD, social and occupational function, quality of life Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2002-8/2005*
Language	English

This question was based on question 10 in the VA/DoD review. However the PICO used in the VA/DoD review excluded pharmacological studies.

4.1.6.2 Studies included in previous reviews

This question was not asked in either of the previous reviews. However two studies of relevance to this question were identified in the NICE review in response to their pharmacological question 2. Both studies investigated adjunctive pharmacological treatments (Hamner et al., 2003; Stein et al., 2002).

4.1.6.3 Studies included in the current review (2002-2005)

No studies were identified in the current review (2002-2005) that compared single and combined pharmacological interventions.

4.1.6.4 Treatment comparisons

4.1.6.4.1 Adjunctive Olanzapine with normal SSRI versus adjunctive placebo with normal SSRI

Previous Evidence: NICE Guidelines evidence statements

There was one study (Stein et al., 2002) of adjunctive olanzapine (taken in conjunction with SSRIs) for male combat veterans. This study examined the efficacy of olanzapine for people already receiving but not responsive to SSRI treatment within the first 12 weeks of SSRI treatment. During the trial, of the total of 19 participants 5 were taking fluoxetine, 7 were taking paroxetine and 7 were taking sertraline.

Acute phase

There is limited evidence favouring adjunctive olanzapine (to SSRI) over placebo on reducing the severity of PTSD symptoms (Structured Interview for PTSD & CAPS - clinician) (k = 1; n = 19; SMD = -0.92; 95% CI, -1.88 to 0.04). I

There is limited evidence favouring adjunctive olanzapine (to SSRI) over placebo on reducing depression (Center for Epidemiologic Studies Depression Scale - self-report) (k = 1; n = 19; SMD = -1.2; 95% CI, -2.2 to -0.21). I

Further evidence identified in the current review

No further studies investigating Olanzapine as an adjunctive treatment were identified in the current review.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.6.4.2 Adjunctive Risperidone with normal pharmacotherapy versus adjunctive placebo with normal pharmacotherapy

Previous Evidence: NICE Guidelines evidence statements

One study of adjunctive risperidone (Hamner et al., 2003) is relevant to this question. In this study, participants (all combat veterans) continued taking their previously prescribed antipsychotic, antidepressant, benzodiazepine or sleep medications. Given the variability in the other (nonrisperidone) medications being taken by participants, some caution is required in interpreting the effect sizes from the review of this study.

Acute phase

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between adjunctive risperidone (misc. medn.) and placebo on reducing the severity of PTSD symptoms (CAPS & Structured Interview for PTSD - clinician) (k = 1; n = 37; SMD = 0.1; 95% CI, -0.55 to 0.74). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between adjunctive risperidone (misc. medn.) and

placebo on reducing the severity of PTSD symptoms (Positive and Negative Symptom Scale - clinician) (k = 1; n = 37; SMD = -0.24; 95% CI, -0.89 to 0.4). I

There is limited evidence favouring adjunctive risperidone (misc. medn.) over placebo on reducing the likelihood of leaving treatment early (k = 1; n = 40; RR = 0.5; 95% CI, 0.05 to 5.08). I

Further evidence identified in the current review

No further studies investigating Risperidone as an adjunctive treatment were identified in the current review.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.6.5 Summary of the evidence

There is very little evidence examining combined pharmacological interventions with limited evidence favouring olanzapine as adjunctive to SSRI treatment in cases of initial non-response.

4.1.6.6 Recommendations

4.1.6.6.1 Where symptoms have not responded to pharmacotherapy, consideration should be given to adding olanzapine as an adjunctive medication (C)

4.1.7 Initial psychological or pharmacological intervention

4.1.7.1 Research questions and PICO

Box 8 Initial pharmacotherapy compared to initial psychotherapy: Research question and study selection criteria

Research Question	
17. For adults with PTSD, is an initial pharmacotherapy more effective than initial psychotherapy?	
Selection criteria	Inclusion criteria
Population	Adults with PTSD
Intervention	Initial pharmacological intervention
Comparator	Initial psychological intervention
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2002-8/2005*
Language	English

This question was addressed by VA/DoD (question 11) with a search period up to 2002.

4.1.7.2 Studies included in the previous reviews

The VA/DoD review identified one meta-analysis of controlled and uncontrolled trials of most available treatments for PTSD that indirectly addressed the question (Van Etten & Taylor, 1998).

Although the question was not asked in the NICE review, one study of relevance was identified in response to their combined psychology and pharmacology question (Frommberger et al., 2004).

4.1.7.3 Studies included in the current review (2002-2005)

The only study meeting criteria for inclusion in the current review, was that previously reported in the NICE review (Frommberger et al., 2004). Another randomised controlled trial was found on the Clinical Trials register that compared fluoxetine with EMDR for treating PTSD, but the results of this trial were not found in the literature (National Institute of Health).

4.1.7.4 Treatment comparisons

4.1.7.4.1 Psychotherapy versus pharmacotherapy

Previous evidence: VA/DoD summary statements

- a) Overall, there was a slightly increased improvement in self-reported symptoms with psychotherapy than with pharmacotherapy.
- b) The most effective of the psychotherapies (behaviour therapy and EMDR) and pharmacotherapies (SSRIs) were equally effective.
- c) Psychotherapy (14%) had lower dropout rate than pharmacotherapy (32%)

Further evidence identified in the current review

No further studies comparing initial psychotherapy with initial pharmacotherapy were identified in the current review.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.7.4.2 Paroxetine versus trauma focused CBT

Previous evidence: NICE Guidelines evidence statements

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between paroxetine and trauma-focused CBT on reducing clinician measured PTSD severity (using CAPS) posttreatment (k = 1; n = 16; SMD = 0.09; 95% CI, -0.89 to 1.07).I

There is limited evidence favouring trauma-focused CBT over paroxetine on reducing self-rated PTSD severity (PSS) posttreatment (k = 1; n = 16; SMD = 1.06; 95% CI, -0.01 to 2.13).I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between paroxetine and trauma-focused CBT on reducing posttreatment depression symptoms using clinician measure MADRS (k = 1; n = 16; SMD = -0.37; 95% CI, -1.36 to 0.62). I

There is limited evidence favouring trauma-focused CBT over paroxetine on reducing self-rated depression symptoms posttreatment using BDI (k = 1; n = 16; SMD = 0.55; 95% CI, -0.46 to 1.55). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between paroxetine and trauma-focused CBT on reducing posttreatment anxiety symptoms using clinician measure HAMA (k = 1; n = 16; SMD = -0.26; 95% CI, -1.25 to 0.72). I

There is limited evidence favouring trauma-focused CBT over paroxetine on reducing the likelihood of leaving the study early due to any reason prior to treatment endpoint ($k = 1$; $n = 21$; $RR = 1.36$; 95% CI, 0.28 to 6.56). I

There is limited evidence favouring paroxetine over trauma-focused CBT on reducing the likelihood of leaving the study early due to any reason prior to 6 month follow-up ($k = 1$; $n = 21$; $RR = 0.57$; 95% CI, 0.28 to 1.16). I

Further evidence identified in the current review

No further studies comparing paroxetine with trauma-focused CBT were identified in the current review.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.7.5 Summary of the evidence

In view of the limited evidence favouring trauma-focused CBT over pharmacotherapy for the initial treatment of PTSD, these guidelines support the NICE guidelines recommendations that trauma-focused CBT be the first line treatment for PTSD over pharmacotherapy.

4.1.7.6 Recommendations

4.1.7.6.1 Drug treatments for PTSD should not be used as a routine first line treatment for adults, either by general medical practitioners or by specialist mental health professionals, in preference to a trauma-focused psychological therapy (B)

4.1.8 Combined psychological and pharmacological intervention

4.1.8.1 Research questions and PICO

Box 9 Combined pharmacological and psychological interventions compared to either pharmacological or psychological intervention alone: Research question and study selection criteria

Research Question	
16. For adults with PTSD, is a single intervention more effective than multiple interventions?	
Selection criteria	Inclusion criteria
Population	Adults with PTSD
Intervention	Single psychological or pharmacological intervention or psychosocial rehabilitation strategy
Comparator (1)	Combined psychological interventions, combined pharmacological interventions, combined psychosocial interventions or combined psychological, pharmacological or psychosocial interventions
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Comparator (2)	Combined psychological intervention and psychosocial rehabilitation (e.g., teaching self-care and independent living skills techniques, providing supported housing, marital/family skills training, social skills training, anger management, vocational rehabilitation and case management) or combined pharmacological intervention and psychosocial rehabilitation
Outcome	Primary outcome: resolution of symptoms of PTSD, social and occupational function, quality of life Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2002-8/2005*
Language	English

This question was based on question 10 in the VA/DoD review. However the PICO used in the VA/DoD review excluded combined psychological and pharmacological studies.

4.1.8.2 Studies included in previous reviews

This question was not asked in either of the previous reviews. However one study of relevance to this question was identified in the NICE review in response to their pharmacological question 2. This was a trial of combined imipramine and psychodynamic therapy versus placebo and phenalpine and psychodynamic therapy versus placebo (Kosten et al., 1992).

4.1.8.3 Studies included in the current review (2002-2005)

Two average-to-good quality randomised controlled trials that assessed the effectiveness of a combination of psychotherapy and pharmacotherapy compared to single pharmacotherapy alone for treating people with PTSD were identified in the current review (Otto et al., 2003 {Rothbaum, in press #25241}).

4.1.8.4 Treatment comparisons

4.1.8.4.1 Imipramine and psychodynamic therapy versus placebo

Previous evidence: NICE Guidelines evidence statements

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between imipramine & other psychological therapy and placebo on reducing the severity of PTSD symptoms (IES – self-report)(k = 1; n = 39; SMD = -0.16; 95% CI, -0.8 to 0.48). I

Further evidence identified in the current review

No further studies comparing imipramine and psychodynamic therapy versus placebo were identified in the current review.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.8.4.2 Phenelzine and psychodynamic therapy versus placebo

Previous evidence: NICE Guidelines evidence statements

There is limited evidence favouring phenelzine & other psychological therapy over placebo on reducing the severity of PTSD symptoms (IES - self-report) (k= 1; n = 34; SMD = -1.01; 95% CI, -1.73 to -0.29). I

Further evidence identified in the current review

No further studies comparing phenelzine and psychodynamic therapy versus placebo were identified in the current review.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.8.4.3 Sertraline combined with prolonged exposure (PE) versus sertraline alone

Previous evidence

Not applicable as the question was not asked in previous reviews.

Further evidence identified in the current review

Rothbaum et al., (in press) compared the effects of 10 weeks of sertraline medication followed by either sertraline alone or a combination of sertraline and prolonged exposure therapy. No statistically significant benefit from the addition of prolonged exposure was observed. However, there was a trend toward lower scores on the Structured Interview for PTSD in the prolonged exposure treatment group.

Table 26 Effectiveness of sertraline vs sertraline plus prolonged exposure

Study	Level and Quality	Population	Outcome	Sertraline (n=31)		Sertraline + prolonged exposure (n=34)		Difference ¥ Effect size [95% CI]
				Pre	Post	Pre	Post	
(Rothbaum et al.)	Level II (RCT) Assignment: b Selection bias: b Blinding: b Assessment: a	65 outpatients with PTSD determined by SCID	SIP	36.0±8.6	14.9±15.3	35.9±9.4	10.2±8.8	F(1,63)<1 not significant SMD -0.38 [-0.87-0.11]
			BDI	22.1±11.7	9.8±9.8	21.0±8.6	8.0±8.3	F(1,62)<1 not significant SMD -0.20 [-0.68-0.29]
			STAI-State	54.2±13.6	39.2±17.8	55.2±11.6	39.1±14.5	F(1,62)<1 not significant SMD -0.01 [-0.49-0.48]

SCID=Structured Interview for PTSD; SIP=Structured Interview for PTSD; BDI=Beck Depression Inventory; STAI= State-Trait Anxiety Inventory; ¥=Author's reported value; SMD=standardised mean difference.

Current review evidence statements

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between Sertraline alone and Sertraline in addition to prolonged exposure therapy for improvement in Structured Interview for PTSD score (k=1; n=65; SMD=-0.38, 95% CI -0.87 to 0.11). II

The relevant and applicable evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between Sertraline alone and Sertraline in addition to prolonged exposure therapy for improvement in Beck depression inventory (k=1; n=65; SMD=-0.20, 95% CI -0.68 to 0.29). II

The relevant and applicable evidence suggests that there is unlikely to be a clinically important difference between Sertraline alone and Sertraline in addition to prolonged exposure therapy for improvement in State-trait anxiety inventory score (k=1; n=65; SMD=-0.01, 95% CI -0.49 to 0.48). II

Updated evidence statements on the combined evidence from previous and current reviews

As there were no previous review evidence statements, there are no updated evidence statements.

4.1.8.4.4 Sertraline combined with CBT versus sertraline alone

Previous evidence

Not applicable as the question was not asked in previous reviews.

Further evidence identified in the current review

Otto et al., (2003) found that the combined treatment with sertraline and cognitive behavioural therapy produced a greater reduction in symptoms than sertraline alone in a group of women who had not previously responded to pharmacological treatment. In a sample of people who had previously failed to respond to a combination of clonazepam and another SSRI, treatment with sertraline alone resulted in an increase in scores for two of the subscales on the Clinician Administered PTSD Scale (CAPS). The addition of CBT reduced scores on all the subscales of the CAPS.

Table 27 Effectiveness of sertraline vs sertraline plus cognitive behavioural therapy

Study	Level and Quality	Population	Outcome	Sertraline (n=5)		Sertraline + CBT (n=5)		Effect size (Cohen's d)‡
				Pre	Post ^a	Pre	Post ^a	Effect size [95% CI]
(Otto et al., 2003) United States	Level II (RCT) Assignment: c Selection bias: a Blinding: c Assessment: a	10 Cambodian refugees who met DSM-IV criteria for PTSD. Women who failed to respond to clonazepam in combination with SSRI other than sertraline Mean age=47.2 years	CAPS reexperiencing	15.2±6.2	-4.6±11.5	21.4±6.3	4.4±10.4	0.82 NC
			CAPS avoidance	21.4±14.7	0.6±9.9	24.4±12.1	18.0±7.1	0.85 NC
			CAPS hyperarousal	20.6±9.8	-0.6±5.6	18.8±10.1	11.6±3.8	0.45 NC
			HSCL-90 anxiety	31.4±6.2	5.2±5.3	29.2±8.5	8.4±5.6	0.59 NC
			HSCL-90 depression	38.2±9.2	8.6±6.0	34.4±7.6	8.6±7.2	0.00 NC
			HSCL-90 somatisation	26.2±6.1	8.6±6.0	36.2±9.4	12.2±4.4	0.62 NC
			ASI	47.8±5.8	1.2±4.8	38.8±11.0	7.8±10.1	0.88 NC

CBT=cognitive behavioural therapy; ^a Change from baseline; CAPS=Clinician-Administered PTSD Scale; HSCL-90=Hopkins Symptom Checklist; ASI=Anxiety Sensitivity Index; NC=unable to calculate due to change scores being reported; ‡=Author's reported value.

Current review evidence statements

No evidence statements could be derived from the Otto et al., (2003) study as it did not provide enough raw data to calculate effect sizes.

Updated evidence statements on the combined evidence from previous and current reviews

As there were no previous or current review evidence statements there are no updated evidence statements.

4.1.8.5 Summary of evidence

There is only a small body of literature examining the effectiveness of combinations of interventions compared with interventions alone. While the evidence is still inconclusive there appears to be a trend toward improved outcomes with the combination of psychological and pharmacological interventions (Otto et al., 2003)

(Rothbaum et al., in press) although little evidence that combined pharmacological or combined psychological interventions alone improve outcomes. As the Otto population was specific to Cambodian refugees, the generalisability of the study to PTSD populations in Australia is limited.

4.1.8.6 Recommendations

4.1.8.6.1 In cases where the person has not gained benefit from first line psychological treatments, health practitioners may wish to consider commencing adjunctive pharmacotherapy. (GPP)

4.1.8.6.2 Where a decision has been made to commence treatment pharmacotherapy, the person's mental state should be constantly monitored with a view to commencing adjunctive psychological treatment if/when appropriate. In the interim, supportive psychotherapy with a substantial psychoeducational component should be offered. (GPP)

These recommendations should be read in conjunction with Recommendations for psychological interventions (section 3.1.1.6) and pharmacological interventions (section 3.1.5.6).

4.1.9 Psychosocial Rehabilitation

4.1.9.1 Research questions and PICO

Box 10 Psychosocial rehabilitation for PTSD: Research questions and study selection criteria

Research Question	12. For adults with PTSD, does psychosocial rehabilitation improve outcomes compared to no intervention? 13. For adults with PTSD, does psychosocial rehabilitation confer an advantage over any other psychological or pharmacological interventions?
Selection criteria	Inclusion criteria
Population	Adults with PTSD
Intervention	Psychosocial rehabilitation (e.g., teaching self-care and independent living skills techniques, providing supported housing, marital/family skills training, social skills training, vocational rehabilitation and case management)
Comparator	12.No intervention 13. Any other psychological or pharmacological intervention (e.g., trauma-focused CBT, stress management therapy, EMDR, narrative exposure therapy, supportive counselling, interapy, SSRIs, other second-generation antidepressants, tricyclic antidepressants, monoamine oxidase inhibitors, benzodiazepines, mood stabilisers, anti-convulsants, and some non-benzodiazepine hypnotics and anti-anxiety medications)
Outcome	Primary outcome: functional improvement, quality of life Secondary outcomes: resolution of symptoms of PTSD, depression, anxiety and substance misuse/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	1966-8/2005*
Language	English

A new search (1996-2005) was conducted on this question as it was not addressed in either the NICE or VA/DoD reviews.

Box 11 Single pharmacological, psychological or psychosocial intervention compared to combined pharmacological or psychological intervention with psychosocial intervention: Research question and study selection criteria

Research Question	
16. For adults with PTSD, is a single intervention more effective than multiple interventions?	
Selection criteria	Inclusion criteria
Population	Adults with PTSD
Intervention	Single psychological or pharmacological intervention or psychosocial rehabilitation strategy
Comparator (1)	Combined psychological interventions, combined pharmacological interventions, combined psychosocial interventions or combined psychological, pharmacological or psychosocial interventions
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Comparator (2)	Combined psychological intervention and psychosocial rehabilitation (e.g., teaching self-care and independent living skills techniques, providing supported housing, marital/family skills training, social skills training, anger management, vocational rehabilitation and case management) or combined pharmacological intervention and psychosocial rehabilitation
Outcome	Primary outcome: resolution of symptoms of PTSD, social and occupational function, quality of life Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2002-8/2005*
Language	English

This question was based on question 10 in the VA/DoD review. However the PICO used in the VA/DoD review excluded combined psychological, pharmacological and psychosocial studies.

4.1.9.2 Studies included in previous reviews

This question was not asked in either the NICE (2005) or the VA/DoD (2004) review.

4.1.9.3 Studies included in the current review

No studies comparing psychosocial rehabilitation to waitlist or to psychological or pharmacological treatment were identified. Similarly, no studies of combined psychosocial interventions or the effectiveness of adjunctive psychosocial interventions were identified.

4.1.9.4 Treatment comparisons

As no studies were identified there were no-treatment comparisons.

4.1.9.5 Summary of existing literature

In the absence of any evidence-based outcome research examining psychosocial rehabilitation in PTSD being identified in this review, these recommendations are derived from a summary of the existing literature and expert consensus opinion.

Psychosocial rehabilitation may improve functional ability and facilitate recovery in people with PTSD by minimising associated problems such as homelessness, social inactivity, high-risk behaviours, and unemployment. Targeted clinical and disability management interventions can assist people with PTSD improve their role

functioning, increase ability, develop skills and resources specific to their individual needs and capacities with the aim of averting, preventing further, or reducing disability associated with the disorder ((HIMH). 2002).

While high level evidence on the efficacy of psychosocial interventions in PTSD-specific populations is not available, interventions based on this approach have strong empirical support in populations experiencing a range of persisting mental health conditions (Mueser et al., 2003). Intensive case management, psychoeducation, and social skills training, for example, have been associated with a number of positive outcomes including reduced time spent in hospital, symptom reduction, improved social functioning, and reduced stress in families (Dilk & Bond, 1996; Heinszen et al., 2000; Mueser et al., 1998; Phillips et al., 2001). Controlled studies have confirmed the effectiveness of supported employment, a vocational rehabilitation approach that involves the rapid placement of people into competitive employment, in helping people retain and maintain employment and significantly reduce symptom severity (Bell et al., 1996; Bond et al., 2001; Cook et al., 2005). Other studies show that people who work are less disabled by their condition, have an improved self esteem, and increased quality of life (Arns & Linney, 1993; Mueser et al., 1997). Provision of housing supports together with case management and clinical services has been reported as contributing significantly to increasing the social integration of people with persisting symptoms of PTSD (Rosenheck & Siebyl, 1998).

While psychosocial rehabilitation includes collaborative psychological and/or pharmacological treatments, interventions also address a number of potential barriers to treatment: homelessness, unemployment, and high-risk lifestyle behaviours, making it a useful approach to disability management for people who are reluctant to engage in, or are resistant to treatment ((HIMH). 2002). Despite the absence of high level evidence of efficacy in PTSD-specific populations, the strong empirical evidence supporting the use of psychosocial interventions in a range of other psychiatric disorders suggests that healthcare professionals should be aware of the potential benefits of these interventions for people who are experiencing persisting symptoms of PTSD.

4.1.9.6 Recommendations

Clinical recommendations

4.1.9.6.1 *There should be a focus on vocational, family and social rehabilitation interventions from the beginning of treatment (GPP)*

4.1.9.6.2 *Where symptoms of PTSD have been present for 3 months or longer, psychosocial rehabilitation should be considered as an intervention to prevent or reduce disability associated with the disorder. (GPP)*

4.1.9.6.3 *In cases where people with PTSD have not benefited from a number of courses of evidence-based treatment, psychosocial rehabilitation interventions may reduce disability, improve functioning and community tenure. (GPP)*

4.1.9.6.4 Healthcare professionals should be aware of the potential benefits of psychosocial rehabilitation and promote practical advice on how to access appropriate information and services. (GPP)

4.1.9.6.5 Psychosocial rehabilitation interventions should be provided by competent and appropriately qualified practitioners who received regular supervision. (GPP)

4.1.9.6.6 Psychosocial rehabilitation may be used as an adjunctive therapy in combination with psychotherapy or pharmacotherapy. (GPP)

Research recommendations

4.1.9.6.7 The impact of a focus on wellness, recovery and rehabilitation on the psychosocial functioning and posttraumatic growth of adults with PTSD should be investigated

4.1.10 Physical therapies and exercise

4.1.10.1 Research questions and PICO

Box 12 Physical therapies and exercise for adults with ASD and PTSD: Research question and study selection criteria

Research Question	
14. For adults with ASD or PTSD, do physical interventions or exercise confer an advantage over psychological or pharmacological intervention?	
Selection criteria	Inclusion criteria
Population	Adults with ASD or PTSD
Intervention	(1) Physical therapy (e.g., electroconvulsive therapy, transcranial magnetic stimulation, massage, acupuncture, acupressure, Healing Touch, CranioSacral therapy) (2) Exercise therapy (e.g., yoga, T'ai Chi, movement-to-music, rhythm activities, competitive sports, walking, jogging, swimming)
Comparator	Any psychological or pharmacological intervention (e.g., trauma-focused CBT, stress management therapy, EMDR, narrative exposure therapy, supportive counselling, interapy, SSRIs, other second-generation antidepressants, tricyclic antidepressants, monoamine oxidase inhibitors, benzodiazepines, mood stabilisers, anti-convulsants, and some non-benzodiazepine hypnotics and anti-anxiety medications)
Outcome	Primary outcome: resolution of symptoms of ASD or PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	1966-8/2005*
Language	English

CBT= cognitive behavioural therapy; EMDR = eye movement desensitization and reprocessing; SSRIs = selective serotonin reuptake inhibitors

A new search (1996-2005) was conducted on this question as it was not addressed in either the NICE or VA/DoD reviews.

4.1.10.2 Studies included in previous reviews

This question was not asked in either the NICE (2005) or the VA/DoD (2004) review. However one study of repeated transcranial magnetic stimulation (rTMS) against placebo (sham treatment) was identified in the NICE review (Cohen et al., 2004).

4.1.10.3 Studies included in the current review

No studies were identified in this review that compared physical interventions or exercise with conventional forms of treatment such as psychological or pharmacological interventions.

4.1.10.4 Treatment comparisons

4.1.10.4.1 Repeated transcranial magnetic stimulation (rTMS) versus placebo

Previous evidence: NICE Guidelines evidence statements

High-frequency rTMS versus control

There is limited evidence favouring high-frequency repetitive transcranial magnetic stimulation (rTMS) over control on reducing the severity of PTSD symptoms as measured by clinician-rated CAPS at 14 day follow-up (k = 1; n = 16; SMD = -0.72; 95% CI, -1.77 to 0.33). I

There is limited evidence favouring high-frequency repetitive transcranial magnetic stimulation (rTMS) over control on reducing the severity of posttreatment PTSD symptoms as measured by self-report PTSD checklist (k = 1; n = 16; SMD = -1.5; 95% CI, -2.67 to -0.32). I

There is limited evidence favouring high-frequency repetitive transcranial magnetic stimulation (rTMS) over control on reducing the severity of PTSD symptoms at 14 day follow-up as measured by self-report PTSD checklist (k = 1; n = 16; SMD = -0.68; 95% CI, -1.73 to 0.36). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between high-frequency repetitive transcranial magnetic stimulation (rTMS) and control on reducing posttreatment depression symptoms as measured by the clinician-rated Hamilton scale (k = 1; n = 16; SMD = -0.3; 95% CI, -1.32 to 0.72). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between high-frequency repetitive transcranial magnetic stimulation (rTMS) and control on reducing depression symptoms at 14 day follow-up as measured by the clinician-rated Hamilton scale (k = 1; n = 16; SMD = -0.13; 95% CI, -1.14 to 0.89). I

There is limited evidence favouring high-frequency repetitive transcranial magnetic stimulation (rTMS) over control on reducing posttreatment anxiety symptoms as measured by the clinician-rated Hamilton Anxiety Rating Scale (k = 1; n = 16; SMD = -1.38; 95% CI, -2.53 to -0.23). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between high-frequency repetitive transcranial magnetic stimulation (rTMS) and control on reducing anxiety symptoms at 14 day follow-up as measured by the clinician-rated Hamilton Anxiety Rating Scale (k = 1; n = 16; SMD = 0; 95% CI, -1.01 to 1.01). I

There is limited evidence favouring high-frequency repetitive transcranial magnetic stimulation (rTMS) over control on reducing the likelihood of leaving the study early due to any reason prior to 14 day follow-up (k = 1; n = 19; RR = 0.36; 95% CI, 0.04 to 3.35). I

Low-frequency rTMS versus control

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between low-frequency repetitive transcranial magnetic stimulation (rTMS) and control on reducing the severity of PTSD symptoms as measured by clinician-rated CAPS at 14 day follow-up (k = 1; n = 14; SMD = 0.12; 95% CI, -0.94 to 1.18). I

There is limited evidence favouring control over low-frequency repetitive transcranial magnetic stimulation (rTMS) on reducing the severity of posttreatment PTSD symptoms as measured by self-report PTSD (k = 1; n = 16; SMD = 0.82; 95% CI, -0.25 to 1.88). I

There is limited evidence favouring control over low-frequency repetitive transcranial magnetic stimulation (rTMS) on reducing the severity of PTSD symptoms at 14 day follow-up as measured by self-report PTSD checklist (k = 1; n = 14; SMD = 0.67; 95% CI, -0.43 to 1.77). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between low-frequency repetitive transcranial magnetic stimulation (rTMS) and control on reducing posttreatment depression symptoms as measured by the clinician-rated Hamilton scale (k = 1; n = 14; SMD = -0.09; 95% CI, -1.15 to 0.97). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between low-frequency repetitive transcranial magnetic stimulation (rTMS) and control on reducing depression symptoms at 14 day follow-up as measured by the clinician-rated Hamilton scale (k = 1; n = 14; SMD = 0.36; 95% CI, -0.71 to 1.43). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between low-frequency repetitive transcranial magnetic stimulation (rTMS) and control on reducing posttreatment anxiety symptoms as measured by the clinician-rated Hamilton Anxiety Rating Scale (k = 1; n = 14; SMD = 0.15; 95% CI, -0.91 to 1.21). I

There is limited evidence favouring control over low-frequency repetitive transcranial magnetic stimulation (rTMS) on reducing anxiety symptoms at 14 day follow-up as measured by the clinician-rated Hamilton Anxiety Rating Scale (k = 1; n = 14; SMD = 0.57; 95% CI, -0.52 to 1.66). I

There is limited evidence favouring low-frequency repetitive transcranial magnetic stimulation (rTMS) over control on reducing the likelihood of leaving the study early due to any reason prior to 14 day follow-up (k = 1; n = 18; RR = 0.8; 95% CI, 0.14 to 4.49). I

Further evidence identified in the current review

No further studies of rTMS were identified in the current review.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

4.1.10.5 Summary of evidence

Only one study of physical therapies was identified. This study examined the effectiveness of high and low-frequency rTMS. There was limited evidence suggesting that high-frequency rTMS was more effective over 14 days on a range of outcome measures, than control. The evidence for low-frequency rTMS was inconclusive. Since only one study was identified, providing only limited evidence and rTMS is not currently available outside of research environments, no recommendations have been made regarding rTMS.

No studies that examined the effectiveness of exercise as an adjunct to other PTSD treatment were identified in the current review. However the positive effect of exercise on mental health conditions more generally (notably depression) has been established and a recent study published after the evidence review (Manger & Motta, 2005) suggests that exercise may have a similarly positive impact on people with PTSD. As such, notwithstanding the limited evidence, practitioners may consider promoting exercise as a self-care and stress management activity, in conjunction with practitioner delivered interventions.

4.1.10.6 Recommendations

4.1.10.6.1 As part of general mental health care, practitioners may wish to advise people with PTSD that regular aerobic exercise may be helpful in managing their symptoms and as part of self-care practices more generally. (GPP)

4.1.11 Comorbidities

4.1.11.1 Research questions and PICO

Box 73 PTSD and comorbidity: Research questions and study selection criteria

Research Question	
18. In the context of PTSD and comorbidity, is sequencing of intervention per diagnosis more effective than simultaneous interventions for both diagnoses?	
Selection criteria	Inclusion criteria
Population	Adults with PTSD and comorbidity (e.g., grief, depression, personality disorder, pain and substance misuse)
Intervention	Sequenced psychological or pharmacological intervention per diagnosis ie treatment for PTSD and then comorbidity or vice versa
Comparator	Simultaneous psychological and/or pharmacological interventions for both diagnoses
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ social and occupational function / quality of life / treatment refusal/ dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2002-8/2005*
Language	English

This question was answered by VA/DoD question 17 with a search period up to 2002.

4.1.11.2 Studies included in previous reviews: VA/DoD

The VA/DoD review identified one randomised control trial (Triffleman, 2000) and eight descriptive/observational studies (Bohus et al., 1999; Donovan et al., 2001; Gershuny et al., 2002; Hertzberg et al., 2001; Kosten et al., 2000; Najavits et al., 1998; Ouimette et al., 2001; Sonawalla et al., 1999). The review summary is as follows.

4.1.11.3 Studies included in the current review

One prospective cohort study that investigated different forms of treatment for people with PTSD and Substance Use Disorder (SUD) was identified in the current review

4.1.11.4 Treatment comparison

4.1.11.4.1 Comorbid PTSD and substance abuse (SA)

Previous evidence: VA/DoD summary statement

Earlier reports of treatment for patients with comorbid PTSD and substance abuse (SA) have proposed that treatment for SA should take place first and that trauma-focused therapy should occur only after the patient has developed a commitment to abstinence.

- *One study (Donovan et al., 2001) suggests that an integrative treatment approach to chronic combat-related PTSD and comorbid SA can be effective. This integrated program focuses first on substance abuse and later on trauma processing.*

- *Another study (Triffleman, 2000) found no differences in effectiveness between a specialised Substance Dependence PTSD Therapy (SDPT) program and Twelve Step Facilitation Therapy. The SDPT Program focuses initially on developing substance abstinence, followed by PTSD symptom-focused treatment, with continuing attention to substance abuse. In Twelve Step Facilitation Therapy, no specific PTSD focus is present.*
- *An additional study (Ouimette et al., 2001) suggests that 12-step programs with no specific PTSD treatment focus may be useful for patients with comorbid PTSD. In this study, greater participation predicted decreased symptom distress among those PTSD patients whose identity was more consistent with 12-step philosophy.*
- *Drug treatment may be helpful in some instances: naltrexone in the treatment of dissociative symptoms in patients with borderline personality disorder and PTSD (Bohus et al., 1999); bupropion sustained-release for smoking cessation in patients with chronic PTSD (Hertzberg et al., 2001); and fluvoxamine in the treatment of major depression with comorbid anxiety disorders (Sonawalla et al., 1999). Each of these studies undertook concurrent treatment of symptoms across both conditions and thus no recommendation for timing can be made.*

Further evidence identified in the current review

One prospective cohort study assessed the relationship between different forms of treatment for people with comorbid substance use disorder (SUD) and PTSD, with the main outcome being the 5 year remission rate for the substance use disorder (Ouimette et al., 2001). This study was part of a larger trial evaluating SUD treatments, where outpatients received treatment for PTSD and/or SUD. One hundred and eighteen participants completed the 5 year follow-up. Logistic regression was performed, and receiving PTSD *and* SUD treatments within the first year of intake was significantly associated with 5 year remission ($\chi^2[2, n=100]=7.12, p=0.03$). When SUD therapy was controlled for, PTSD treatment was found to be beneficial, with people who received PTSD therapy being 3.7 times more likely to be in remission than those who did not receive PTSD therapy in the first year (95%CI 1.34, 10.26; $\chi^2[1, n=100]=6.33, p=0.01$). Treatment for the substance use disorder alone within the first year did not correlate with 5 year SUD remission.

These results provide limited evidence (level II-2) to suggest that in the case of comorbid substance use disorder and PTSD, PTSD therapy should not be delayed, as treatment within the first three months of receiving a PTSD diagnosis can be beneficial in assisting the remission of substance use disorder 5 years later. The authors hypothesised that providing PTSD treatment may provide people with more adaptive coping methods, which help their ability to abstain from drugs or alcohol (Ouimette, 2001 #9009}.

Current review evidence statements

There is limited relevant and applicable evidence favouring substance use disorder treatment plus PTSD treatment over substance use disorder treatment or PTSD treatment on remission of substance use disorder at 12 months (k=1; n=100; RR 3.7; 95% CI, 1.3 to 10.3). III-2

Updated evidence statements on the combined evidence from previous and current reviews

The VA/DoD summary statements are not in a form that can be combined with evidence statements from the current review. Consideration of both bodies of evidence will be reflected in the summary and recommendations.

4.1.11.5 Summary of the evidence

The limited research in the area of sequencing treatment in the context of comorbidity has primarily focused on PTSD and comorbid substance abuse. Overall, there is some evidence, albeit limited, favouring combined SA and PTSD treatment. Dismantling studies are required to provide stronger evidence regarding elements of the interventions that may be applied sequentially or simultaneously. In the absence of such evidence, these guidelines provide additional recommendations for practitioners based on expert consensus opinion. This may involve commencing the education and symptom management components of PTSD treatment with the trauma focused component delayed until some level of control over substance use is achieved.

Depression is another condition often comorbid with PTSD. The early and ongoing assessment of suicide risk is of primary importance in these circumstances. There are as yet no studies examining the sequencing of the treatment of comorbid depression and PTSD. There are, however, studies outlining the effectiveness of PTSD treatment on comorbid depression and prediction studies (outlined in the introduction) identifying comorbid depression severity as a negative influence on PTSD outcome. This information has been considered in the recommendations below on the sequencing of treatment in the context of PTSD and Major Depression.

If these comorbid conditions are also associated with personality disorder, specific therapy tailored to that condition may be required prior to any trauma-focused therapy.

The range of trauma populations included in the above studies and the interventions provided are generalisable to the PTSD populations in Australia and the Australian healthcare context.

4.1.11.6 Recommendations

- 4.1.11.6.1 In the context of comorbid PTSD and depression, health practitioners may consider treating the PTSD first as the depression will often improve with treatment of the PTSD. (B)*
- 4.1.11.6.2 Where the severity of comorbid depression precludes effective engagement in therapy and/or is associated with high-risk suicidality, health practitioners are advised to manage the suicide risk and treat the depression prior to treating the PTSD. (GPP)*
- 4.1.11.6.3 In the context of PTSD and substance use disorders, practitioners should consider treating both conditions simultaneously. (C)*
- 4.1.11.6.4 In the context of PTSD and substance use disorders, the trauma-focused component of PTSD treatment should not commence until the PTSD sufferer has demonstrated a capacity to manage distress without recourse to substance use and to attend sessions without being drug or alcohol affected. (D)*
- 4.1.11.6.5 In the context of PTSD and substance use disorders where the decision is made to treat substance use disorders first, treatment should include information on PTSD and strategies to deal with PTSD symptoms as the person controls their substance abuse. (GPP)*

5 Evidence review and treatment recommendations: Early Intervention

There are two early interventions sections. The first addresses interventions for all adults exposed traumatic events, regardless of the presence or absence of symptoms of psychological disorder. So called *treatment for all* interventions are intended to prevent the developed of psychiatric sequelae following exposure to potentially traumatic events. The second early intervention section addresses interventions for the subgroup of adults exposed to traumatic events that have developed symptoms of ASD or early PTSD.

5.1 Interventions for adults exposed to potentially traumatic events

5.1.1 Psychological interventions

5.1.1.1 Research questions and PICO

Box 8 Early psychological interventions for adults exposed to trauma: Research questions and study selection criteria

Research Questions	
1. For adults exposed to trauma, do early psychological interventions improve outcomes compared to no intervention?	
2. For adults exposed to trauma, does any early psychological intervention confer any advantage over other early psychological interventions?	
Selection criteria	Inclusion criteria
Population	Adults exposed to trauma, including the subgroup with ASD
Intervention	Early psychological intervention (e.g., debriefing, trauma-focused counselling, education, performed within one month of trauma)
Comparator	1. No intervention (e.g., assessment only) 2. Other early psychological intervention
Outcome	Primary outcomes: symptoms of ASD and PTSD Secondary outcomes: symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials
Search Period	2004-8/2005*
Language	English

This questions was addressed by NICE (2005) research questions 3 and 4 with a search period up to 2004.

5.1.1.2 Studies included in the previous review: NICE (2005)

The NICE review team conducted a new systematic search for RCTs (randomised controlled trials) that assessed the efficacy of early psychological treatments following exposure to potentially traumatic events.

Ten studies that investigated treatments delivered to all traumatic incident survivors, normally within the first month after the incident, were identified: (Bisson et al., 1997; Brom et al., 1993; Campfield & Hills, 2001; Conlon et al., 1999; Dolan et al., unpublished; Hobbs et al., 1996; Lee et al., 1996; Mayou et al., 2000; Rose et al.,

1999; Zatzick et al., 2001). Four different types of early intervention were identified: education, collaborative care, trauma-focused counselling and debriefing.

- 1 study (Rose et al., 1999) tested an educational intervention against control
- 1 study (Zatzick et al., 2001) compared a collaborative care program with usual care
- 1 study (Brom et al., 1993) compared trauma-focused counseling with monitoring control
- 6 studies compared individual psychological debriefing to control (Bisson et al., 1997; Conlon et al., 1999; Dolan et al., unpublished; Hobbs et al., 1996; Lee et al., 1996; Mayou et al., 2000; Rose et al., 1999)
- 1 study compared delayed debriefing with immediate debriefing (Campfield & Hills, 2001).

5.1.1.3 Studies included in the current review (2004-2005)

One further study that compared the effectiveness of an early psychological intervention (single session counselling) with no intervention, was identified in the current review (Gamble et al., 2005).

5.1.1.4 Treatment comparisons

5.1.1.4.1 Education versus control

Previous evidence: NICE Guideline evidence statements

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between education and control on reducing the likelihood of having a PTSD diagnosis at 6 months' follow-up (k=1; n=103; RR=0.69, 95% CI 0.37 to 1.3). I

There is evidence suggesting there is unlikely to be a clinically important difference between education and control on reducing the severity of PTSD symptoms (self-reported) at 6 months' follow-up (k=1; n=91; SMD=-0.18, 95% CI -0.59 to 0.24). I

Further evidence identified in the current review

No further studies comparing education with control were identified in the current review.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

5.1.1.4.2 Collaborative care versus control

Previous evidence: NICE Guideline evidence statements

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between collaborative care and control on reducing the severity of PTSD symptoms (self-report measures) at 1 month's follow-up (k=1; n=29; SMD=-0.5, 95% CI -1.24 to 0.24). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between collaborative care and control in severity of PTSD symptoms (self-report measures) at 4 months' follow-up (k=1; n=26; SMD=0.4, 95% CI -0.38 to 1.18). I

Further evidence identified in the current review

No further studies comparing collaborative care with control were identified in the current review.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

*5.1.1.4.3 Trauma-focused counselling versus control***Previous evidence: NICE Guideline evidence statements**

There is evidence suggesting there is unlikely to be a clinically important difference between trauma-focused counselling and control on reducing the severity of PTSD symptoms (self-report measures) at 6 months' follow-up (k=1; n=151; SMD=0.17, 95% CI -0.15 to 0.49). I

Further evidence identified in the current review

No further studies comparing trauma-focused counselling with control were identified in the current review.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

*5.1.1.4.4 Debriefing versus control***Previous evidence: NICE Guideline evidence statements**

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between debriefing and control on reducing the

likelihood of having a PTSD diagnosis at 3–6 months' follow-up (k=2; n=238; RR=1.2, 95% CI 0.84 to 1.71). I

There is limited evidence suggesting a difference favouring control over debriefing on reducing the likelihood of having a PTSD diagnosis at 13 months' follow-up (k=1; n=133; RR=1.87, 95% CI 1.12 to 3.12). I

There is evidence suggesting there is unlikely to be a clinically important difference between debriefing and control on reducing the severity of PTSD symptoms (self-report measures) at 1–4 months' follow-up (k= 5; n=356; SMD=0.11, 95% CI –0.1 to 0.32). I

There is evidence suggesting there is unlikely to be a clinically important difference between debriefing and control on reducing depression symptoms at 1–4 months' follow-up (k= 3; n=225; SMD=0, 95% CI –0.27 to 0.26). I

Further evidence identified in the current review

No further studies comparing debriefing with control were identified in the current review.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

5.1.1.4.5 Single session counselling versus control

Previous evidence: NICE Guideline evidence statements

No studies comparing single session counseling with control were identified in the NICE review.

Further evidence identified in the current review

Only one further study (Gamble et al., 2005, - level II intervention evidence) met the inclusion criteria for the research question comparing the effectiveness of an early psychological intervention with no intervention. This study concerned a population of women in Australia at risk of developing psychological trauma symptoms after experiencing a traumatic childbirth. A single session of counselling was provided within 72 hours of the birth and contained elements of critical incident stress debriefing, as well as covering issues pertinent to childbirth (Gamble et al., 2005). For the purposes of a meta-analysis, the treatment may be defined as debriefing. Results from this study are presented in Table 28. Overall, there was little difference between the control group and the counselling intervention group at 4-6 weeks postpartum. However, at 3 months postpartum, there were fewer women in the counselling group with a diagnosis of PTSD (not statistically significant), and the counselling group had significantly less posttraumatic symptoms than the control group ($t[101]=2.144$, $p=0.035$). At 3 months postpartum, the intervention group also had less depression on both the Edinburgh Postnatal Depression Scale (75% reduction in risk relative to the control group) and the Depression Anxiety and Stress Scale-21 (56% relative risk reduction), but no significant difference in levels of anxiety. Between four and five

women would need to receive a single session of counselling to have one woman with a clinically important improvement in depression at 3 months post-partum.

The methodology reported in this study indicates that an intervention was provided over the course of the 4-6 week follow-up. As such only the 4-6 week posttreatment data have been used to calculate evidence statements regarding early intervention.

Table 28 New evidence for early psychological interventions for adults exposed to trauma

(treatment for all)

Study	Quality appraisal ^a	Population	Effectiveness	Single session Counselling	Control group	Relative risk (CI 95%) [‡]	Difference* Effect size [95% CI]																															
(Gamble, 2005) Level II: RCT	Allocation	a	103 women who met DSM-IV-TR definition of traumatic event after childbirth Mean age= n/a	PTSD at 4-6 weeks	17/50	16/53	1.15 (0.66, 2.02)	$\chi^2[1]=0.236$ p=0.392 RR 1.15 [95% CI 0.66 to 2.02]																														
	Selection bias	b							PTSD at 3 mo	3/50	9/53	0.35 (0.10, 1.23)	$\chi^2[1]=3.014$ p=0.075 RR 0.35, [95% CI 0.10 to 1.23]																									
	Blinding	b												EPDS score >12 at 4-6 wks	16/50	18/53	0.96 (0.56, 1.67)	not significant RR 0.96, [95% CI 0.56 to 1.67]																				
	Outcome assessment	a																	EPDS score >12 at 3 mo	4/50	17/53	0.25 (0.09, 0.69)	$\chi^2[1]=9.188$ p=0.002 RR 0.25, [95% CI 0.09 to 0.69]															
	ITT: Yes																							DASS-depression (>13) at 3 mo	3/50	14/53	0.23 (0.07, 0.76)	$\chi^2[1]=7.549$ p=0.005 RR 0.23, [95% CI 0.07 to 0.76]										
																													DASS-anxiety (>9) at 3 mo	1/50	6/53	0.18 (0.02, 1.45)	not significant RR 0.18, [95% CI 0.02 to 1.45]					
																																		DASS-stress (>19) at 3 mo	7/50	17/53	0.44 (0.20, 0.96)	$\chi^2[1]=4.478$ p=0.029 RR 0.44, [95% CI 0.20 to 0.96]

RCT=randomised controlled trial; **DSM-IV-TR=**Diagnostic and Statistical Manual of Mental Disorders-Fourth edition- text revision; **PTSD=**post traumatic stress disorder; **EPDS=**Edinburgh Postnatal Depression Scale; **DASS=**Depression Anxiety and Stress Scale-21; **n/a=**not available; ^aSee Appendix E ACPMH
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Appendix for checklist for appraising the quality of intervention studies; ¥=Author's reported value; RR=risk ratio.

Appendix E ACPMH Project Support Team

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Appendix

Current review evidence statements

There is relevant evidence suggesting that there is unlikely to be a clinically important difference between single-session counselling and control on reducing the likelihood of having a PTSD diagnosis at 4-6 weeks following traumatic childbirth (k=1; n=103; RR=1.15, 95% CI 0.66 to 2.02). II

The relevant evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between single-session counselling and control in reducing the likelihood of having a PTSD diagnosis at three months following traumatic childbirth (k=1; n=103; RR=0.35, 95% CI 0.10 to 1.23). II

The relevant evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between single-session counselling and control on reducing the likelihood of having an Edinburgh Postnatal Depression Scale score greater than 12 at 4-6 weeks following traumatic childbirth (k=1; n=103; RR=0.96, 95% CI 0.56 to 1.67). II

There is limited relevant evidence favouring single-session counselling over control on reducing the likelihood of having an Edinburgh Postnatal Depression Scale score greater than 12 at three months following traumatic childbirth (k=1; n=103; RR=0.25, 95% CI 0.09 to 0.69). II

There is limited relevant evidence favouring single-session counselling over control on reducing the likelihood of having a Depression Anxiety and Stress Scale-21 score greater than 13 at three months following traumatic childbirth (k=1; n=103; RR=0.23, 95% CI 0.07 to 0.76). II

The relevant evidence is inconclusive and so it is not possible to determine whether there is a clinically important difference between single-session counselling and control on reducing the likelihood of having a Depression Anxiety and Stress Scale-21 score greater than nine at three months following traumatic childbirth (k=1; n=103; RR=0.18, 95% CI 0.02 to 1.45). II

There is limited relevant evidence favouring single-session counselling over control on reducing the likelihood of having a Depression Anxiety and Stress Scale-21 score greater than 19 at three months following traumatic childbirth (k=1; n=103; RR=0.44, 95% CI 0.20 to 0.96). II

The generalisability of the evidence is limited as the study population was specific to women with PTSD following traumatic childbirth

Updated evidence statements on the combined evidence from previous and current reviews

As there was no previous evidence statements there are no updated evidence statements.

5.1.1.5 Summary of the evidence

One additional study has been published since the NICE guidelines (Gamble et al., 2005). This study reports improved post natal depression scores at follow-up when debriefing is delivered following traumatic childbirth. However, there was an additional intervention at 4-6 weeks that may have contributed to this outcome. The essential recommendations reported by NICE are therefore not altered by this additional study.

The evidence statements generated both by the NICE and this review derived from the eleven adequately controlled studies, suggest there is unlikely to be a clinically important difference between debriefing and control in the development of PTSD symptoms or developing a PTSD diagnosis. These recommendations, therefore, are consistent with those outlined by NICE suggesting that structured debriefing interventions, including ventilation of emotions or narration of events, should not be delivered on a routine basis. Instead, practitioners are advised to adopt a stance of “watchful waiting” combined with the provision of general psychological first aid where required. Psychological first aid includes provision of information, comfort, emotional and instrumental support. Additional assistance should be progressively provided according to individual need. The ventilation of emotions and narration of events on a routine basis is not supported by the evidence. However, individuals who wish to discuss the experience, and who demonstrate a capacity to tolerate associated distress, should be supported in doing so. Where adults exposed to trauma develop an extreme level of distress or are at risk of harm to self or others, immediate crisis intervention and possible psychiatric intervention should be provided

5.1.1.6 Recommendations

- 5.1.1.6.1** *For adults exposed to trauma, structured psychological interventions such as psychological debriefing should not be offered on a routine basis. (C)*
- 5.1.1.6.2** *For adults exposed to trauma, clinicians should implement psychological first aid in which survivors of potentially traumatic events are supported, immediate needs met, and monitored over time. Psychological first aid includes provision of information, comfort, emotional and instrumental support to those seeking help. Psychological first aid should be provided in a stepwise fashion tailored to the person’s needs. (GPP)*
- 5.1.1.6.3** *Adults exposed to trauma who wish to discuss the experience, and demonstrate a capacity to tolerate associated distress, should be supported in doing so. In doing this the practitioner should keep in mind the potential adverse effects of excessive ventilation in those who are very distressed. (GPP)*
- 5.1.1.6.4** *For adults who develop an extreme level of distress or are at risk of harm to self or others, immediate psychiatric intervention should be provided (GPP)*

5.1.2 Pharmacological interventions

5.1.2.1 Research questions and PICO

Box 9 Pharmacological interventions for adults exposed to trauma: Research questions and study selection criteria

Research Question	
	8. For adults exposed to trauma, do early pharmacological interventions improve outcomes compared to no intervention?
	9. For adults exposed to trauma, does any early pharmacological intervention confer any advantage over other early pharmacological interventions?
Selection criteria	Inclusion criteria
Population	Adults exposed to trauma, including the subgroup with ASD
Intervention	Early pharmacological intervention, (e.g., imipramine, propranolol, benzodiazepines, other sympatholytics, other antidepressants, anticonvulsants, antipsychotics, chloral hydrate, given within one month of trauma)
Comparator	8. No intervention (e.g., assessment only) 9. Other early pharmacological intervention
Outcome	Primary outcomes: symptoms of ASD or PTSD Secondary outcomes: symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	8. Systematic reviews of randomised controlled trials, randomised controlled trials 9. Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	8. 2004-8/2005 ^a 9. 1966-8/2005 ^b
Language	English

This question was answered by NICE pharmacology questions 3 and 4 with a search period up to 2004.

5.1.2.2 Studies included in the previous review: NICE (2005)

Two studies of early intervention drug treatments that met the inclusion criteria were identified in the NICE review (Pitman et al., 2002; Schelling et al., 2001). Both studies compared intervention against no intervention. No studies were identified that compared one type of pharmacological intervention against another.

5.1.2.3 Studies included in the current review (2004-2005)

No further studies were identified in the current review.

5.1.2.4 Treatment comparisons

5.1.2.4.1 Propranolol versus placebo

Previous evidence: NICE Guidelines evidence statements

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between propranolol and placebo on reducing the likelihood of having a PTSD diagnosis at 1 month (k=1; n=41; RR=1.14, 95% CI 0.55 to 2.35). I

There is limited evidence suggesting a difference favouring placebo over propranolol on reducing the likelihood of having a PTSD diagnosis at 3 months' follow-up (k=1; n=41; RR=1.28, 95% CI 0.69 to 2.38). I

Further evidence identified in the current review

No further studies comparing propranolol with placebo were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

5.1.2.4.2 Hydrocortisone versus placebo

Previous evidence: NICE Guidelines evidence statements

There is limited evidence suggesting a difference favouring hydrocortisone over placebo on reducing the likelihood of having a PTSD diagnosis at approximately 31 months after treatment (k=1; n=20; RR=0.17, 95% CI 0.03 to 1.17). I

Further evidence identified in the current review

No further studies comparing hydrocortisone with placebo were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

5.1.2.5 Summary of the evidence

The NICE review found only two controlled trials examining pharmacological treatment for all interventions, one of which (Pitman et al., 2002) found in favour of the placebo condition. We found no further studies since the NICE review with regard

to pharmacological prevention and early intervention following traumatic exposure. Thus, in line with the NICE recommendations, we do not recommend drug treatments for use as a preventive intervention non-selectively with traumatised populations.

5.1.2.6 Recommendation

5.1.2.6.1 For adults exposed to trauma, drug treatments should not be used non-selectively as a preventive intervention (C)

5.1.3 Combined psychological and pharmacological interventions

5.1.3.1 Research questions and PICO

Box 10 Combined early interventions for adults exposed to trauma: Research question and study selection criteria

Research Question	
15. For adults exposed to trauma, is a single early intervention more effective than multiple early interventions?	
Selection criteria	Inclusion criteria
Population	Adult exposed to trauma, including the subgroup with ASD
Intervention	Single early psychological or pharmacological intervention
Comparator	Early combined psychological or combined pharmacological interventions or combined psychological and pharmacological interventions
Outcome	Primary outcomes: symptoms of ASD or PTSD Secondary outcomes: symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ side-effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	1966-8/2005*
Language	English

A new search (1996-2005) was conducted on this question as it was not addressed in either the NICE or VA/DoD reviews.

5.1.3.2 Studies included in previous reviews

There were no studies identified in previous reviews (NICE, 2005; VA/DoD, 2004) as the question was not addressed.

5.1.3.3 Studies included in the current review (1996-2005)

As stated in the search strategy, in the absence of Levels I or II evidence, lower levels of evidence was sought. Two Level III studies were identified that examined combination psychological treatment for all interventions (Eid et al., 2001; Richards, 2001).

5.1.3.4 Treatment Comparisons

5.1.3.4.1 Critical incident stress debriefing vs critical incident stress management

Previous evidence: NICE Guideline evidence statements

No studies comparing critical incident stress debriefing with critical incident stress management were identified in the NICE review.

Further evidence identified in the current review

One poor quality historically controlled study (Richards et al 2001) assessed the benefits of critical incident stress debriefing (CISD) versus critical incident stress management (CISM) in a group of financial institution employees following armed robberies (See Table 29). CISD included group discussions on thoughts, emotions and stress reactions, and participants received education about potential symptoms. The group who received CISM received pretrauma training, CISD and an individual counselling session one month after the incident, with therapy structured around a cognitive behavioural model of intervention (such as prolonged exposure). Historical control studies are susceptible to history effects, and this study had high loss to follow-up, therefore any conclusions should be tentative. Despite the group receiving CISM reporting consistency less mean symptoms on the Impact of Event Scale or Posttraumatic Stress Scale, no clinically significant differences were found between treatment groups.

Table 29 Effectiveness of critical incident stress debriefing vs critical incident stress management for preventing development of PTSD symptoms

Study	Level and Quality	Population	Outcome	CISD	CISM	Effect size [95 % CI]	
Richards 2001 United Kingdom	Level III-3 (historically controlled trial) Assignment: d Selection bias: d Blinding: c Assessment: a	Employees of a financial institution who were victims of armed robberies	Impact of Events Scale (IES)	Day 3 (n=225)	Day 3 (n=299)	SMD 0.12 [95%CI -0.06 to 0.29]	
				31.6±16.5	33.5±16.5		
				1 month (n=114)	1 month (n=249)	SMD 0.20 [95%CI -0.02 to 0.42]	
				8.5±12.0	11.1±13.8		
				Follow-up (n=106)	Follow-up (n=152)	SMD 0.43 [95%CI 0.18 to 0.68]	
				8.9±13.0	11.1±13.9		
				Posttraumatic stress scale (PSS)	Day 3 (n=225)	Day 3 (n=299)	SMD 0.15 [95%CI -0.03 to 0.32]
				13.9±16.5	15.4±10.7		
	1 month (n=114)	1 month (n=249)	SMD 0.15 [95%CI -0.07 to 0.37]				
	4.4±6.1	5.4±7.0					
	Follow-up (n=106)	Follow-up (n=152)	SMD 0.30 [95%CI 0.05 to 0.55]				
	4.4±6.1	2.8±5.0					

CISD=Critical Incident Stress Debriefing; CIDM=Critical Incident Stress Management; ITT=Intent-to-treat; Follow-up computed by taking mean score from 3, 6, or 12 month points;

Current review evidence statements

There is evidence suggesting that there is unlikely to be a clinically significant difference between critical incident stress debriefing and critical incident stress management on reducing intrusion and avoidance symptoms (IES) at three days (k=1; n=524; SMD=0.12; 95%CI, -0.06 to 0.29). III-3

There is evidence suggesting that there is unlikely to be a clinically significant difference between critical incident stress debriefing and critical incident stress management on reducing intrusion and avoidance symptoms (IES) at one month (k=1; n=363; SMD=0.20; 95%CI, -0.02 to 0.42). III-3

There is evidence suggesting that there is unlikely to be a clinically significant difference between critical incident stress debriefing and critical incident stress management on reducing intrusion and avoidance symptoms (IES) at 3 – 12 months (k=1; n=258; SMD=0.43; 95%CI, -0.02 to 0.42). III-3

There is evidence suggesting that there is unlikely to be a clinically significant difference between critical incident stress debriefing and critical incident stress management on reducing severity of PTSD symptoms (PSS) at three days (k=1; n=524; SMD=0.15; 95%CI, -0.03 to 0.32). III-3

There is evidence suggesting that there is unlikely to be a clinically significant difference between critical incident stress debriefing and critical incident stress management on reducing severity of PTSD symptoms (PSS) at one month (k=1; n=363; SMD=0.15; 95%CI -0.07 to 0.37). III-3

There is evidence suggesting that there is unlikely to be a clinically significant difference between critical incident stress debriefing and critical incident stress management on reducing severity of PTSD symptoms (PSS) at 3 – 12 months (k=1; n=258; SMD=0.30; 95%CI 0.05 to 0.55). III-3

Updated evidence statements on the combined evidence from previous and current reviews

As there are no previous review evidence statements, there are no updated evidence statements

5.1.3.4.2 Operational debriefing vs operational debriefing and group psychological debriefing

Previous evidence: NICE Guideline evidence statements

No studies comparing operational debriefing with operational debriefing and group psychological debriefing were identified in the NICE review.

Further evidence identified in the current review

One poor quality Norwegian study compared the effects of different interventions on a group of firefighters and military personnel who attended the same serious traffic incident (See Table 30).

Both groups received stress management education and operational debriefing, while only the military personnel received additional semi-structured group critical incident debriefing (which they called psychological debriefing to distinguish from operational

debriefing). Overall the military personnel who received both operational and group psychological debriefing had less symptoms of posttraumatic symptoms than the firefighters who received only operational debriefing, although this difference was only significant on the Posttraumatic Symptom Scale – 10. The differences in participant characteristics lead the study results to be prone to bias, so should be treated with caution.

Table 30 Effectiveness of operational debriefing vs operational debriefing and group debriefing for preventing development of PTSD symptoms

Study	Level and Quality	Population	Outcome	Debriefing	Debriefing + group debriefing	Difference‡ Effect size [95 % CI]
Eid 2001 Norway	Level III-2 (non-randomised controlled trial) Assignment: d Selection bias: a Blinding: c Assessment: a	Participants had assisted at the site of a serious traffic incident in a road tunnel Civilian volunteer firefighters	Impact of Events Scale (IES)	17.0±10.7	11.4±6.4	ES=0.10 NS SMD 0.60 [95%CI -0.33 to 1.55]
			Posttraumatic Symptom Scale – 10 (PTSS-10)	20.4±7.1	13.2±3.6	ES=0.31 p<0.001 NS SMD 1.22 [95%CI 0.21 to 2.22]
		Debriefing n=9				
		Debriefing + group debriefing n=9 Conscripted military personnel				

‡=Author's reported value for statistical analyses; ES=effect size; SMD=standardised mean difference; NS=not significant

Current review evidence statements

There is evidence suggesting that there is unlikely to be a clinically significant difference between operational debriefing and combined operational debriefing and psychological debriefing on reducing intrusion and avoidance symptoms (IES) (k=1; n=18; SMD=0.10; 95%CI, -0.33 to 1.55). III-2

There is evidence favouring combined operational debriefing and psychological debriefing over operational debriefing alone on reducing severity of PTSD symptoms (PTSS-10) (k=1; n=18; SMD=1.22; 95%CI, 0.21 to 2.22). III-2

Updated evidence statements on the combined evidence from previous and current reviews

As there are no previous review evidence statements, there are no updated evidence statements

5.1.3.5 Summary of the evidence

There was insufficient quality evidence from which to derive practice recommendations. As stated in the search strategy, in the absence of Levels I or II evidence, lower levels of evidence was sought. Two Level III studies were identified that examined combination psychological treatment for all interventions. The Richards et al. (2001) study suggested no benefit of combining CISM with a single individual counseling session at one month. Eid et al. (2001) compared a military sample which received stress management, operational debriefing and psychological debriefing to fire fighters who attended the same accident and just received stress management and operational debriefing, without the group psychological debriefing. While this study suggested some benefit from the addition of psychological debriefing, the comparison of combination treatments in the context of two different populations must be interpreted with great caution. As such, there is considered to be insufficient evidence at this stage from which to derive practice recommendations for combined psychological treatment for all interventions for adults exposed to potentially traumatic events with any reasonable confidence. There was also insufficient evidence

to make recommendations regarding combined psychological and pharmacological treatment for all adults exposed to potentially traumatic events.

5.1.3.6 Recommendations

No recommendations have been made.

5.2 Interventions for adults with ASD

5.2.1 Psychological interventions

5.2.1.1 Research questions and PICO

Box 11 Early psychological interventions for adults with PTSD: Research questions and study selection criteria

Research Questions	
1. For adults exposed to trauma, do early psychological interventions improve outcomes compared to no intervention?	
2. For adults exposed to trauma, does any early psychological intervention confer any advantage over other early psychological interventions?	
Selection criteria	Inclusion criteria
Population	Adults exposed to trauma, including the subgroup with ASD
Intervention	Early psychological intervention (e.g., debriefing, trauma-focused counselling, education, performed within one month of trauma)
Comparator	1. No intervention (e.g., assessment only) 2. Other early psychological intervention
Outcome	Primary outcomes: symptoms of ASD and PTSD Secondary outcomes: symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials
Search Period	2004-8/2005*
Language	English

These questions were answered by NICE questions 3 and 4 with a search period up to 2004.

5.2.1.2 Studies included in previous review: NICE (2005)

The NICE review team conducted a new systematic search for randomised controlled trials that investigated treatments delivered to people with ASD and acute PTSD, initiated within 3 months of the incident.

Nine studies were identified as falling within the category of early interventions for acute PTSD and acute stress disorder: (Bisson et al., 2004; Bryant et al., 1998; Bryant et al., unpublished; Bryant et al., 2005; Bryant et al., 2003b; Bryant et al., 1999; Echeburua et al., 1996; Ehlers et al., 2003; Ost et al., unpublished). In Ehlers (2003)2003A the self-monitoring period was taken to be part of the active intervention and as occurring within 3 months of the trauma. The studies were of 5 different types of intervention: (trauma-focused cognitive-behavioural therapy, trauma-focused CBT supplemented with hypnosis or anxiety management, relaxation techniques and a self help booklet).

5.2.1.3 Studies included in the current review (2004-2005)

No further studies were identified in the current review.

5.2.1.4 Treatment comparisons

5.2.1.4.1 Trauma focused CBT versus control

Previous evidence: NICE guideline evidence statements

There is limited evidence suggesting a difference favouring trauma-focused CBT over waiting list (random effects) on reducing the likelihood of having a PTSD diagnosis posttreatment (k=3; n=252; RR=0.4, 95% CI 0.16 to 1.02). I

There is limited evidence suggesting a difference favouring trauma-focused CBT over waiting list (random effects) on reducing the likelihood of having a PTSD diagnosis at 9–13 months' follow-up (k=2; n=209; RR=0.41, 95% CI 0.11 to 1.45). I

There is limited evidence suggesting a difference favouring trauma-focused CBT over waiting list (random effects) on reducing the severity of PTSD symptoms (self-report measures) (k=3; n=224; SMD=-0.98, 95% CI -1.81 to -0.14). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and waiting list (random effects) on reducing the severity of PTSD symptoms (self-report measures) at 9–13 months' follow-up (k=2; n=171; SMD=-0.68, 95% CI -1.23 to -0.12). I

There is limited evidence suggesting a difference favouring trauma-focused CBT over waiting list (random effects) on reducing the severity of PTSD symptoms (clinician-rated measures) (k=3; n=224; SMD=-0.88, 95% CI -1.72 to -0.04). I

There is evidence suggesting there is unlikely to be a clinically important difference between trauma-focused CBT and waiting list (fixed effects) on reducing the severity of PTSD symptoms (clinician-rated measures) at 9–13 months' follow-up (k=2; n=171; SMD=-0.45, 95% CI -0.75 to -0.14). I

Further evidence identified in the current review

No further studies comparing trauma-focused CBT with control were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

5.2.1.4.2 Trauma focused CBT versus relaxation

Previous evidence: NICE guideline evidence statements

There is limited evidence suggesting a difference favouring trauma-focused CBT over progressive muscular relaxation training on reducing the likelihood of having a PTSD diagnosis posttreatment ($k=1$; $n=20$; $RR=0.4$, 95% CI 0.1 to 1.6). I

There is limited evidence suggesting a difference favouring trauma-focused CBT over progressive muscular relaxation training on reducing the likelihood of having a PTSD diagnosis at 12 months' follow-up ($k=1$; $n=20$; $RR=0.2$, 95% CI 0.01 to 3.7). I

Further evidence identified in the current review

No further studies comparing trauma-focused CBT with relaxation were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

5.2.1.4.3 Trauma focused CBT versus supportive psychotherapy

Previous evidence: NICE guideline evidence statements

There is evidence suggesting a difference favouring trauma-focused CBT over supportive psychotherapy on reducing the likelihood of having a PTSD diagnosis at 6 months' follow-up ($k=3$; $n=105$; $RR=0.51$, 95% CI 0.32 to 0.8). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and supportive psychotherapy on reducing the likelihood of having a PTSD diagnosis at 4 years' follow-up ($k=1$; $n=80$; $RR=0.9$, 95% CI 0.61 to 1.33). I

There is evidence suggesting a difference favouring trauma-focused CBT over supportive psychotherapy on reducing the severity of PTSD symptoms (self-report measures) ($k=3$; $n=94$; $SMD=-1.11$, 95% CI -1.55 to -0.67). I

There is limited evidence suggesting a difference favouring trauma-focused CBT over supportive psychotherapy on reducing the severity of PTSD symptoms (self-report measures) at 6 months' follow-up ($k=3$; $n=94$; $SMD=-0.8$, 95% CI -1.22 to -0.37). I

Further evidence identified in the current review

No further studies comparing trauma-focused CBT with supportive psychotherapy were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

5.2.1.4.4 Self help education versus control

Previous evidence: NICE guideline evidence statements

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between self-help booklet and waiting list on reducing the likelihood of having a PTSD diagnosis posttreatment (k=1; n=57; RR=1.09, 95% CI 0.81 to 1.46)

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between self-help booklet and waiting list on reducing the likelihood of having a PTSD diagnosis at 9 months' follow-up (k=1; n=57; RR=1.1, 95% CI 0.71 to 1.71). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between self-help booklet and waiting list on reducing the severity of PTSD symptoms (self-report measures) (k=1; n=52; SMD=-0.27, 95% CI -0.81 to 0.28). I

There is evidence suggesting there is unlikely to be a clinically important difference between self help booklet and waiting list on reducing the severity of PTSD symptoms (clinician-rated measures) at 9 months' follow-up (k=1; n=52; SMD=0.07, 95% CI -0.47 to 0.62). I

Further evidence identified in the current review

No further studies that compared self help education with control were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

5.2.1.5 Summary of evidence

There is now an increasing body of evidence for the effectiveness of trauma-focused CBT over control, relaxation and supportive psychotherapy conditions for ASD and acute PTSD. A CBT self help booklet does not appear to be superior to a control condition (Ehlers et al., 2003). These guidelines are therefore consistent with those of NICE in recommending that practitioners consider trauma focused CBT treatment for problems consistent with ASD and acute PTSD. While length and number of sessions have not been empirically tested as independent variables in their own right, the recommendations below draw on the length and number of sessions reported in the cited controlled studies, expert consensus and with reference to recommendations in the NICE guidelines. Note that recommended treatment is the same for ASD and acute PTSD.

The range of trauma populations included in the above studies and the interventions provided are generalisable to the PTSD populations in Australia and the Australian healthcare context.

5.2.1.6 Recommendations

5.2.1.6.1 Adults displaying ASD or PTSD reactions at least two weeks after the traumatic event should be offered trauma focused cognitive behaviour therapy including exposure and/or cognitive therapy once a clinical assessment has been undertaken. (A)

5.2.1.6.2 For adults with ASD, treatment should be provided on an individual basis. (B)

5.2.1.6.3 For adults with ASD, trauma focused CBT should, under normal circumstances, be provided in 5 – 10 sessions. (C)

5.2.1.6.4 For adults with ASD, ninety minutes should be allowed for sessions that involve imaginal exposure. (C)

5.2.1.6.5 Trauma focused interventions should not commence within two weeks of trauma exposure. (GPP)

5.2.1.6.6 Combination psychological interventions for ASD should not be used routinely. (C)

Research recommendation

5.2.1.6.7 The conduct of effectiveness trials is recommended to evaluate trauma-focused cognitive behavioural therapy and cognitive therapy for ASD in naturalistic clinical settings

5.2.2 Pharmacological interventions

5.2.2.1 Research questions and PICO

Box 12 Pharmacological interventions for adults with acute stress disorder: Research questions and study selection criteria

Research Question	
8. For adults exposed to trauma, do early pharmacological interventions improve outcomes compared to no intervention?	
9. For adults exposed to trauma, does any early pharmacological intervention confer any advantage over other early pharmacological interventions?	
Selection criteria	Inclusion criteria
Population	Adults exposed to trauma, including the subgroup with ASD
Intervention	Early pharmacological intervention, (e.g., imipramine, propranolol, benzodiazepines, other sympatholytics, other antidepressants, anticonvulsants, antipsychotics, chloral hydrate, given within one month of trauma)
Comparator	8. No intervention (e.g., assessment only) 9. Other early pharmacological intervention
Outcome	Primary outcomes: symptoms of ASD or PTSD Secondary outcomes: symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	8. Systematic reviews of randomised controlled trials, randomised controlled trials 9. Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	8. 2004-8/2005 ^a 9. 1966-8/2005 ^b
Language	English

This question was answered by NICE pharmacology questions 3 and 4 with a review period up to 2004.

5.2.2.2 Studies included in previous reviews: NICE (2005)

No studies meeting the selection criteria were identified in the NICE review.

5.2.2.3 Studies included in the current review (2004-2005)

No studies meeting the selection criteria were identified in the current review.

5.2.2.4 Treatment comparisons

As no studies were identified there are no-treatment comparisons to report.

5.2.2.5 Summary of evidence

We found no further studies since the NICE review with regard to pharmacological early intervention following traumatic exposure. Thus, in line with the NICE recommendations, we do not recommend drug treatments for use as an early intervention for ASD or related conditions. However, we do recognise the benefits of pharmacological interventions in terms of managing current acute (and chronic) symptoms in certain cases.

5.2.2.6 Recommendations

Clinical recommendations

5.2.2.6.1 *Drug treatments should generally not be used to treat ASD or related conditions (i.e., within four weeks of symptoms onset) in adults unless the severity of the person's distress can not be managed by psychological means alone, particularly when there is a pattern of extreme hyperarousal. (GPP)*

5.2.2.6.2 *In individuals who have a prior history of depression that has responded well to medication, the prescription of an antidepressant should be considered if a progressive pattern of clinically significant symptoms, such as persistent intrusions with increasing affective distress, begin to emerge. (GPP)*

5.2.2.6.3 *Where significant sleep disturbance does not settle in response to reassurance and simple psychological first aid, cautious use of hypnotic medication or other drug treatment may be appropriate for adults in the short term. (GPP)*

Research recommendation

5.2.2.6.4 *The effect of pharmacological treatment of ASD on subsequent PTSD status/severity following cessation of medication, should be investigated..*

5.2.3 Combined interventions

5.2.3.1 Research questions and PICO

Box 13 Combining interventions for adults with ASD: Research question and study selection criteria

Research Question	
15. For adults exposed to trauma, is a single early intervention more effective than multiple early interventions?	
Selection criteria	Inclusion criteria
Population	Adult exposed to trauma, including the subgroup with ASD
Intervention	Single early psychological or pharmacological intervention
Comparator	Early combined psychological or combined pharmacological interventions or combined psychological and pharmacological interventions
Outcome	Primary outcomes: symptoms of ASD or PTSD Secondary outcomes: symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ side-effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	1966-8/2005*
Language	English

A new search (1996-2005) was conducted on this question as it was not addressed in either the NICE or VA/DoD reviews.

5.2.3.2 Studies included in previous reviews

This question was not addressed in either of the previous reviews (NICE, 2005; VA/DoD, 2004). However two studies that compared single and multiple psychological interventions for ASD were identified in response to the psychology intervention questions put by NICE (Bryant et al., 2005; Bryant et al., 1999).

- 1 study compared prolonged exposure with prolonged exposure and anxiety management (Bryant et al., 1999)
- 1 study compared trauma-focused CBT with trauma-focused CBT and hypnotherapy (Bryant et al., 2005)

5.2.3.3 Studies included in the current review (2004-2005)

No studies, beyond those identified in the NICE review, were found to address whether a single or multiple early intervention is more effective in a population with ASD.

5.2.3.4 Treatment comparisons

5.2.3.4.1 Prolonged exposure versus prolonged exposure and anxiety management

Previous evidence: NICE guideline evidence statements

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between prolonged exposure and prolonged exposure & anxiety management on reducing the severity of PTSD symptoms (IES - self-report) (k = 1; n = 29; SMD = -0.31; 95% CI, -1.04 to 0.43). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between prolonged exposure and prolonged exposure & anxiety management on reducing the severity of PTSD symptoms (IES - self-report) at follow-up (6 months) (k = 1; n = 26; SMD = 0.03; 95% CI, - 0.74 to 0.8). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between prolonged exposure and prolonged exposure & anxiety management on reducing the severity of PTSD symptoms (CAPS2 - clinician) (k = 1; n = 29; SMD = -0.21; 95% CI, -0.94 to 0.52). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between prolonged exposure and prolonged exposure & anxiety management on reducing the severity of PTSD symptoms (CAPS2 - clinician) at follow-up (6 months) (k = 1; n = 26; SMD = -0.17; 95% CI, -0.95 to 0.6). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between prolonged exposure and prolonged exposure & anxiety management on reducing depression symptoms (BDI –self-report) (k = 1; n = 29; SMD = -0.13; 95% CI, -0.86 to 0.6). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between prolonged exposure and prolonged exposure & anxiety management on reducing depression symptoms (BDI – self-report) at follow-up (6 months) (k = 1; n = 26; SMD = -0.11; 95% CI, -0.88 to 0.66). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between prolonged exposure and prolonged exposure & anxiety management on reducing anxiety symptoms (STAI self-report) (k = 1; n = 29; SMD = 0.11; 95% CI, -0.62 to 0.84). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between prolonged exposure and prolonged exposure & anxiety management on reducing anxiety symptoms (STAI – self-report) at follow-up (6 months) (k = 1; n = 26; SMD = 0.12; 95% CI, -0.65 to 0.89). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between prolonged exposure and prolonged exposure & anxiety management on reducing the likelihood of leaving treatment early (k = 1; n = 37; RR = 0.95; 95% CI, 0.28 to 3.23). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between prolonged exposure and prolonged exposure & anxiety management on reducing the likelihood of leaving treatment early at follow-up (6 months) (k = 1; n = 37; RR = 1.14; 95% CI, 0.42 to 3.08). I

There is limited evidence favouring prolonged exposure over prolonged exposure & anxiety management on reducing the likelihood of having a PTSD diagnosis at follow-up (6 months) (k = 1; n = 38; RR = 0.64; 95% CI, 0.37 to 1.11).

Further evidence identified in the current review

No further studies that compared combination prolonged exposure and anxiety management with prolonged exposure alone, were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

5.2.3.4.2 Trauma focused CBT versus trauma focussed CBT and hypnosis

Previous evidence: NICE guideline evidence statements

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and trauma-focused CBT & hypnosis on reducing the severity of PTSD symptoms (IES -self-report) (k = 1; n = 47; SMD = 0.13; 95% CI, -0.45 to 0.7). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and trauma-focused CBT & hypnosis on reducing the severity of PTSD symptoms (IES -self-report) at follow-up (6 months) (k = 1; n = 47; SMD = 0.07; 95% CI, -0.5 to 0.64). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and trauma-focused CBT

& hypnosis on reducing the severity of PTSD symptoms (CAPS2 -clinician) (k = 1; n = 47; SMD = -0.01; 95% CI, -0.58 to 0.56). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and trauma-focused CBT & hypnosis on reducing the severity of PTSD symptoms (CAPS2 -clinician) at follow-up (6 months) (k = 1; n = 47; SMD = -0.02; 95% CI, -0.59 to 0.56). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and trauma-focused CBT & hypnosis on reducing depression symptoms (BDI2 – self-report) (k = 1; n = 47; SMD = -0.2; 95% CI, -0.77 to 0.37). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and trauma-focused CBT & hypnosis on reducing depression symptoms (BDI2 –self-report) at follow-up (6 months) (k = 1; n = 47; SMD = -0.26; 95% CI, -0.83 to 0.32). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and trauma-focused CBT & hypnosis on reducing anxiety symptoms (BAI – self-report) (k= 1; n = 47; SMD = -0.04; 95% CI, -0.62 to 0.53). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and trauma-focused CBT & hypnosis on reducing anxiety symptoms (BAI – self-report) at follow-up (6 months) (k = 1; n = 47; SMD = -0.15; 95% CI, -0.72 to 0.43). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and trauma-focused CBT & hypnosis on reducing the likelihood of leaving treatment early (k = 1; n = 63; RR = 1.17; 95% CI, 0.5 to 2.75). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and trauma-focused CBT & hypnosis on reducing the likelihood of leaving treatment early at follow-up (6 months) (k = 1; n = 63; RR = 1.17; 95% CI, 0.5 to 2.75). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and trauma-focused CBT & hypnosis on reducing the likelihood of having a PTSD diagnosis (k = 1; n = 63; RR = 1.21; 95% CI, 0.6 to 2.46). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT and trauma-focused CBT & hypnosis on reducing the likelihood of having a PTSD diagnosis at follow-up (6 months) (k = 1; n = 63; RR = 1.06; 95% CI, 0.59 to 1.92). I

Further evidence identified in the current review

No further studies that compared combination trauma-focused CBT and hypnosis with trauma-focused CBT alone, were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

5.2.3.4.3 Trauma focused CBT and hypnosis versus supportive psychotherapy

Previous evidence: NICE guideline evidence statements

There is limited evidence favouring trauma-focused CBT & hypnosis over supportive psychotherapy on reducing the severity of PTSD symptoms (IES - self-report) (k = 1; n = 45; SMD = -1.07; 95% CI, -1.7 to -0.44). I

There is limited evidence favouring trauma-focused CBT & hypnosis over supportive psychotherapy on reducing the severity of PTSD symptoms (IES -self-report) at follow-up (6 months) (k = 1; n = 45; SMD = -0.73; 95% CI, -1.33 to -0.12). I

There is limited evidence favouring trauma-focused CBT & hypnosis over supportive psychotherapy on reducing the severity of PTSD symptoms (CAPS2 - clinician) (k = 1; n = 45; SMD = -0.92; 95% CI, -1.54 to -0.3). I

There is limited evidence favouring trauma-focused CBT & hypnosis over supportive psychotherapy on reducing the severity of PTSD symptoms (CAPS2 - clinician) at follow-up (6 months) (k = 1; n = 45; SMD = -0.59; 95% CI, -1.19 to 0). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT & hypnosis and supportive psychotherapy on reducing depression symptoms (BDI2 – self-report) (k = 1; n = 45; SMD = -0.45; 95% CI, -1.04 to 0.15). I

The evidence is inconclusive and so it is not possible to determine if there is a clinically important difference between trauma-focused CBT & hypnosis and supportive psychotherapy on reducing depression symptoms (BDI – self-report) at follow-up (6 months) (k = 1; n = 45; SMD = -0.27; 95% CI, -0.85 to 0.32). I

There is limited evidence favouring trauma-focused CBT & hypnosis over supportive psychotherapy on reducing anxiety symptoms (BAI – self-report) (k = 1; n = 45; SMD = -0.62; 95% CI, -1.22 to -0.02). I

There is limited evidence favouring trauma-focused CBT & hypnosis over supportive psychotherapy on reducing anxiety symptoms (BAI – self-report) at follow-up (6 months) (k = 1; n = 45; SMD = -0.62; 95% CI, -1.22 to -0.02). I

There is limited evidence favouring supportive psychotherapy over trauma-focused CBT & hypnosis on reducing the likelihood of leaving treatment early (k = 1; n = 54; RR = 2.8; 95% CI, 0.64 to 12.26). I

There is limited evidence favouring supportive psychotherapy over trauma-focused CBT & hypnosis on reducing the likelihood of leaving treatment early at follow-up (6 months) (k = 1; n = 54; RR = 2.8; 95% CI, 0.64 to 12.26). I

There is evidence favouring trauma-focused CBT & hypnosis over supportive psychotherapy on reducing the likelihood of having a PTSD diagnosis (k = 1; n = 54; RR = 0.6; 95% CI, 0.3 to 1.18). I

There is evidence favouring trauma-focused CBT & hypnosis over supportive psychotherapy on reducing the likelihood of having a PTSD diagnosis at follow-up (6 months) (k = 1; n = 54; RR = 0.69; 95% CI, 0.39 to 1.19). I

Further evidence identified in the current review

No further studies that compared combination trauma-focused CBT and hypnosis with supportive psychotherapy, were identified.

Current review evidence statements

As no new studies were identified, there are no current review evidence statements.

Updated evidence statements on the combined evidence from previous and current reviews

As there are no current review evidence statements, there are no updated evidence statements.

5.2.3.5 Summary of the evidence

There is a body of evidence supporting trauma – focused CBT for the treatment of acute stress disorder and acute PTSD. There appears to be little advantage in the addition of anxiety management therapy or hypnosis, although methodological issues limit the inferences that can be made about this (see section 4.1.4.5). As such, in the interests of simplicity, these guidelines support the NICE recommendations and those outlined in the previous section that the practitioners consider the application of trauma focused CBT for the treatment of ASD and acute PTSD. Currently no studies

have been identified that examine combination pharmacological interventions or combination pharmacological and psychological interventions for ASD.

5.2.3.6 Recommendations

5.2.3.6.1 Trauma-focused CBT should be used for the treatment of ASD and acute PTSD. (A)

6 Economic considerations

A search of economic databases (ECONLIT, National Health Service Economic Evaluation database and Health Economic Evaluations Database (HEED).was undertaken to identify studies that reported an economic evaluation of treatments for ASD and PTSD.. Key search terms included: economic, cost, resource, economic evaluation, cost-benefit, cost-utility, cost-effectiveness.

6.1 Summary of literature collected

Twelve records were retrieved of which five were considered potentially useful. The excluded studies and reason for exclusion are listed in Appendix H.

Issakidis et al (2004) conducted a cost-effectiveness study that aimed to identify the averted burden and economic efficiency of current and optimal treatment for the major mental disorders. Outcome was calculated as averted 'years lived with disability' (YLD), with direct health care costs were calculated in Australian dollars for the year 1997-98. The cost per YLD averted (efficiency) was calculated for those already in contact with the health system for a mental health problem (current care) and for a hypothetical optimal care package of evidence-based treatment for this same group. Current coverage was around 40% for most disorders with the exception of social phobia at 21%. Receipt of interventions consistent with evidence-based care ranged from 32% of those in contact with services for social phobia to 64% for posttraumatic stress disorder. In terms of direct treatment costs, Issakidis found that PTSD treatment has higher per case per year costs than any of the other anxiety disorders (\$1,224 compared to \$1,188 for panic/agoraphobia, \$1,011 for social phobia and \$795 for generalised anxiety disorder). According to this study, individuals with PTSD constitute one third of people treated for an anxiety disorder, but their treatment including mental health, general health and pharmaceutical services, accounts for 40% of the total cost of treatment for all anxiety disorders. The cost of this care was estimated at \$400 million, resulting in a cost per YLD averted ranging from \$7,761 for generalised anxiety disorder to \$34 389 for panic/agoraphobia. Cost per YLD averted for PTSD was \$23,656 and \$15,728 for current and optimal treatment (cognitive behavioural therapy and/or medication) , respectively. Overall, under optimal care, costs remained similar but health gains were increased substantially, reducing the cost per YLD to < \$20 000 for all disorders. The authors conclude that evidence-based care for anxiety disorders would produce greater population health gains at a similar cost to current care, resulting in a substantial increase in the cost-effectiveness of treatment.

Chan et al (2003) aimed to determine the impact of motor vehicle accident-related psychiatric disorders on health and economic costs in quantitative terms. Using data on victims of motor vehicle accidents through the State Insurance Commission, South Australia, the authors calculated that the total health and economic cost in Australian dollars for the 391 victims was A\$6,369,519.52. Approximately 9 months after the accident, of the 391 subjects who replied to the questionnaires, 31% were identified as depressed and 62% as anxious, while 29% met criteria for PTSD. Chan concluded that PTSD cases incurred significantly higher health care costs compared with non-PTSD

cases ($p < .001$) with untreated PTSD cases incurring significantly higher economic losses compared with treated PTSD and non-PTSD cases ($p < .05$).

A US study by Walker et al (2003) examined the health care costs of a large group of women who were members of a large metropolitan health maintenance organisation (HMO). Participants were classified into 3 groups on the basis of PTSD Checklist (PCL: Weathers et al., 1993) score: low (<30), moderate (30-44) and high (>45). The cost accounting system of the HMO was used to collect data on health care costs, controlling for chronic medical illness and other forms of psychological distress. The authors estimated that total unadjusted mean annual health care costs were \$USD3,060 for the high PCL score group, \$USD1,779 for the moderate PCL score group, and \$USD1,646 for the low PCL score group. After adjusting for depression, chronic medical disease, and demographic factors, women with high PCL scores had significantly greater odds of having non-zero health care costs compared with women with low PCL scores. Compared with women in the low PCL score group, those in the moderate PCL score group had, on average, a 38% increase in adjusted total annual median costs, and those in the high PCL score group had a 104% increase. The authors suggest that instituting health services interventions to improve recognition and treatment of PTSD in primary and specialty care clinics may be a cost-effective approach for lowering the prevalence of this disorder.

Zatzick et al (2000) investigated the association between psychiatric disorders, length of stay (LOS) and cost in a large cohort of trauma inpatients in the US. The authors identified all trauma-registry recorded psychiatric diagnoses among people admitted to University of California Davis Medical Center between January 1993 and December 1996. Linear and logistic regressions were used to assess the unique effects of psychiatric diagnoses on inpatient LOS and cost. The authors estimated that 29% of participants had one or more registry-recorded psychiatric diagnosis with patients with stress disorders, delirium, and psychoses demonstrating a 46% to 103% increases in LOS and cost ($p < 0.01$). Key conclusions from this research are that people with recognised psychiatric disorders uniquely impact inpatient trauma surgery LOS and cost. Further investigations of the processes and outcomes of care could lead to cost-effective performance improvement efforts that target the amelioration of comorbid psychiatric disorders among physically injured trauma survivors.

A US study by Fontana et al (1997) compared the outcomes and costs of three models of Department of Veterans Affairs (VA) inpatient treatment for posttraumatic stress disorder (PTSD): 1) long stay specialised inpatient PTSD units, 2) short-stay specialised evaluation and brief treatment PTSD units, and 3) nonspecialised general psychiatric units. Data were drawn from 785 Vietnam veterans undergoing treatment at 10 programs across the country. The veterans were followed up at 4 month intervals for 1 year after discharge. Successful data collection averaged 66.1% across the three follow-up intervals. All models demonstrated improvement at the time of discharge, but during follow-up symptoms and social functioning rebounded toward admission levels, especially among participants who had been treated in long stay PTSD units. Veterans in the short-stay PTSD units and in the general psychiatric units showed significantly more improvement during follow-up than veterans in the long stay PTSD units. Greatest satisfaction with their programs was reported by veterans in the short-stay PTSD units. Finally, the long stay PTSD units proved to be 82.4% and 53.5% more expensive over 1 year than the short-stay PTSD units and general psychiatric

units, respectively. The authors concluded that the paucity of evidence of sustained improvement from costly long stay specialised inpatient PTSD programs and the indication of high satisfaction and sustained improvement in the far less costly short-stay specialised evaluation and brief treatment PTSD programs suggest that systematic restructuring of VA inpatient PTSD treatment could result in delivery of effective services to larger numbers of veterans.

Although one of these studies provided a cost-benefit analysis of current and optimal, evidenced-based treatment approaches for PTSD and three identified the high cost of PTSD when left untreated, no study was found that systematically outlined the economic burden of post traumatic mental health problems, either in the early stages of development or once they become long-term or chronic. There is also no overall assessment of the cost and benefit of approaches currently used to treat ASD and PTSD that fully takes into account the type and timing of the intervention and the impact of comorbidity.

6.2 Commentary on economic burden

The reviewed literature clearly outlines the high cost associated with access to healthcare and long term disability when people have PTSD symptoms. PTSD is a high burden disorder that impairs functioning in many, if not all, areas of life with consequences extending beyond the individual to impact on family members and society as a whole. To date there has been no comprehensive economic assessment of PTSD from a social perspective. Studies included in this review focus mainly on health service utilisation and there is a paucity of evidence that uses surrogate outcomes of burden including rates of hospitalisation, work impairment and a greater risk of motor vehicle accidents. Further, the lack of evidence pertaining to treatment costs makes it difficult to identify whether increased health care costs are a direct result of PTSD or are indirectly accounted for by the poor physical health commonly associated with PTSD. The importance of addressing these issues though the use of health economic techniques was comprehensively addressed by McCrone et al (2003). Health economics provides tools (including cost-effectiveness, cost-benefit, and cost-utility analyses) to ascertain the relative efficiency of different treatment options. McCrone concludes that the quality of life and resource consequences of PTSD require a better understanding of the economics of the disorder and the alternative ways to treat it. These sentiments are echoed by the authors of the costing articles identified in the preceding section. The economic burden associated with PTSD is significant, treatments are available to alleviate this burden but treatments require the use of scarce resources. In this environment of increased fiscal restraint, there is a need to identify those health care interventions, whether they are psychosocial or pharmacological, that provide the greatest benefit for the limited health dollar.

6.3 Current funding of ASD/PTSD treatment

In the Australian healthcare system, a diverse range of practitioners provides treatment services for adults with PTSD, variously funded by commonwealth and state governments as well as third party insurers and the affected individuals themselves. As a result of these diverse funding arrangements there are differences in availability of treatment between states. To date, there is no overall assessment of financing arrangements for the treatment of ASD and PTSD in Australia and the extent of unmet need for treatment is not known. In this context, it is difficult to make an assessment

of the feasibility or cost and benefit of recommendations made in these guidelines. It is worth noting for example however, that the guideline recommendation for 90 minute sessions for trauma-focused therapy has important costing implications. Currently, fee structures for GPs, psychiatrists and psychologists do not support consultation times of this length. The briefer consultation times supported by fee structures inevitably favour brief, interactions rather than the recommended trauma-focused interventions. Thus, under the current health care system, practitioners are not rewarded for providing evidence-based treatment.

6.4 Potential implications

A number of implications follow from the above discussion. First, there is an urgent need for a comprehensive assessment of the economic burden associated with PTSD. Such research would provide the platform for identifying, measuring and valuing the private and social costs associated with PTSD. Second, rigorous research is required to ascertain the cost-effectiveness of different interventions identified by the systematic review and recommended as treatment options. Of particular interest would be a study that looks at each recommendation if delivered as first, second or third line treatment and is then able to identify the optimal package of cost-effective interventions. Given the impact of PTSD on morbidity and quality of life, it is particularly important that the economic evaluation uses a measure of disease burden as the outcome (i.e. DALY, QALY, YLD). Third, an assessment of current financing arrangements for treating ASD and PTSD should be conducted to ensure that adequate resources are provided. This strategy should complement the economic evaluation approach to ensure that the full spectrum of treatment options are evaluated and costed.

6.5 Recommendations

Given the scarcity of available data, the breadth of social, personal and health cost associated with ASD and PTSD and the large number of interventions assessed for the purpose of developing these guidelines, it is not possible to conduct a full evaluation of the cost-effectiveness of recommended interventions. Instead, key economic considerations and recommendations for further research are outlined.

- 6.5.1** *Conduct a comprehensive assessment of the economic burden associated with PTSD.*
- 6.5.2** *Implement economic evaluation studies along side clinical evaluations of various treatment options.*
- 6.5.3** *Review financing arrangements from the treatment of PTSD in Australia.*

Table 31: Summary of economic evaluation literature

Reference	Framework	Intervention and Comparator	Outcome Measures	Result	Comments
Issakidis et al Psychological Medicine 2004	Costs: Govt/Health System perspective 1 year time horizon No discounting as only 1 year Year 1997- 98 Study population: All those who meet criteria for the disorder and are currently in contact with health services. Study based in Australia.	Comparator: Null Intervention: Optimal care MILD PTSD: 30% Psychiatrist CBT 30% Psychologist CBT 30% GP prescribed SSRI/TCA 10% GP referred self help MOD/SEVERE PTSD: 36% psychologist CBT 13% GP SSRI/TCA 17% Psychiatrist SSRI/TCA 34% combined CBT+SSRI/TCA	Cost per YLD averted Costed using data from NSMHWB. Number of consultations measured in survey. Length not measured. Drugs not measured so uses those recommended under optimal care Health State Preference Values measured using time trade off method in a population of GP's familiar with the disorder	Cost of evidence-based optimal care for PTSD: Current total \$158.2M Optimal total \$149.2M YLD averted: Current 6687 Optimal 9489 CEA Current \$24656/YLD averted Optimal \$15728/YLD averted	Optimal care package for PTSD from: Davidson 2000, Foa et al 2000 No indirect costs included Only does CEA as a package, not for individual interventions. Cannot see if initial treatment with, for e.g. CBT v's pharmacotherapy is more CE.
Chan et al J Clinical Psychiatry 2003	Study population: Victims of Motor Vehicle Accidents in South Australia November 1996-March 1999.	29% of study population were suffering PTSD.	Costs: Accounting Records on health and economic costs	Mean total costs PTSD: Health Care: \$7662 Economic: \$23254 Non-PTSD: Health Care: \$4377 Economic: \$13832	Statistically significant difference in both Health Care and economic costs between the two groups
Walker et al Archives of General Psychiatry 2003	1996- 97.1225 female members of metropolitan health		Costs assessed using HMO's automated cost accounting system, inc. inpatient	Annual health care costs High: \$3060(+/- 6381) Medium:	

	<p>maintenance organisation suffering PTSD. Classified into low, moderate and high. Using defined cut-offs, the low group is unlikely to be suffering PTSD, where as the other two groups are potential patients. US study.</p>		<p>services, outpatient services, prescription drugs and ancillary services such as laboratory use.</p>	<p>\$1779(+/- \$3008) Low: \$1646 (+/- 5156)</p>	
<p>Zatzick et al Journal of Trauma Injury, Infection and Critical Care 2000</p>	<p>Trauma-registry patients with a recorded psychiatric diagnosis Jan 1993- Dec 1996. California. Costs expressed in 1996 USD</p>		<p>Direct hospital inpatient costs from health system financial services. Variable costs – clinical salaries, supplies etc. Fixed costs – Administration, equipment depreciation etc. Non-Clinical operating costs – Medical records, billing operations etc</p>	<p>Mean cost per admission \$16,174. SD: \$32045 Median cost: \$6,340 Mean length of stay 5.8 days Most costly 10% of pts accounted for 53% of costs</p>	
<p>Fontana and Rosenheck. American Journal of Psychiatry 1997</p>	<p>Comparison of 3 models of inpatient care. Vietnam Veterans</p>	<p>1) long stay specialised inpatient PTSD units 2) short-stay specialised evaluation and</p>	<p>Health care costs from multiplying units of health service by cost. Usage from structured</p>	<p>1) \$34,211 (SD \$14,560) 2) \$12,616 (SD \$7,847)</p>	<p>Veterans were not randomised, and baseline characteristics differ between the three groups</p>

	enrolled in study from November 1991-Jan 1994. Across 10 sites in the US.	brief treatment PTSD units 3) nonspecialised general psychiatric units	interviews and national computerised workload databases. Cost from VA cost distribution report.	3) \$10,485 (SD \$6,854)	
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7 Specific populations and trauma types: issues for consideration in the application of the guidelines

This section contains broad comment on issues to be considered when applying the guideline recommendations to particular populations who develop PTSD following trauma, and to particular types of trauma. It is beyond the scope of the section to include an exhaustive list of all traumatised populations and so it is limited to populations for whom specific contextual information may assist practitioners in the sensitive application of recommended treatments.

While there are significant differences between the trauma populations identified in this section, an experience common to many is exposure to sustained and/or repeated traumatic experiences, sometimes referred to as *Type II trauma* (Terr, 1991). In many cases these sustained and/or repeated traumatic events are of human design, intended to leave the victim fearing, and feeling helpless to prevent, recurrence. Examples of Type II trauma include childhood sexual or physical abuse, domestic violence, incarceration as a prisoner of war, torture and, arguably, prolonged combat. Repeated exposure to trauma on a community and familial level, such as may be the case in the Aboriginal and Torres Strait Islander community, is also consistent with this definition. It is also worth noting that, because of the sustained nature of some these traumatic experiences, people presenting for treatment may still be facing ongoing threat and be at risk of further exposure to trauma. Emergency and defense personnel, victims of domestic violence and victims of sexual assault perpetrated in the context of their current employment or intimate and family relationships are some of the groups whose treatment may be affected by having to return to unsafe environments. In the context of such ongoing risk, the focus of interventions should be on ensuring safety, stabilisation and symptom management, rather than commencing the trauma-focused components of treatment.

As outlined in the introduction, there is a body of literature suggesting that the symptom constellation that follows Type II trauma is broader than PTSD, although not necessarily reflected merely in more extensive comorbidity with other psychological disorders (van der Kolk et al., 1996). This presentation, often referred to as Complex PTSD or Disorders of Extreme Stress, Not Otherwise Specified (DESNOS), includes features such as impulsivity, problems with emotional regulation, identity disturbance, dissociative symptoms, self-destructive behaviour, abnormalities in sexual expression, and somatic symptoms (DSM-IV: APA, 1994). Issues of deliberate self harm and suicidality are more likely to be present in this group. All of these features need to be considered in both treatment

planning (see Recommendations in Section 1.9.1) and in delivering psychological interventions (see Recommendations in Section 4.1.1.6)

The section differs from the clinical practice recommendations sections in that it is not based on systematic review of the empirical evidence. Rather, it is based on information provided by specialists in these areas. Within the section, emphasis has been placed on populations under-represented in the studies included in the systematic review. Consequently the first two sections, on Aboriginal and Torres Strait Islander peoples and refugees and asylum seekers respectively, are more comprehensive with background information provided as a context for understanding the impact of specific traumatic experiences. This material should be used in conjunction with the information about particular types of traumatic events that follows.

The special populations covered in the section are thus:

- Aboriginal and Torres Strait Islander peoples
- Refugees and asylum seekers

The categories of traumatic event covered in the section are:

- Military and emergency service
- Motor vehicle accidents
- Crime
- Sexual assault
- Natural disasters
- Terrorism

7.1 Aboriginal and Torres Strait Islander peoples

As stated in the introduction to this Special Populations section, the information provided is derived from expert opinion as to the application of the guidelines for this population. There were no studies in the systematic review that included participants reported to be Aboriginal or Torres Strait Islander peoples.

Specialised training in cultural competency and safety has been developed for practitioners working with Aboriginal and Torres Strait Islander peoples and wherever possible, Aboriginal and Torres Strait Islander peoples should be treated by practitioners with this training. However, in circumstances where this is not possible, culturally informed care for Aboriginal and Torres Strait Islander

peoples should be available within non-specialised primary and mental health care settings. The information presented here is intended to assist practitioners in these settings, in their work with Aboriginal and Torres Strait Islander peoples.

Background issues

Since white settlement in Australia Aboriginal and Torres Strait Islander peoples have suffered separation from land, family, and cultural identity. This has resulted in multiple experiences of trauma, grief, and loss which have affected people at the level of the individual, family, and community. In this process, some aspects of traditional kinship and community systems have been destroyed and in some cases formerly protective influences within those systems that functioned to buffer individuals and families from further trauma, have been lost. Thus, the legacy of historical trauma is still apparent in the increased risk and incidence of traumatic exposure amongst Aboriginal and Torres Strait Islander peoples today. In effect, family and community functioning can continue to be compromised in each subsequent generation by social and psychological problems (such as substance use), leading to a vicious cycle of deteriorating conditions, pervasive social disadvantage, and for individuals, increased risk of further victimisation and traumatic exposure, coupled with reduced psychological resilience. Notwithstanding these comments, it needs to be acknowledged that Aboriginal and Torres Strait Islander peoples have shown remarkable resilience in surviving such historical and ongoing adversity and continue to display cultural strengths today.

Impact of traumatic experience on the individual

Given this context, the notion of trauma and PTSD in Aboriginal and Torres Strait Islander peoples is inevitably complex. It is multigenerational and across all communities. Most Aboriginal and Torres Strait Islander peoples presenting with mental health problems in both urban and rural/remote locations, have multiple, severe traumatic exposure within their family, community and personally, that may include domestic violence, sexual abuse, murder, and suicide. In seeking to understand the impact of traumatic experiences on the individual, the practitioner should consider not just the nature or number of specific experiences, but the contextual factors that predispose and/or amplify the experience of and response to trauma. Traumatic experiences that are recurrent and difficult to talk about are likely to have had the most profound impact. Therefore, even when the focus is on a specific recent event (for instance a violent death), it is critical for the practitioner to explore the person's prior experience of traumatic events – particularly those that occurred in early life, such as physical and sexual abuse.

Due to the importance of extended kinship systems to Aboriginal and Torres Strait Islander peoples, a traumatic loss is likely to be felt broadly throughout the kinship group, rather than confined to the immediate nuclear family. That is, a person may have several mothers or be considered a mother to several nieces/nephews/grandchildren and if this is not recognised, the intensity of the loss may be underestimated. The impact on children of exposure to the event or

the subsequent psychological illness in the parent should always be considered. In addition, given the frequency of traumatic events in Indigenous communities, a broader approach may be required than what can be offered to an individual.

Presentation

Aboriginal and Torres Strait Islander peoples are generally very tolerant and hence when they do present to services, it is likely to be very serious even if it may not appear so on the surface, or at first contact. It is not uncommon for the individual to be in crisis at first contact with presentations of acute distress, including, interpersonal chaos, self harm and depression. Substance abuse/dependence is very often the presenting problem, with abused substances including alcohol, illicit drugs, and prescribed medications, such as analgesics. It is common to see high levels of dissociative symptoms and prominent auditory and visual phenomena that could be mistaken for psychosis. In many cases PTSD co-exists with prolonged grief/depression. While some people experience textbook PTSD symptoms, many more present with the range of additional symptoms associated with chronic and complex trauma (i.e, enduring patterns of social, psychological and behavioural difficulties, usually compounded by substance use). Further, culture-bound expressions of distress are often interpreted by non-indigenous people as anger. The complexity of these presentations can lead to a diagnosis of personality disorder, with PTSD being overlooked. Clinicians should be aware that many Aboriginal and Torres Strait Islander women and men in refuges and in prison suffer PTSD.

Assessment

Access, engagement, and trust in the therapeutic setting are complicated for Aboriginal and Torres Strait Islander peoples by a number of factors. These include the complexity of the trauma (particularly community level trauma), cultural factors and the historical legacy of mistrust of authorities. The potential for stigma and discrimination associated with mental health treatment to pose a barrier to engagement should be considered. Experiences of chronic loss mean that issues of abandonment and (the potential for) shaming may be heightened. As such, the recommendation noted in section 4.1.1.6 regarding the need to allow more time and attention to the therapeutic relationship for people who have experienced prolonged and repeated trauma would generally apply to this group.

Due to the complexity of the presenting problems for this population, PTSD is often overlooked. A culturally appropriate assessment is required for any diagnosis to be reliable. If no suitably trained practitioner is available, consultation with an Aboriginal and Torres Strait Islander mental health worker is highly recommended.

Issues of eldership, traditional law, and taboo need to be understood at least to some extent, for reliable assessment. The following general practical advice is offered:

- Gain permission from the person (and others in attendance) for interview.

- With empathy, explain purpose of questions, the timeframe of the assessment, and potential outcomes.
- Identify relationships between the person and others present and be aware of their significance.
- Check with the person whether they prefer to be interviewed with/without significant others present.
- Observe cultural norms (eg: eye contact, seating arrangements).
- Do not refer to a dead person by name.
- Do not refer to certain close relatives by name (a Torres Strait Islander male may not refer to his brother-in-law by name).
- Do not criticise an elder or other members of the extended family.
- Be aware of confiding certain personal information to a member of the opposite sex as men's and women's business are usually kept separate.
- Anxiety can be generated by interviewing someone in a confined space.
- Spiritual experiences are not necessarily hallucinations or delusions.
- Be aware of possible somatisation symptoms.
- Allow for reflection, periods of silence and any questions.
- Minimise the use of direct questions.
- Advise the person of confidentiality.

Source: Adapted from Tim Armstrong, Mental Health Project Officer for Northern Rivers Division of General Practitioners
www.medicineau.net.au/clinical/abhealth/abhealt1345.html

As noted in Recommendations for Assessment (1.8.2.1) and re-iterated above, the assessment of PTSD should not be limited to a recent traumatic event, but should take into account previous traumatic experiences. Even if the person's PTSD or presentation for treatment has been triggered by a recent event, it is often the case that a recent loss or trauma brings up unresolved past events. The potential impact of the traumatic experiences of previous generations on members of the current generation, either directly (e.g., family environments characterised by psychosocial problems, violence, impaired parenting), or indirectly (e.g., vicarious traumatisation), should be considered.

Further, given the high physical health morbidity even in young people, careful screening or review of general health status may be important, especially if pharmacological treatment is likely to be prescribed, or if there is a lack of progress in treatment. Diseases such as diabetes, renal failure, chronic infection, anaemia etc can complicate recovery from traumatic events and vice versa.

Treatment

In the review of evidence-based treatment for PTSD, no trials have investigated treatment for Aboriginal and Torres Strait Islander peoples. In the application of these treatment guidelines to Aboriginal and Torres Strait Islander peoples the practitioner is advised to consider the recommendations in combination with common sense and knowledge of traditional practices. Where available, appropriate partnerships with indigenous mental health workers should be developed. In cases where this is not possible, consultation with indigenous mental health workers or other practitioners with appropriate cultural training is recommended.

Within Aboriginal and Torres Strait Islander cultures, traditional therapies include the use of healers, rituals, and ceremonies. In working with an Aboriginal person or Torres Strait Islander with PTSD, practitioners should apply the guidelines in a culturally sensitive way, with consideration given to what combination of traditional, pharmacological, and psychological approaches to treatment will be most effective for the individual. Narrative exposure therapy has been identified as a culturally sensitive approach for Aboriginal and Torres Strait Islander peoples. The value of using cultural social processes has been demonstrated in indigenous Cambodians who escaped to the US post Vietnam and in American indigenous veterans.

In establishing treatment goals, practitioners should give consideration to a number of factors in addition to those outlined in Section 1.9.1 above. First, the magnitude of trauma in Aboriginal peoples and Torres Strait Islander families may be overwhelming to practitioners and lead them to feel powerless and be inclined to give up. Good supervision is essential and collaboration with an Aboriginal peoples or Torres Strait Islander mental health professional is preferred. Second, as noted in Section 4.1.1.6 above, with people who have suffered prolonged or repeated traumatic experiences, more preparatory work is required before trauma focused work begins. As such, unless the practitioner has the capacity to make a commitment to being available in the longer term, it is often more appropriate to address current life and behavioural problems, focusing on issues of structure and problem solving, rather than delving into a potentially long history of trauma. Third, specific cultural factors should also be considered. Issues of age, seniority, and gender impact on who should provide treatment and how the treatment should be given. If the practitioner is ignorant of, or disregards these traditions, the Aboriginal or Torres Strait Islander person may be less likely to engage effectively in treatment.

In regards to early interventions following traumatic events affecting whole communities, local and traditional Aboriginal peoples and Torres Strait Islander approaches should be identified and supported in preference to debriefing or other psychological interventions.

There are significant challenges in the application of these guidelines to Aboriginal and Torres Strait Islander peoples. In addition to the historical and current socio-political factors outlined, the pervasive and enduring social disadvantage and the prevalence and complexity of traumatic experience, geographical isolation and limited availability of appropriately trained mental health practitioners all combine to create considerable barriers to effective care for posttraumatic mental health conditions.

Recommended Reading:

Milroy, H. preface to Western Australian Aboriginal Child Health Study Vol 2

Swan, P & Raphael, (1995) Ways Forward: National Aboriginal and Torres Strait Islander Mental Health Policy. National consultancy report.

Human Rights and Equal Opportunity Commission (1997): Bringing Them Home: A guide to the findings and recommendations of the National Inquiry into the separation of Aboriginal and Torres Strait Islander Children from their Families

Working with Indigenous Australians: A Handbook for Psychologists: Pat Dudgeon, Darren Garvey, Harry Pickett. Gunada Press, Curtin Indigenous Research Centre WA 2000

7.2 Refugees and Asylum seekers

As stated in the introduction to this Special Populations section, the information provided is derived from expert opinion as to the application of the guidelines for this population. Three studies in the systematic review included participants that were refugees and asylum seekers. The limited evidence-base in the field for both direct clinical trauma work and more general psychosocial interventions thus needs to be acknowledged.

In treating refugees and asylum seekers with PTSD, the practitioner is faced with a number of complex factors over and above the individuals' traumatic experiences, including language, ethnocultural, socio-political, and community issues, as well as the persons' current clinical and psychosocial situation. It is not uncommon for practitioners to feel overwhelmed by these cultural and clinical complexities. In some cases this can lead the practitioner to being immobilised for fear of making mistakes and in other cases it can lead to practitioners ignoring the complexities completely and proceeding as though they did not exist. Either response is unlikely to result in effective treatment. The middle ground in which the practitioner is mindful of ethnocultural issues, but does not attempt to deal with them as the end in itself, is ideal. The practitioner's genuine interest and respect are the most effective tools for building trust and the positive therapeutic relationship needed to help the individual recover from their traumatic experience.

Practitioners working with refugees and asylum seekers need to be culturally skilled including having awareness of biases, awareness of values, avoidance of stereotyping, the capacity to respond to potential conflicts between traditional values and values of the dominant culture and the ability to choose the appropriate approach. Clinicians should also recognise that cultural factors interact with what are commonly termed social factors - class, education, social status, rural or urban background.

In working with refugees and asylum seekers, interpreters are often involved. Practitioners should be mindful of the following issues when working with interpreters. First, in regard to perceptions of confidentiality, in small migrant communities, interpreters are frequently educated members the community, often community leaders. People may feel that their confidentiality is compromised when they have to disclose their experiences, through known members of their own community. Secondly, when interpreters are used for specific interventions such as imaginal exposure, it is important that the interpreter understands the procedure as well as the underlying rationale and potential client responses, so that the intervention is not unintentionally compromised. Finally, practitioners should be aware of the potential negative emotional impact on interpreters of re-telling the client's traumatic experiences. In addition to the general point made in Section 2.5.5 regarding the potential for all practitioners in the field of

posttraumatic mental health to be adversely affected by the work, the possibility that the interpreter has suffered similar traumatic experiences of their own, needs to be considered.

The following section outlines a range of general issues with which practitioners working with refugees and asylum seekers in Australia should be familiar. Further information about the specific background and experience of each person is of course still required.

Background issues

There is an inevitable political context in which the traumatic experiences and subsequent treatment of refugees and asylum seekers occur. Within Australia, as well as internationally, government policy, community attitudes, and media coverage of refugee and asylum seeker issues impact the mental health and well-being of this group. The impact can be direct, creating a welcoming or hostile environment, or indirect, potentially influencing public attitudes. For asylum seekers, these factors have a direct bearing on government policies relating to detention, visa options, and fundamental rights and entitlements such as access to medical care.

The traumatic experiences of refugees need to be understood in the context of socio-political factors in the country of origin. It is helpful for the practitioner to have an understanding of these factors at both the macro level - the nature and history of the conflict and its impact on the individual, their family, and community over time – as well as at the level of the individual's experience.

There are three defining characteristics of the refugee and asylum seeker experience, common to most:

- Trauma (experienced or witnessed situations where their lives have been threatened or people have been killed);
- Loss (of family friends and relatives, possessions, livelihood, country, status, etc); and
- Deprivation (of food, water, shelter, education, and medical attention)

The frequency and nature of traumatic exposure inevitably varies, but the following experiences, designed to maximize psychic injury, are common:

- Extreme forms of violence that have been repeated and/or prolonged.

- Destruction of identity and the breakdown of families and communities, which may occur deliberately through the systematic disruption of core attachments to families, friends, and religious and cultural systems.
- Conditions of inescapability and unpredictability, maximizing the experience of helplessness.
- Loss under violent circumstances with consequences such as prolonged grief.
- Witnessing atrocities such as mass killings, children targeted for violence and death, the violation of sacred values, betrayal, and the weakness of restorative justice.
- Deliberate erosion of personal integrity - physical boundaries invaded, the right to privacy violated, basic functions of eating, sleeping closely controlled, confronted with impossible choices, such as choosing who should die or who should be left behind.

The practitioner should also be aware that once in Australia there are several stressors that can continue to impact upon the mental health of refugees, including:

- Concern about the safety of relatives and friends remaining in the country of origin when conflict is ongoing.
- Loss or separation from family and friends.
- Difficulties in tasks of settlement such as learning a new language, gaining employment, and inter-generational tensions.
- Discrimination in the host community.
- Minority status in dominant Australian culture.
- In the case of asylum seekers, environmental and policy factors such as mandatory detention and temporary protection .(see additional issues specific to this group below)

Presentation

As noted above, refugees and asylum seekers have typically been exposed to prolonged and repeated traumatic experiences. In those with PTSD, common comorbid problems include:

- Anxiety, depression, substance abuse, compulsive gambling and brief reactive psychoses.
- Interpersonal difficulties associated with mistrust, fear, anger, and withdrawal.

- High risk and maladaptive behaviours.
- Grief responses such as numbing, anger, hopelessness, and meaninglessness.
- Family conflict, family breakdown, and domestic violence.
- Physical illness.

In seeking to understand refugees and asylum seekers with PTSD, the potential existential impact of this particular type of traumatic experience needs to be recognised. For example:

- Violence and uncertainty experienced during trauma may lead to anxiety, fear, and helplessness.
- Forced impossible choices, and experiences of humiliation experienced, may lead to feelings of guilt and shame.
- Disruption of relationships, separation, and isolation may lead to grief, depression, and altered interpersonal relatedness (e.g., fear of relationships, dependency or extreme self-sufficiency).
- Shattered values of human existence resulting from trauma may lead to a loss of faith in humanity, distrust, sensitivity to injustice, and idealisation and devaluing of others.
- Anger and potentially aggressive behaviour can result from low frustration tolerance, protest about loss, reaction to injustice and betrayal, and as a defense against shame and guilt.

It is also important to recognize that individual strengths can emerge in the face of trauma.

Assessment

A framework for assessment that covers the multiple potential contributing factors to a refugee or asylum seeker’s PTSD and related problems, is critical. The following table summarizes the information that should be collected for a comprehensive assessment.

Assessment domain	Implications
Country of origin and date of arrival	This information alone alerts the assessor to: <ul style="list-style-type: none"> ▪ Region specific physical health problems ▪ Nature and duration of violence and hardship ▪ Access to health care
Visa status	Visa status is critical to understanding rights and

Language	entitlements and thereby the stresses of the client's everyday environment Check preferred language and country of origin of interpreter as some prefer that the interpreter does not come from their country
Cultural background	<ul style="list-style-type: none"> ▪ Cultural notions of causal attributions, stigma, help-seeking behaviour, and concepts of healing are important to assess, as well as familiarity with systems in Australia ▪ A cultural, ethnic or religious group is very diverse; generalizations need to be cautious. ▪ Some may wish to involve other family members in health care decision making
Extent of exposure to violence and other traumatic events	A “thumbnail” sketch is sufficient for the assessment process and provides an indication of likely physical and psychological health sequelae
Family functioning	Children and adolescents have usually been directly affected through the experience and/or witnessing of violence, disrupted schooling and ongoing loss or separation from important caregivers. Ascertaining whether children and other family members require support involves proactive and sensitive exploration
Economic circumstances including housing, employment	Potential sources of stress or strength
Legal-immigration situation re refugee determination or family sponsorship	Sponsorship issues and refugee determination processes are major sources of stress and mental health problems
Physical health screening including dental care	Considerations include: <ul style="list-style-type: none"> ▪ physical injuries or pain which are the result of torture/physical trauma ▪ somatisation of a psychological problem

As noted in recommendations for assessment in Section 2.4.2.1.1 above, a comprehensive assessment should go beyond the DSM-IV diagnosis of PTSD to include broader psychosocial factors. In refugees and asylum seekers particular attention should be paid to: indicators of family breakdown, behavioural problems, quality of daily functioning, socially disruptive, aggressive or withdrawn behaviour, and physical symptoms. In undertaking the assessment and planning treatment, the recommendations outlined in sections 4.1.1.6 and 1.9.1

respectively, for people with PTSD arising from prolonged and repeated trauma, apply. The following additional considerations are recommended for refugees and asylum seekers with PTSD:

- Trust and rapport are very important. First appointments often need to be longer and/or several appointments may be needed for a comprehensive assessment.
- Refugees need to be seen in a safe place which does not trigger traumatic memories of overly-officious, authoritarian behaviour.
- Awareness that medical settings may act as reminders of torture.
- Gender of the therapist can be especially important for survivors of sexual assault.
- Understanding that a person's hostility may be a reaction to fear and uncertainty.
- Information provision and encouraging the person to ask questions promotes a sense of control.
- Explanations of the meaning of confidentiality are helpful.
- Fear of intrusive investigative procedures.
- Factors affecting "non-compliance" are important to anticipate, such as cultural beliefs about damaging effects of investigations such as taking blood, attitudes to medication and misunderstanding of side-effects, suddenly stopping medication.

Treatment

A small number of studies suggest that culturally-adapted CBT (including exposure) may be effective for refugees with trauma-related disorders. There is a need, however, to define more clearly who needs specific psychological (specifically CBT) interventions and/or pharmacological interventions over and above the general psychosocial assistance and counselling that is given in contemporary programs provided by torture and trauma services.

Consistent with the treatment guidelines for individuals with complex PTSD outlined above in Section 4.1.1.6, it is essential that a therapeutic relationship and conditions of trust and safety are established in working with refugees and asylum seekers. In addition, the clinician should consider the following issues:

- The need for a holistic framework for treatment, which parallels the holistic framework for assessment.
- Recognising the value of different levels of intervention - individual, family, community, and important settings such as schools.

- Having regard for coping strategies that develop in response to situations of chronic violence and extensive losses - such as denial, withdrawal, and anger – and their protective value for the person.
- The critical role of guilt and shame in maintaining health problems.

In working with a refugee or asylum seeker, treatment goals need to extend beyond PTSD. Of uppermost importance for refugees and their families, is usually the rebuilding of their lives through a successful settlement process. The practitioner should facilitate opportunities for retraining, employment, recovery of status, and establishing connections. Attention also needs to be paid to physical health as the alleviation of physical health problems can be a pathway to mental health well-being.

Finally, it needs to be recognised that mental health problems in refugees are the result of systematic violation of their human rights. Restoration of faith in human beings, the right to health, the right to protection from human rights violations, and restoration of justice are part of the process of healing for refugee survivors of torture and trauma. Services which address the mental health needs of survivors must respect and reinforce the concept of human rights as expressed in various international charters and agreements (Aristotle, 1990).

Additional issues specific to asylum seekers subject to mandatory detention and temporary protection

Australia's policies of mandatory detention and temporary refugee protection have been implicated as predictors of PTSD in refugees in Australia. Steel and colleagues (2004; 2006) report extremely high incidence of PTSD in temporary visa holders and asylum seekers in detention.

The particular difficulties of working with this group of asylum seekers should be noted. Asylum seekers subject to mandatory detention or temporary protection often have difficulty engaging in therapy to address their trauma, as their traumatic experiences are, in many cases, ongoing. Most have a history of pre-migration trauma, followed by a dangerous and traumatic flight to safety and finally detention in penal-like institutions. The limitations of the temporary visas (reduced access to settlement services and welfare benefits) cause severe distress to many. Some visa conditions do not allow the visa holder to work, to access welfare support or to access a Medicare card, conditions which provoke extreme levels of anxiety.

During their time as temporary visa holders, they face further distressing events – interviews to apply for permanent protection, the frequent rejections of their application, the appeals to the Refugee Review tribunal and other courts of appeal. Many report that their intense intrusive and disturbing thoughts and nightmares are about being arrested by detention guards and returned to detention or being deported – they experience ‘flash-forwards.’ McInerney and Kaye (2006)

argue that standard diagnostic categories and individual therapy in these conditions may be inadequate to address these complexities that have such a devastating impact on asylum seekers' lives.

There are significant challenges in the application of these guidelines to Refugees and Asylum Seekers. In addition to the complexity and severity of their traumatic experience, with its potential impact on fundamental beliefs about self and others, in many cases refugees and asylum seekers face ongoing stressors of re-settlement and in some cases, ongoing trauma of detention. Asylum seekers in detention are generally in geographically remote areas with limited or no access to appropriately trained mental health practitioners. Thus, there are considerable barriers to effective care for their posttraumatic mental health needs.

Recommended Reading

Andary, L., Stolk, Y., Klimidis, S. (2003), *Assessing Mental Health Across Cultures* Australian Academic Press

Aristotle, P.(1990), A Wholistic Approach in Hosking, P.(Ed.), *Hope After Horror: Helping Survivors of Torture and Trauma*, Uniya, Sydney, 157-176

McInerney, D. and Kaye, J. (2006). Asylum Seekers, therapy and ethics. *Critical Psychology* 2006; 16: 166 – 179.

Steel, Z., Momartin, S., Bateman, C., Hafshejani, A., Silove, D., Everson, N., Roy, K., Dudley, M., Newman, L., Blick, B. and Mares, S. (2004). Psychiatric status of asylum seeker families held for a protracted period in a remote detention centre in Australia. *Aust. NZ J Public Health* 2004; 28 (6): 23 – 32.

Steel, Z., Silove, d., Brooks, R., Momartin, S., Alzuhairi, B. and Susljik, I. (2006) Impact of immigration detention and temporary protection on the mental health of refugees. *British Journal of Psychiatry* 2006: 188: 58 – 64.

Victorian Foundation for Survivors of Torture (2002) *Promoting Refugee Health: A handbook for doctors and other health care providers caring for people from refugee backgrounds*, VFST publication

Victorian Foundation for Survivors of Torture (1998) *Rebuilding Shattered Lives*, VFST publication

7.3 Military and Emergency Service Personnel

As stated in the introduction to this Special Populations section, the information provided is derived from expert opinion as to the application of the guidelines for this population. Twenty seven studies in the systematic review included participants that were military (25) or emergency service (2) personnel. This section addresses a number of the issues common to military and emergency service personnel. Additional issues specific to military veterans are outlined at the end of the section.

The nature of the exposures experienced in military and emergency service personnel is somewhat different to that in other trauma exposed populations. Their operational role entails an expectation of trauma exposure. While systems are in place within organisations to minimize the risks of injury and personnel are specifically trained to deal with threat and danger, these strategies clearly have their limitations.

Increasingly, as the armed services are involved in humanitarian and peacekeeping duties, military personnel can be exposed to situations of considerable human suffering without any immediate threat to themselves. In this regard, over the last decade, the exposures of military personnel have an increasing commonality with that of emergency service workers. As such, the issues common to both groups will be outlined first, followed by specific issues for consideration in the military veteran population.

Organisational factors

The particular challenge with these groups of people is to implement treatment as early as possible. Using the principles of secondary prevention, this minimises the development of a series of secondary patterns of adaptation that in themselves can present a significant disadvantage. The systems of care that ensure early identification, such as screening and addressing stigmatisation in the workplace are of particular importance. Recognition of the value to an organization of maintaining the skill base of highly trained officers is an important priority in encouraging a general attitudinal change within these organizations. Significant experience in dealing with these particular groups is also an important matter for clinicians because understanding the specific culture of these organizations can be central to the development of a positive therapeutic relationship with the ASD or PTSD sufferer.

Screening

Systematic screening potentially has an important role in identifying ASD or PTSD in groups of military and emergency services personnel who are either engaged in repeated high risk exposures or have had a recent deployment or major event which carries a significant risk of PTSD. However, it should be recognised that the emergence of symptoms might be delayed, pointing to the value of an annual health assessment above and beyond an initial screening process. The administration of screening questionnaires should only be seen as a guide to a more systematic diagnostic assessment by a trained clinician.

A range of psychometric instruments have been trialled in police, military and fire services for monitoring the emergence of symptoms. Given the issues about under reporting, there is some evidence that lower thresholds should be used in determining referral for a clinical assessment. Any screening process should also regularly interview a fixed proportion of people who are symptomatic to remove the stigma of referral for follow-up. Measures of an exposure and symptom questionnaires need to be flexibly applied in regards to the nature of the exposure. The PCL (described in Section 1.8.6) has a military version which addresses this challenge because it does not simply focus on exposure to a sole traumatic event. This approach should be considered with other standard measures.

Symptom presentation

The presentation of symptoms for this group tends to be somewhat different to other traumatic stress victims. The association between the trauma exposures and the workplace means PTSD often has an indirect presentation in these cases. For example, the individual's difficulties may become manifest as increasing conflict with senior personnel over a variety of operational and disciplinary issues. Furthermore, the individual may have had a prolonged period of symptomatic distress which they have attempted to minimise and deny. The general sense of camaraderie and collegial support in these organizations often assists the individual in maintaining a façade of functioning. A failed promotion or a disciplinary charge often becomes the focal point around which an individual's distress is manifest and may themselves be a consequence of the individual's increasingly disorganized behaviour. The indirect manifestation of the individual's distress can delay the appropriate assessment and diagnosis.

The clinical manifestation of an individual's distress in these situations can occur in a variety of ways, including:

- Comorbid alcohol abuse is not an uncommon presentation where the individual attempts to self medicate. The associated interpersonal and work related difficulties may lead to individuals other than the person suffering from PTSD, being aware of the difficulties prior to the sufferer.
- Interpersonal conflict with family and in particular violent outbursts is another indirect manifestation that may first be brought to the attention of welfare services from a secondary victim, such as the spouse.
- The individual may initially present with a prolonged period of numbing and increasing interpersonal insensitivity. This can be manifest as inappropriate management of junior personnel or conflict with superiors.
- An intense pattern of distress may emerge in response to a recent traumatic event. The recent event may have some particular similarity to prior exposure which played an important role in the initial disruption of the individual's reactivity to stress. Hence, the longitudinal pattern of symptoms needs to be assessed, as well as the acute disorganisation in response to recent exposures.

- Individuals who leave an organization may first present some time after their discharge. The loss of identity and support through the structure of the organisation which has provided the *raison d'être* for the individual's functioning can lead to the progressive emergence of PTSD symptoms, including increasing and distressing recollections and nightmares.

Assessment

Individuals with a work related disability are often placed in a difficult conflict about seeking assistance because this can lead to significant discrimination and disadvantage in the workplace. This is a recognised difficulty when presenting to occupational health services. This requires a high index of suspicion from the assessing clinician. It is important that supervisors who are familiar with the individual's normal disposition and capability have some awareness of the indirect manifestation of the effects of PTSD in the workplace so that appropriate referrals can occur. The health professional needs to have access to personnel records to assist in a clinical assessment.

The clinical presentation of emergency service and military personnel infrequently occurs following the initial exposure to a single traumatic incident. The more typical scenario is where the individual breaks down after repeated experiences of a variety of traumatic incidents which entail varying degrees of a sense of personal threat often combined with the witnessing of harm or death to others. The extent to which a specific incident is personalised through some identification with the event or the victim, plays an important role in modifying the resilience and vulnerability of the individual. Major terrorist incidents, disasters with multiple losses of life, and exposure to gruesome or horrific accident scenes carry a particular risk for such individuals.

The available evidence suggests that prolonged exposure or repeated intense exposures over a period of time leads to an accumulated risk. As a consequence, the recommendation regarding assessment for people exposed to prolonged or repeated trauma in Section 1.8.2.1 applies; the history obtained from military and emergency service personnel should focus on the lifetime exposure, as well as the immediate antecedent event that may have prompted the presentation for treatment.

Treatment

In general, the standard evidence based treatments apply to military and emergency service personnel. Specific consideration of the following points may be helpful:

- Treatment planning needs to take into consideration the multiplicity of traumatic exposures that military and emergency service personnel have had to deal with and the consequent multiple *triggers* or trauma reminders.

- Addressing the issues of emotional numbing can be of particular relevance to those individuals who have had a prolonged period of service where this method of adaptation may have become engrained.
- The existence of comorbid substance abuse is a frequent therapeutic challenge. Evidence suggests this should be dealt with alongside of the initial control of an individual's symptomatic distress. This approach takes account of the fact that frequent alcohol usage has been a form of self medication which the individual has used to address their difficulties.

A particular challenge when working with currently serving emergency service or military personnel is the management of exposure to further stressors in the workplace during the immediate aftermath of treatment. In general, it is important to remove the external threat and triggers to the individual's distress. A model of sensitisation and kindling is a valuable theoretical construct to inform any cognitive behavioural management.

The challenge of determining recommendations for future duties should be based on an individual's residual pattern of arousability and general adaptation. If a significant degree of triggered distress remains, it is probable that further exposures will exacerbate the individual's symptoms. In these instances, it is best to minimise the probability of such exposures and recommend alternative duties.

Additional issues specific to military and ex-military personnel

There is some evidence to suggest that military recruits have increased rates of childhood physical abuse, sexual abuse and neglect, as well as high rates of family dysfunction compared with community averages. The practitioner needs to be aware of any such pre-military history, as it is likely to influence the establishment of a therapeutic relationship as well as treatment planning.

On joining the service, military personnel are then confronted with a range of experiences that may contribute to mental health problems. Perhaps of most importance, is the unique requirement for military personnel to be prepared to kill other human beings in the course of their duties. This capacity is fostered through their training to respond to threat with aggression and to respond to orders with "instinctive obedience". For most, the preparedness to kill another person challenges their personal values and the act of doing so can have long term effects on their fundamental beliefs.

During deployment, it is not uncommon for military personnel to experience multiple traumatic events. Military deployment almost invariably involves exposure to real or threatened death and serious physical injury that can lead to PTSD. Furthermore, the nature of traumatic events experienced on deployment can challenge fundamental beliefs about the self, the world, and humanity. For example, traumatic events may involve the death of civilians and destruction of communities on a scale that is often unimaginable and for which the veteran has had little preparation. Military personnel themselves may have committed acts of violence that, with the benefit of hindsight or emotional distance

from the event, may be deemed to be atrocities – such experiences may shatter previously held beliefs about the self.

It was initially thought that peacekeepers suffered low rates of exposure to traumatic stressors, however a number of studies have indicated that peacekeeping missions may present a range of unique stressors that can have a significant psychological impact on deployed personnel. Peacekeepers are often exposed to war zone stress as well as experiencing frustrations associated with peacekeeping duties, such as restrictive rules of engagement (Litz et al., 1997). Experiences that were rated to be moderately to extremely negative in a recent study of peacekeepers deployed to Kosovo included: knowing that many of the war criminals were not arrested (73%), seeing children who were the victims of war (67%), seeing civilians in despair (58%), seeing the physical devastation (52%), knowing that there was a lack of supplies for civilians (52%).

An understanding of the psychological underpinnings of the veteran's initial presentation and a preparedness to give sufficient time to the veteran to establish a trusting relationship will be immeasurably helpful. Given the war-related nature of traumatic events experienced by many veterans, they may anticipate negative evaluation on the part of the clinician. To work effectively with military personnel, the clinician must demonstrate a willingness to listen and the capacity to tolerate the details of traumatic experiences whilst maintaining a positive regard for the individual throughout.

Most clinical treatment trials with veteran populations, both pharmacological and psychological, have shown treatment to be less effective than for non-veterans with PTSD. This may be due to characteristics of the veterans themselves (their gender, nature and duration of traumatic experiences, chronicity of PTSD, high rate of co-morbidity), the less rigorous treatment interventions generally used with this population, or potentially complicating factors relating to veterans' compensation, pensions, and other entitlements. Although the clinician may anticipate more modest outcomes, the general recommendations regarding treatment for PTSD still apply.

7.4 Motor Vehicle Accident and other injury survivors

As stated in the introduction to this Special Populations section, the information provided is derived from expert opinion as to the application of the guidelines for this population. Thirty-two studies in the systematic review included participants that were injury survivors, from motor vehicle accidents or other causes. With study participants recruited from hospital admissions, most of what we know about motor vehicle accident (MVA) and other injury survivors is based on people who have been severely injured and hospitalised, or at least admitted to a hospital emergency department. MVA survivors with less severe injuries, for example soft tissue injury, may of course also develop PTSD, and many of the issues discussed in this section are relevant to that group. The section addresses issues of PTSD in the context of physical injury and so does not include MVA survivors with PTSD who have sustained no physical injuries. The guideline recommendations can be applied to this group without need for special consideration.

Approximately 2% of all Australians every year are injured severely enough to require a hospital admission. The frequency with which severe injury occurs makes it one of the greatest causes of PTSD in Australia. MVAs are a major cause of severe injury and therefore contribute significantly to the PTSD rate in Australia. Consistent with common responses to traumatic experience noted in Section 2.1.3 above, many injury survivors will display PTSD symptoms (nightmares, intrusive memories) in the initial weeks after being injured, but for most these symptoms will resolve within three months. Approximately 10%-15% of injury survivors will go on to develop chronic PTSD.

The severity of the injury in terms of its relationship to mortality does not predict the development of PTSD. That is, those with a life threatening injury are no more likely to develop PTSD than those who suffer a serious injury that is not life threatening. The rate of PTSD in those with soft tissue injury has not been established, but if the rate of PTSD is unrelated to injury severity, it may also be in the 10-15% range. The relationship between injury severity and PTSD is, however, different with traumatic brain injury (TBI). Those with severe TBI are less likely to develop PTSD while those who suffer a mild TBI are just as likely to develop PTSD as those with no brain injury. This is probably associated with the high level of amnesia experienced by those with a severe TBI – those with no memory of the event are less likely to develop PTSD.

Common presenting problems in injury survivors include distressing memories and nightmares about the accident, insomnia, irritability, elevated startle response, and concentration problems. Individuals often avoid situations that are consistent with the event in which they were injured. For example, those injured in a MVA often experience fear of driving and avoidance of traffic. Individuals surviving assault are often avoidant of social situations especially where there may be

crowds or intoxicated people. In some cases individuals become avoidant of hospitals and fail to attend appointments, or do not have follow-up surgery. This may significantly impact their physical recovery. Practitioners should be aware that many injury survivors suffer mild TBI, and have no memory of some parts of the event in which they were injured. Interestingly, although these people may not be able to remember critical aspects of the event they can still be fearful and avoidant of situations which trigger memories of the event. Depression is very commonly comorbid with PTSD in injury survivors. This is especially the case with those who experience orthopaedic injuries which require long term rehabilitation. The loss of important roles, financial difficulties and uncertainty about the future often contributes to depression. Many injury survivors also suffer chronic pain and this pain can serve to trigger memories of the accident. This can result in individuals avoiding situations which may cause pain to escalate such as exercise or physiotherapy.

Assessment

There are three main issues pertaining to injury survivors with PTSD that need to be considered during assessment.

First, be aware of the timing of the assessment. There is strong evidence that many PTSD-type reactions that occur in the initial two months will subside in the following period. Intense reactions in this period are less likely to subside without intervention and may need immediate attention. Less severe reactions, however, which are common in this period, are more likely to be transient and resolve without treatment.

Second, injury survivors are characterized by comorbid presentations that have implications for treatment planning. As discussed, depression, mild TBI, and chronic pain are the major problems that co-exist with PTSD after severe injury. It is important to ask specifically about each of these problems to determine the primary presenting problem. Often patients will focus on pain because of its highly intrusive and aversive nature, and the clinician needs to focus interview questions specifically on PTSD or depression in order to avoid missing important information. In the case of mild TBI, it should be noted that people can meet the reexperiencing criteria for PTSD if they are distressed by reminders of the injury causing event (e.g., returning to driving) even if they cannot recall some critical aspects of the accident.

Third, many injury survivors are involved in litigation for criminal or civil purposes. This issue can complicate treatment planning because it can confound the motivational stance of the patient, especially if legal advice is suggesting a particular view about PTSD and its treatment. Assessment should explicitly enquire about litigation status.

Treatment

Injury survivors are often entitled to treatment for mental health conditions arising from their accident through individual state based authorities. This is especially the case for MVAs and work place accidents. Practitioners should be familiar with entitlements and procedures in the state in which they work.

Treating injury survivors should follow standard guidelines, with particular attention to several possible modifications that are dependent on comorbid presentations.

Chronic pain is a major obstacle to treating PTSD because it can actively interfere with attention on therapy tasks. Also, pain can act as a reminder of the trauma and complicate treatment for pain and PTSD. Depending on the severity of the pain, it may be preferable to achieve adequate pain management prior to the commencement of PTSD treatment.

Depression that is comorbid with PTSD typically leads to a more severe clinical presentation. As outlined in the guideline recommendations, suicidal ideation requires careful assessment and management prior to commencement of exposure therapy.

Patients with brain injury who are amnesic of the accident (or part of it) may benefit more from in vivo exposure to situations that elicit anxiety than imaginal exposure. This approach can be beneficial because imaginal exposure can be limited when there are few memories of the trauma and when attentional deficits interfere with focus on trauma memories for prolonged periods.

Although exposure therapy is the treatment of choice for people who develop PTSD following injury, clinicians should be aware that any therapy that actively addresses trauma memories, has the potential to alter memory, and therefore may be subjected to scrutiny in court. Some courts are particularly concerned about the use of hypnosis and EMDR as techniques that have the potential to modify trauma-related memories. Thus the use of these treatments (and potentially others – specifically?) may lead to a client’s evidence being inadmissible in court. It is advisable to avoid these treatments in cases that are subject to litigation. If such approaches are adopted, the practitioner would be advised to videotape all sessions.

7.5 Victims of Crime

As stated in the introduction to this Special Populations section, the information provided is derived from expert opinion as to the application of the guidelines for this population. Twenty seven studies in the systematic review included participants that were victims of crime.

Background

There is debate in the literature about what constitutes a victim of crime, but the following U.N. (1985) definition is widely accepted:

“persons who, individually or collectively, have suffered harm, including physical or mental injury, emotional suffering, economic loss or substantial impairment of their fundamental rights, through acts or omissions that are in violation of criminal laws operative within Member States, including those laws proscribing criminal abuse of power”

Around 30% of the Australian population report being a victim of crime (including robbery, burglary, attempted burglary, car theft, car vandalism, bicycle theft, sexual assault, theft from car, theft of personal property, assault and threats) in a given year. However, PTSD is not a potential outcome for all victims of crime. The diagnosis is applicable only in cases where the crime constituted a potentially traumatic event as defined by DSM-IV. In general terms these are crimes of an interpersonal and violent nature. A much lower, though still significant figure of 4% of the Australian population, report being a victim of personal crimes, such as robbery, sexual assault and assault with force, that are more likely to be associated with subsequent PTSD. When looking at recorded (by the police) crimes, males are more likely than females to be victims of all personal crimes, except sexual assault and abduction. For example, in 2003, just under 1% of males reported to police that they were a victim of assault and 0.15% of females reported being a victim of sexual assault or kidnapping (ABS, 2005). However because there is suspected low incidence of reporting, the true figure of victimization, particularly for sexual crimes is unknown.

The prevalence of PTSD in victims of crime is dependent upon the type of crime, the method of measurement and the definitions used. The lifetime PTSD prevalence rate for victims of crime is estimated to be about 25% - 28%, with higher rates following interpersonal crimes such as rape (e.g., 45% to 60% following rape in women). In an Australian representative sample, it was found that 5.4% of women reported experiencing a rape and 10.2% reported molestation. Of those who reported that the most traumatic event they had experienced was rape, 9.2% met criteria for PTSD in the past 12 months. Males who are raped appear to report a higher prevalence rate of PTSD.

Anecdotal reports suggest that PTSD in victims of crime is frequently erroneously diagnosed. It has been noted that the diagnosis is sometimes given based upon the type of incident leading to therapy, rather than the actual presentation, and the symptoms cited to support the diagnosis were frequently not PTSD criteria. With this in mind it has been found that victims of crime are more likely to suffer from depression rather than PTSD, with up to 13 percent of rape victims attempting suicide.

Assessment

In addition to the recommendations regarding assessment in Section 1.8.2.1 above, issues of particular relevance to victims of crime during assessment include:

- The practitioner should clarify with the person whether the interview is a forensic assessment or a therapeutic assessment.
- A full assessment of the person's functioning and impairment *before* the crime in question and an assessment of *current* functioning needs to be conducted.
- The full breadth of areas affected by the crime needs to be assessed – including reactions to both personal victimisation and property damage, subsequent family, vocational and social relationships, as well as the affective and psychological reaction of the victim.
- General interview based questions need to initiate the assessment procedure rather than the use of specific questions or structured questionnaires, which may prime the person to answer in certain ways.
- Unless conducting a forensic assessment, conclusions should be fed back to the person and explained appropriately so as to minimise later confusion should these results be called into court.
- It is essential that complete and full notes be taken during the assessment interviews and subsequent treatment sessions. Failure to do so may later prejudice the victims' rights should any court case ensue.

Treatment

An awareness of the legal system is important when treating victims of crime with PTSD. In Australia the rights and laws pertaining to victims of crime are predominantly state based rather than national and hence vary between states. However, all the states have some mechanism whereby victims of crime can claim either compensation or/and access to mental health treatment for conditions related to their victimisation. Mental health practitioners need to have knowledge of these laws and services specific to where they practice.

In addition to the recommendations regarding treatment outlined in Section 4.1.1.6, issues of particular relevance to victims of crime include:

- Due to the nature of criminal compensation some people may perceive a vested interest in maintaining symptomatology until all proceedings have completed. It is advised that the therapist address this issue with the person before initiating treatment.
- Prolonged imaginal exposure to the event, when managed by a well trained therapist, has demonstrated efficacy with victims of crime and should be administered, sensitively, as a matter of course.
- It can be difficult for new therapists to avoid being compromised in their role as an agent of change and becoming, instead, an advocate. Therapeutic outcomes are best served through objective analysis of the presenting problems and the impartial application of evidence based practice.
- Treatment sessions should be recorded, where possible, so that any accusations of tainted evidence arising during later litigation can be evaluated. Of course the rationale for recording sessions should be carefully explained to the person and their consent obtained before recording begins.

Beyond these general considerations, an individual's needs will vary depending on the nature of the crime. For example, there is domain specific knowledge related to rape victims that may be less relevant to victims of assault and practitioners should acquaint themselves with these areas before providing treatment. Secondary consultation with a counsellor from a specialist sexual assault centre in your state would be recommended. The practitioner may also consider referring the person to a specialist sexual assault centre for advocacy or assistance with court proceedings if the practitioner is not going to offer this service themselves.

7.6 Sexual Assault

As stated in the introduction to this Special Populations section, the information provided is derived from expert opinion as to the application of the guidelines for this population. Twenty four studies in the systematic review included participants that were survivors of sexual assault.

This section applies to adults with PTSD arising from sexual assault, whether that assault occurred during childhood or adulthood. As such, the nature of the traumatic event is highly variable (from repeated childhood sexual abuse to a discrete adult rape) and the posttraumatic mental health sequelae are consequently also highly variable. The guidelines are applicable to survivors of sexual assault with PTSD, with or without comorbid disorders. Of course not all survivors of sexual assault will have PTSD and therefore PTSD treatment guidelines will not be applicable to all.

Background

The mental health practitioner treating survivors of sexual assault should be aware of a number of important background issues. Sexual assault is a unique crime in that it is most often carried out in private, is shrouded in secrecy and involves a victim who often blames himself or herself. In children the majority of sexual abuse is perpetrated by a family member or person known to the child. (The media push for awareness via the concept of ‘stranger-danger’ only addressed a minority of perpetrators and victims). As a consequence, many adult survivors of child sexual abuse may still have contact with their abuser.

Sexual assault was rarely discussed in Australia until the 1970’s and childhood sexual assault was almost never disclosed. Unfortunately, when childhood sexual abuse *was* disclosed, the victim risked being accused of fantasizing, lying, seeking attention or seeking revenge. In the past 30 years survivors of sexual assault have increasingly reported the assault, but there is still considerable societal, familial and individual pressure to remain silent. People alleging sexual assault are the least likely of all crime victims to report the offence to the police. Further, of those reported, only a small proportion are prosecuted - one in six rapes and less than one in seven reports of incest/sexual penetration of a child. These conviction rates are substantially lower than rates for other offences and unfortunately there is no trend towards successful convictions over time. Convictions for rape have actually fallen since the late 1980s.

Negative stereotypes of sexual assault survivors as unworthy or undeserving continue to prevail in both the legal system and broader society. These stereotypes inevitably impact on the individual, creating additional distress beyond the traumatic experience itself.

Given the “hidden” nature of sexual assault and low reporting and conviction rates, it is perhaps not surprising that there is little reliable information on the prevalence of sexual assault or childhood sexual assault in the Australian population. Existing data is based on the Australian Institute of Criminology’s studies on sexual assault and the criminal justice system, and the Australian Bureau of Statistics Women’s Safety Survey. To-date there has been no large-scale national population survey that includes childhood violence against boys. As a result, current knowledge about childhood sexual assault on boys is dependent on reports made to statutory child protection agencies. It is estimated that the prevalence of sexual assault before the age of 18 years in the Australian community ranges between 15 -30 % for females, and between 3 -15 % for males. As adults, those at greater risk of sexual assault are female, young and single, have a prior history of sexual assault, and have existing relationships with offenders.

It is important to acknowledge the intergenerational transmission of abuse. Women abused as children may repeatedly form relationships with abusive, violent partners who may, in turn, sexually and/or physically abuse her children. Additionally, if female caregiver’s are depressed (for example) children may be receiving little protection and/or no positive parenting guidance or strategies.

Adult vs childhood sexual assault

For adults with PTSD following sexual assault, the trauma may range from a discrete adult trauma of rape to repeated sexual abuse during childhood, or a combination of both. The nature of childhood sexual abuse itself is highly variable. Sexual abuse involving penetration (digital or otherwise) as opposed to touching or fondling has been found to be the most harmful of the abuse experience/s. This is also true of sexual abuse involving degradation and violence. Not surprisingly, typical presenting problems differ according to the type and number of sexual assaults experienced. The clinician should be aware of these typical presentations (outlined below) and ensure a comprehensive assessment of sexual assault especially if a prior history of assault or sexual abuse is suspected. In some cases, the individual who has been sexually abused as a child will present for treatment of PTSD for the first time as an adult.

a. Common presenting problems in survivors of adult sexual assault:

- Recurrent daytime memories/flashbacks and distressing dreams.
- Intrusive physical symptoms such as palpitations, sweating, breathing difficulties.
- Hypervigilance – e.g. Fear of going out.
- Sleep problems.
- Eating difficulties.
- Mistrust of males/females affecting the formation of relationships.
- Loss of interest in usual activities.

b. Common presenting problems in adult survivors of childhood sexual assault:

- PTSD with prominent avoidance/numbing symptoms.
- Depression/anxiety.
- Personality Disorders (e.g. Borderline Personality Disorder).
- Attachment disorders.
- Self harming.
- Recurrent thoughts of death, suicidal behaviour.
- Drug and/or alcohol abuse.
- Substance abuse.
- Eating disorders.
- Relationship problems.
- Sexual difficulties.
- Promiscuity or acting out sexually.
- Parenting problems.
- Regular dissociative episodes.

Assessment

As noted above, many survivors of sexual assault have experienced prior assault in adulthood or as children. It can be difficult in some cases to assess whether the most recent assault is the cause of PTSD or whether it is the result of previous or repeat assault/s. Consistent with the assessment recommendation in Section 2.4.1 above, a comprehensive assessment should include a detailed lifetime history of sexual assault and psychological sequelae of any previous trauma. In addition, with survivors of childhood sexual assault it is important to gain an understanding of their family background. It is unclear whether there is a direct causal link between childhood sexual assault and adverse psychological and social outcomes. It has been suggested that the fundamental damage is to the child's developing capacities for trust, intimacy, agency and sexuality, and that many of the mental health problems of adult life associated with histories of abuse are second-order effects.

Given the societal context of sexual assault, it is essential that the practitioner accepts the person's account of their traumatic experience without seeking to investigate the authenticity of their claims. Victim/survivors have often had negative responses to their disclosures from friends, family or the criminal justice system and may anticipate disbelief and denial from the clinician.

The gender of the practitioner needs to be given due consideration in working with survivors of sexual assault. It cannot be assumed that a female or male will prefer to work with a practitioner of either the same or the opposite gender. This matter needs to be discussed and if possible, the person given the choice of therapist gender.

Treatment

Recommended treatments for PTSD outlined in Section 4.1.1.6 above, apply to survivors of sexual assault. The recommendation to allow more time for

establishing a therapeutic relationship and teaching emotional regulation skills in those with prolonged and/or repeated traumatic experiences is generally relevant to survivors of childhood sexual assault. In addition, the following specific considerations apply to sexual assault survivors with PTSD.

Given the broader legal context, practitioners working with survivors of sexual assault should have knowledge of relevant reporting, compensation and restorative justice approaches in order to provide the person with appropriate support and advice.

If the person has ongoing involvement with the criminal justice system there is a high risk of additional distress from a variety of sources, including contact with the alleged offender, cross examination and the general experience of the court system. This will inevitably impact on treatment and should be taken into consideration in treatment planning. In general terms, it would not be reasonable to postpone treatment until the end of (often lengthy) legal proceedings, but the clinician and PTSD sufferer should give careful consideration to the appropriate timing of trauma focused work in this context. In circumstances when the decision *is* made to defer treatment, the practitioner should consider referring the person to a specialist sexual assault centre for support during legal proceedings.

7.7 Natural disasters

As stated in the introduction to this Special Populations section, the information provided is derived from expert opinion as to the application of the guidelines for this population. Four studies in the systematic review included participants that were survivors of natural disaster.

Please note that this section does not provide guidelines for disaster response more broadly. The National Mental Health Disaster Response Committee has been established to inform planning, preparation, rescue and response as well as the recovery period in terms of mental health.

Disasters, by their nature, are large-scale events that impact upon significant groups within the community. There are a variety of natural and other types of disasters. Some, such as earthquakes and bushfires affect a local community and impact on a relatively well defined geographical region. Others, such as aeroplane crashes, involve individuals from many geographic regions as well as a local community where the actual accident occurred. Furthermore, these events may be brief and dramatic, such as a bushfire, or may have evolved over a much longer time frame, such as a flood or drought. The nature of exposure to trauma in disasters varies considerably according to the type of disaster and the proximity of the individual to the causal agent. Equally, the various roles that people can play in disasters means there will be a significant difference in the impact upon the primary victims, compared with the impact on secondary victims, (i.e., emergency service personnel who are required to become engaged in the search and rescue). This section includes issues for consideration by both service planners and service providers.

Issues for service planners

For natural disasters, there is some support for the utility of generic, community based low level services as preferred sources of support that underpin the identification of needs and uptake of more specialist mental health interventions. The size of the population affected by a natural disaster is critical in determining the structure of the treatment services required to deal with the aftermath. Optimally, any treatment services should be linked to the existing health services in which disaster victims have confidence prior to the event. A frequent mistake is that planners presume there will be an early need for services when in fact there tends to be low rates of uptake of services in the immediate aftermath of the disaster, with a progressive increase in need over a period of approximately two years after the event. In the aftermath of the disaster, particularly in light of the evidence about debriefing, those responsible for disaster management should attempt to limit the many volunteers who have emerged to provide “post disaster counselling” in the aftermath of such an event. These individuals and their desire to assist can at times become a major issue in terms of the logistics and

management of the large number of people converging on the disaster zone. It is important that the evidence about debriefing and acute treatments are provided to those involved in policymaking to ensure that the structure and nature of the services provide evidence based interventions.

In the acute aftermath, psychological first aid is optimally provided in conjunction with the acute welfare needs of the population. Also, a decision should be made in the early recovery phase as to whether a systematic outreach, with an emphasis on screening, is to be instigated. If such a program is to be implemented, the high risk groups should be identified and targeted. At risk groups will be those who have lost family or suffered major property destruction or sustained injury.

Disasters are an opportunity to address many longstanding deficiencies in the provision of mental health care in the affected populations. Therefore, these events are of considerable importance in ensuring that high quality evidence based care programs are put in place. They provide an opportunity for upgrading and improving the quality of clinical care for the broader population. Individuals who have been previously traumatised may first present for treatment in the aftermath of a disaster. Therefore, the skill base of the clinicians intervening with a disaster affected population should be capable of dealing with the broad range of traumatic events.

In disasters involving the loss of a large number of lives, specific consideration needs to be given to the issue of traumatic bereavement. In such instances, the sole treatment of PTSD will not address the full extent of the person's predicament. The interaction between an individual's traumatic memories and the grief process needs to be addressed. Also, in large mass casualty situations, providing basic skills and training to the surgeons, doctors and nurses involved in care can be a method of disseminating information and basic principles to a large number of people.

Media coverage of disasters provides an opportunity to use this coverage to provide information to a large number of people. Equally, it is important to have a series of information resources that can be made available to various organisations that have ongoing contact with those affected by the disaster. Such information sheets can assist in facilitating the linking of those in need with appropriate treatment services.

Issues for service providers

The immediate aftermath of a disaster involves a dramatic period where there is an attempt to mitigate the immediate physical threats and take steps to ensure the physical safety and wellbeing of the affected population. This involves the provision of emergency food and shelter and securing people's possessions if their homes have been destroyed. There is also the need to document and take stock of the losses incurred. In the immediate aftermath of these events there is a

small group of people who become acutely distressed and may develop an acute distress disorder. However, the majority of people rise to the practical demands of the situation and their psychological distress is not an immediate issue.

There is often a long window of presentation to health services following such events. There is an expectation within communities that people who have sustained significant losses will experience a degree of enduring distress. However, once there is a relative degree of normality returning within a community, the experience of distress for some individuals will remain and may even intensify. It is at such times that presentations for care often increase in frequency. In other words, once the external demands begin to decrease and the obvious causes of distress lessen, individuals begin to acknowledge the possibility that their distress is out of keeping with the reality of their circumstances and may seek care.

Psychological distress in the aftermath of disasters can emerge in the form of family dysfunction, substance abuse, and conflict within the affected community. Disasters not only trigger PTSD but a range of other possible presentations, such as adjustment disorders, somatic distress, major depressive disorder, and substance abuse.

One of the more characteristic presentations of PTSD in this setting is the considerable anxiety that the individuals will demonstrate if the threat of a similar event begins to emerge. Their triggered pattern of distress is a matter that is readily observed.

Assessment

Unless the entire infrastructure of a community is destroyed, most disaster victims prefer to utilise the care networks that they are familiar with, focusing primarily on the local general practitioners. Given the delay in help-seeking, an opportunity exists for training general practitioners in the diagnosis and assessment of PTSD and other psychiatric conditions which are likely to emerge.

Given the predictability of disorder, if the affected population can be well circumscribed, an outreach program involving screening should be considered for high-risk individuals. Such an approach should only be contemplated if the appropriate clinical services are in place to provide care to those who are identified. Standard diagnostic tools such as the PCL and the CAPS, described in Section 1.8.6, are appropriate for use in this setting.

The assessments conducted in these populations should consider the fact that there will be a background pool of psychiatric morbidity within the affected community. The challenge is to define those individuals who have had an exacerbation or modification of existing symptom patterns, as opposed to the emergence of a new condition. This is relevant to the provision of treatment.

Treatment

As noted above, various forms of psychological distress are seen in survivors of natural disasters and there is likely to be a wide range of clinical needs. For those who develop ASD and/or PTSD, the recommended treatments generally apply. There are however, a number of specific challenges, which include:

- Large numbers of people potentially requiring access to treatment over a prolonged period of time. It is important that evidence based treatments for PTSD are available to these affected communities. This is a particular challenge in rural and remote communities where there is often a paucity of appropriately trained practitioners.
- Multiple members of the same family may be suffering simultaneously, possibly impacting upon the pattern of symptomatic distress, for example, if both a husband and wife are suffering. Treatment may need to address these relationship dimensions because they can serve to influence the patterns of withdrawal and avoidance.
- In cases where the individual with PTSD has suffered economic and social disadvantage as a result of the disaster, the circumstances in which they find themselves can serve as a constant reminder of their traumatic experience and thus complicate the treatment.

Recommended Reading

J. Clin. Psychiatry. 2006: 67 Suppl on Tsunami

Drabek, T. E., (1986). Human System Responses to Disaster: An inventory of sociological findings. New York, Springer-Verlag.

Kaniasty, K. & Norris, F., (1999). The experience of disaster: Individuals and communities sharing trauma. In R. Gist & B. Lubin (Eds) Response to Disaster: Psychosocial, community, and ecological approaches. Ann Arbor, Brunner/Mazel

7.8 Terrorism

As stated in the introduction to this Special Populations section, the information provided is derived from expert opinion as to the application of the guidelines for this population. No studies in the systematic review included participants that were reported to be survivors of acts of terrorism.

Please note that this section does not provide guidelines for disaster response more broadly. The National Mental Health Disaster Response Committee has been established to inform planning, preparation, rescue and response as well as the recovery period in terms of mental health.

There have been several attempts to develop precise working definitions of terrorism. The United Nations has proposed a short legal definition: “[*an act of terrorism is] the peacetime equivalent of a war crime*”. More precise definitions of terrorism tend to be relative, because judgments about acts of political violence are often subjective. For example, the United States Department of Defense defines terrorism as: “*the calculated use of unlawful violence or threat of unlawful violence to inculcate fear; intended to coerce or to intimidate governments or societies in the pursuit of goals that are generally political, religious, or ideological*”. Although more comprehensive, this definition is problematic because it relies on vague terms which are left open to interpretation (such as “unlawful violence”, “intended to coerce or intimidate”, “the pursuit of goals...”).

Terrorist acts usually involve high levels of destruction to property and, more importantly, to people. There is likely to be widespread threat to life and actual loss of life. There may well be exposure to grotesque sights for those involved, including the death and suffering of others; this may include close family members and friends. Difficulty (or inability) in helping others in the aftermath of the attack may precipitate feelings of helplessness and guilt.

The fear generated by terrorist attacks is unsurprising; they are characterised by many features typical of high severity traumatic events. Terrorist acts are generally unpredictable in terms of place, timing, and potential victims; as such, they are completely uncontrollable (at least for the general population), increasing the risk of perpetual hypervigilance. Bioterrorism carries added threat since it is so poorly understood and is, effectively, “invisible”. It is hard to be definite about whether an individual or group has been “contaminated” and, even if individuals have clearly been exposed to pathogens, the likely health effects are rarely clear.

It is important to remember that the main goal of terrorism is exactly that – to generate feelings of terror in the community. Acts of terrorism are extremely rare (particularly in Australia) and the effects of fear and hypervigilance are often well in excess of the actual damage posed by, or caused by, the terrorist act.

In short, terrorist acts are generally high magnitude traumatic events, of very rare occurrence, capable of generating widespread fear and hypervigilance.

Importantly for these guidelines, there has recently been an increase in the (perceived) threat of imminent terrorist activity. For mental health professionals, this raises questions as to the best way to prepare for such attacks and the best way to manage the mental health consequences.

Preparing for the threat of terrorism

Reactions to terrorism can be made worse by sensational media reports and by poor communication by public officials. Thus, a key role for mental health professionals is often that of working with the media and public officials to ensure that appropriate messages are disseminated. Communications to the general population should be informed by the following recommendations (adapted from Foa et al., 2005):

- Provide realistic information on the likelihood of a terrorist attack and possible impact.
- Communicate that the individual risk is quite low.
- Explain that negative health behaviours which may increase during times of stress (e.g., smoking, unhealthy eating, substance use) constitute a greater health hazard than the hazards likely to stem from terrorism.
- Emphasise that the only action required on the individual level is increased vigilance of suspicious actions, which should be reported to authorities.
- Clearly communicate the meaning of different levels of warning systems.
- When issuing a warning, specify the type of threat, the type of place threatened, and indicate specific actions to be taken.
- Make the public aware of steps being taken to prevent terrorism without inundating people with unnecessary information.
- Provide the public with follow-up information after periods of heightened alert.

Communications by the media and public officials should also include simple information about resilience and about expectations of recovery. Many simple fact sheets on resilience in the face of terrorism are available on the internet.. (See for example, www.acpmh.unimelb.edu.au; www.ncptsd.org; www.usuhs.mil/csts; www.apa.org/topics/topictrauma.html)

Responding to an attack

a) Immediate

An attack of small to moderate impact is likely to generate moderate to major psychological and behavioural reactions in the short term, and the greater the harmful impact of the attack, the greater the likely reaction. Proximity to the attack and number of attacks will influence the severity of individual reactions. There is no reason to assume that the nature of clinical reactions, when they occur, would be significantly different to those seen following other types of traumatic events.

Immediate reactions are likely to include heightened anxiety, panic attacks, sleep and substance use problems, absenteeism from work, and retaliatory reactions against minorities identified with the terrorists. Reactions are likely to subside over the medium term (days to weeks), although repeated attacks and/or widespread loss of life and/or significant damage to infrastructures may result in increased psychological and behavioural reactions.

It is important to remember that most people will recover without any mental health assistance; thus, interventions at this stage should be based around providing information and activating community support:

- Support the work of the emergency services.
- Activate and facilitate community support networks.
- Provide accurate information about the event and its consequences.
- Facilitate accurate and balanced communication by the media, schools, workplaces, etc.
- Establish information and drop-in centres to provide information, support, contacts, etc.

Although debate exists in this area, it seems reasonable to implement some kind of low key screening to facilitate identification of those individuals who are not showing the normal recovery trajectory and who are developing identifiable mental health problems. This might be done as part of a public health approach (“.....if you are experiencing several of these symptoms, we suggest you visit your local GP”) or in a more restricted manner (such as through advertising telephone numbers for trained personnel to conduct screening). The key point is that secondary prevention – early intervention for individuals with mental health problems following trauma – is demonstrably effective IF they can be identified. This approach requires that educational material is made available to general practitioners to ensure that appropriate assessment, education and advice is forthcoming.

b) Longer term

Significant longer term mental health reactions are likely to be limited to a relatively small proportion of the population. These reactions may include traumatic stress symptoms, other anxiety disorders, depression, and substance use, all of which may be associated with impaired functioning and increased distress. The on-going fear of another attack is likely to pervade all reactions to a greater or lesser extent.

With regard to interventions, there is little empirical knowledge about optimum interventions following terrorism and no available empirical knowledge about interventions following bio-terrorism. However, there is no reason to assume that interventions for those developing PTSD and related conditions following terrorism should be any different to those recommended for other trauma survivors. Thus, decisions regarding interventions with populations who have undergone a terrorist attack should be driven by the recommendations in the remainder of these guidelines.

Notes:

1. Parts of the first paragraph were adapted from <http://en.wikipedia.org/wiki/Terrorism>
2. The remainder of this section relied heavily on information taken from:

Recommended Reading:

Ursano, R. (Ed.). (2003). *Terrorism and disaster: Individual and community mental health interventions*. New York: Cambridge University

7.9 Addendum to the special populations section: NICE guideline recommendations for the recognition and management of PTSD in children and young people

As noted in section 1.4, the current guidelines did not include a systematic review of the literature on children. As a guide to assist clinicians, however, we include the following recommendations made by the UK National Institute for Clinical Excellence (NICE) in their Clinical Practice Guidelines for PTSD. The full NICE Guideline is available from their website at www.nice.org.uk

Recognition in primary care

For children, particularly younger children, consideration should be given to asking the child and/or the parents about sleep disturbance or significant changes in sleeping patterns. **C**

Specific recognition issues for children

Children, particularly those aged under 8 years, may not complain directly of PTSD symptoms, such as re-experiencing or avoidance. Instead children may complain of sleeping problems. It is therefore vital that all opportunities for identifying PTSD in children should be taken. Questioning the children as well as parents or guardians will also improve the recognition of PTSD. PTSD is common (up to 30%) in children following attendance at emergency departments for a traumatic injury. Emergency department staff should inform parents or guardians of the risk of their child developing PTSD following emergency attendance for a traumatic injury and advise them on what action to take if symptoms develop.

- When assessing a child or young person for PTSD, healthcare professionals should ensure that they separately and directly question the child or young person about the presence of PTSD symptoms. They should not rely solely on information from the parent or guardian in any assessment. **GPP**
- When a child who has been involved in a traumatic event is treated in an emergency department, emergency staff should inform the parents or guardians of the possibility of the development of PTSD, briefly describe the possible symptoms (for example, sleep disturbance, nightmares, difficulty concentrating and irritability) and suggest that they contact their GP if the symptoms persist beyond 1 month. **GPP**

Early intervention

The treatments for children with PTSD are less developed but emerging evidence provides an indication for effective interventions.

- Trauma-focused cognitive behavioural therapy should be offered to older children with severe post-traumatic symptoms or with severe PTSD in the first month after the traumatic event. **C¹**

PTSD where symptoms have been present for more than 3 months after a trauma

- Children and young people with PTSD, including those who have been sexually abused, should be offered a course of trauma-focused cognitive behavioural therapy adapted appropriately to suit their age, circumstances and level of development. **B**
- The duration of trauma-focused psychological treatment for children and young people with chronic PTSD should normally be 8–12 sessions when the PTSD results from a single event. When the trauma is discussed in the treatment session, longer sessions than usual are usually necessary (for example, 90 minutes). Treatment should be regular and continuous (usually at least once a week) and should be delivered by the same person. **C**
- Drug treatments should not be routinely prescribed for children and young people with PTSD. **C**
- Where appropriate, families should be involved in the treatment of PTSD in children and young people. However, treatment programmes for PTSD in children and young people that consist of parental involvement alone are unlikely to be of any benefit for PTSD symptoms. **C**
- When considering treatments for PTSD, parents and, where appropriate, children and young people should be informed that, apart from trauma-focused psychological interventions, there is at present no good evidence for the efficacy of widely-used forms of treatment of PTSD such as play therapy, art therapy or family therapy. **C**

Appendix A Guideline Working Party Members

Chair	A/Prof David Forbes
Trauma Experts:	Prof Richard Bryant Prof Mark Creamer Prof Grant Devilly Prof Alexander McFarlane
Psychosocial Rehabilitation Expert:	Dr Lynda Matthews
Health Economist:	A/Prof Chris Doran
Project Manager:	Ms Andrea Phelps

Appendix B Multidisciplinary panel members

Chair	Prof Beverly Raphael
Psychology APS Trauma Specialist Generalist	Mr David Stokes Dr Rob Gordon Ms Anne Arnott
Social Work AASW Trauma Specialist	Ms Elizabeth Sommerville Ms Carolyn Worth
Psychiatry RANZCP Trauma Specialist Refugee trauma specialist	Dr David Barton A/Prof David Crompton Professor Derrick Silove
Mental Health Nursing ANZCMHN Generalist	Ms Julie Sharrock Ms Brenda Happell
General Practice RACGP Rural & Remote	Dr Ian Wilson Dr Alex Tahmindjis
Indigenous Mental Health	Prof Helen Milroy
Occupational Therapy AAOT	Ms Bronwen Browning
Consumer Representatives	Ms Charlene Micallef Mr Brian McKenzie
MHCA nomination	Ms Vivian Jarrett

Appendix C Expert panel members

Aboriginal and Torres Strait Islander Peoples

Panel Convenor: Helen Milroy

Panel Members: Tom Brideson
Anne Harrison
Ernest Hunter
Joylene Koolmatrie
Beverley Raphael

Refugees and Asylum Seekers

Panel Convenor: Derrick Silove

Panel Members: Mariano Coello
Ida Kaplan
Harry Minas

Appendix D Adelaide Health Technology Assessment Reviewers

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Emma Steggles, BAppSc (Bio, Env and Park Management)

Admin Officer, Adelaide Health Technology Assessment, Department of Public Health, University of Adelaide, Adelaide, SA 5005

Tracy Merlin BA (Hons), MPH

Manager, Adelaide Health Technology Assessment, Department of Public Health, University of Adelaide, Adelaide, SA 5005

Janet Hiller MPH, PhD

Professor of Public Health and Director, Adelaide Health Technology Assessment, Department of Public Health, University of Adelaide, Adelaide, SA 5005

Appendix E ACPMH Project Support Team

Isla Carboon (Research Assistant)
Jessica Carty (Research Assistant)
Joanne Cesario (Administration)
John Cooper (Clinical Specialist)
Anne-Laure Couineau (Clinical Specialist)
Jacinta Cubis (Communications)
Konstancja Densley (Research Assistant)
Tarni Jennings (Research Assistant)
Terry Lewis (Administration)
Meaghan O'Donnell (Senior Research Fellow)
John Pead (Clinical Specialist)
Richard Todd (I.T.)

Appendix E Process Report

In August 2003 ACPMH submitted a proposal to develop treatment guidelines for ASD and PTSD to the NH&MRC. The proposal was accepted and the guidelines were registered on October 2, 2003. An initial meeting with NH&MRC to discuss the guideline development process was held in February 2004. Dr Adele Weston was appointed by the NH&MRC as the Guideline Assessment Registrar (GAR) consultant to the project. Terms of reference for the project were drafted. These included an organisational structure comprising Steering Group, Working Party and Multidisciplinary Panel, that satisfied NH&MRC requirements for broad input into the development of guidelines.

In early 2004, ACPMH approached a number of key trauma experts from throughout Australia and invited them to join the Working Group for the Guideline development. Those approached were Professors Richard Bryant, Mark Creamer, Grant Devilly, Alexander McFarlane and Derrick Silove. With the exception of Professor Derrick Silove, all accepted the invitation. Professor Silove was unable to make the necessary time commitment but accepted an invitation to be on the Multidisciplinary Panel as expert in refugee issues. Professor Lynda Mathews was invited and accepted to join the Working Party in view of her expertise in psychosocial rehabilitation and interest in PTSD. Associate Professor Chris Doran was invited and accepted the position of consultant to the Working Party on health economics.

As a key trauma expert with prior experience in guideline development, Professor Beverley Raphael was invited to join Professor Mark Creamer Director of ACPMH, on the Steering Group for the project. Professor Raphael also agreed to chair the Multidisciplinary Panel.

The composition of the multidisciplinary panel was based on inclusion of representatives of the broad range of individuals and groups who would ultimately use and/or benefit from the guidelines. Before approaching potential panel members, a briefing document that outlined the project, the role of the multidisciplinary panel and anticipated time commitment was developed. All of the professional associations potentially involved in the care of people with PTSD were asked to nominate a representative. These associations were: The Royal College of General Practitioners, The Royal College of Psychiatrists, the Royal College of Mental Health Nurses, The Australian Psychological Society, The Australian Association of Social Work and The Australian Association of Occupational Therapists. Representatives from each of the associations were made available. In addition, a number of specialist and generalist practitioners from the professional groups were invited to participate. Nominations were received from members of the working party and in some cases, the professional associations. MDP members to represent the issues of rural and remote general practitioners, Aboriginal and Torres Strait Islander people and Refugees were specifically nominated. In addition to these health practitioners, three consumer representatives were invited to join the multidisciplinary panel. Two of these represented specific trauma groups (veterans and

sexual assault survivors) while the third was a consumer with experience in guideline development, recruited through the Mental Health Council of Australia. Through consultation with this body, appropriate remuneration for consumer representatives was established. The final composition of the multidisciplinary panel was 17.

Once the panel was established the list of names and bodies represented were sent to the chair of the MDP and GAR consultant for approval.

ACPMH approached international colleagues involved in the development of the NICE and VA/DoD PTSD guidelines (U.K. and U.S. respectively) to seek access to the systematic reviews used in their guideline development. These were forthcoming in both cases. The NICE and VA/DoD guidelines were then forwarded to the GAR consultant to consider their suitability as the foundation upon which to build the Australian guidelines. Both guidelines were approved by the GAR consultant for this purpose.

ACPMH and the working party then reviewed the NICE and VA/DoD guidelines to determine which areas of research were relevant for the Australian guideline and would therefore be updated, and to identify any gaps for which additional research questions would be required. Research questions for the Australian guideline were then drafted including PICO's as specified by NH&MRC.

A meeting of the working party in December 2004 finalised the draft research questions and terms of reference. These were then forwarded to the GAR consultant and chair of the MDP for review and comment. Further modification to the questions as the PICO specifications were made following feedback from the Chair of the MDP and the GAR consultant. Following their approval, in February 2005 the research questions and terms of reference were circulated to the multidisciplinary panel for comment. A comprehensive report documenting all of the MDP feedback and WP responses was compiled and sent to the chair of the MDP in May 2005. The chair of the MDP identified a number of issues arising from the MDP feedback that warranted further consideration, the most substantial of which was the need to adequately address issues of specific populations such as Aboriginal and Torres Strait Islander people.

The working party decided to convene expert panels for Aboriginal and Torres Strait Islanders and Refugees and Asylum Seekers, to establish expert consensus on the application of the Guidelines to these people. A Delphi process was deemed to be the appropriate methodology and approved by the GAR consultant. A decision was also made to include advice for clinicians on the application of the guidelines for particular trauma types in a Specific Populations section of the guideline.

A second report documenting the MDP feedback and WP responses that included the feedback of the Chair of the MDP, was sent to the Chair in June 2005, together with the updated research questions and terms of reference modified on the basis of the consultation. The chair approved the working party's response to the MDP feedback and revised Research Questions and Terms of Reference. These documents were then forwarded to the GAR consultant for approval of the consultation process and outcomes. This approval was forthcoming and in July 2005 the final report of the stage 1

consultation and modified terms of reference and research questions were circulated to MDP members. The terms of reference are attached as Appendix D1.

In April 2005 ACPMH sought recommendations from the GAR consultant for organisations equipped to undertake the systematic review. Two recommendations were received, from Monash Institute of Health Services Research (MIHSR) and Adelaide Health Technology Assessment (AHTA). A briefing document for the systematic review was developed and sent to the GAR consultant for approval in May 2006. Invitations were sent to MIHSR and AHTA to tender for the research in June. Detailed quotes were received from both in July 2006 and AHTA was the successful applicant.

AHTA developed a protocol for undertaking the systematic review and in September 2005 the Working Party met with AHTA and the GAR consultant to review the protocol and finalise the research questions. The working party undertook to contact international trauma experts to identify any *in press* articles and forward details of same to AHTA more inclusion. This was done in October. The process report of AHTA's systematic review is included in Appendix D2.

AHTA submitted a draft report to ACPMH in November 2005. A meeting between ACPMH, the Working Party and AHTA was held in November to review the draft report in detail. At this time final decisions were also made about the subsections to be included in the Specific Populations section of the report and the person/s designated to write each section.

Expert panels for Aboriginal and Torres Strait Islander peoples and refugee populations led by the MDP representatives for those populations were formed. The following questions were circulated to the expert panels.

Specific populations: Key issues

Under the following broad headings, please note the information that any primary care or mental health practitioner should bear in mind when working with an indigenous client with PTSD and other trauma-related mental health problems. Please bear in mind that the average practitioner is likely to read no more than 2-3 pages and keep your responses as brief as possible. The interested reader will be referred to more comprehensive guides.

1. Context

- Current sociopolitical context including prevalent community issues and problems

2. Type of trauma

- Frequency and nature of traumatic exposure

3. Presentation

- Common presenting problems
- Clinical manifestations of PTSD and other trauma-related conditions

4. Issues regarding assessment

- Cultural norms and expectations
- Considerations in applying standard mental health assessment methods

5. Issues regarding treatment

- Traditional/cultural approaches
- Considerations in applying standard mental health treatment methods

6. General advice/suggestions on application of the guidelines for indigenous Australians

The responses of panel members were collated, edited and recirculated for approval. In addition to consideration of these specific populations, clinically useful information for types of trauma was also prepared. These sections were written by members of ACPMH, the Working Party and MDP according to their areas of specialty.

With information from both the systematic review of the research evidence and expert consensus on application of the guidelines to specific populations, ACPMH and WP wrote the draft guideline and submitted it to the GAR consultant for feedback in March 2006. The GAR consultant advised ACPMH and the WP to:

1. consult with the health economist and include the outcome of that consultation in the guideline document;
2. include the NH&MRC grading sheets for each recommendation in appendix; and,
3. develop a dissemination plan.

These tasks were completed and forwarded to the GAR consultant for approval. The dissemination plan is included as Appendix D3.

Concurrently, the Draft guideline was circulated to MDP and the GAR consultant in June 2006. Feedback was received throughout June and July. The Chair of the WP and ACPMH project manager met with the Chair of the MDP in July to discuss feedback in general, the Chair's feedback specifically and the MDP consultation process. A comprehensive report documenting all of the feedback and WP responses to that feedback was compiled and the draft guideline amended accordingly.

Public consultation on the draft guideline was advertised in the Australian on 15th September 2006, with a 30 day period to respond. On the same day, it was announced to the approximately 200 delegates of the annual Australian Society for Traumatic Stress Studies/ Australian Centre for Posttraumatic Mental Health Conference. Over the consultation period the guideline was available for download from the Australian Centre for Posttraumatic Health website, together with a pro forma for written submissions.

Submissions were received from the following:

1. Roger Peters, Consultant Psychologist in private practice
2. Beverley Raphael, Professor of Population Mental Health and Disasters and Director of the Centre for Disasters and Terrorism, University of Western Sydney
3. Damien McInerney, Clinical Psychologist, Migrant Health Service, Adelaide
4. Derrick Silove, Professor of Psychiatry, University of New South Wales
5. Meaghan O'Donnell, Senior Research Fellow, ACPMH and National Trauma Research Institute

The submissions and working party responses to the submissions were documented and submitted to the NHMRC independent review. This document has been included in the Process Report as Appendix D4.”

In recognition that the full version of the Guidelines is not likely to be used by the average practitioner or member of the public, two brief guides, for practitioners and the public respectively, have been developed as the main vehicles for transmitting key recommendations from the full guidelines. The practitioner guide outlines the key recommendations made in the guidelines. It aims to help practitioners identify posttraumatic mental health problems early and become aware of best practice in the field so they can refer or treat people affected by trauma appropriately. The guide for the public will help people affected by trauma, their family and carers to recognise the onset of posttraumatic mental health disorders make informed decisions about seeking help and actively participate in their treatment.

The draft practitioner and public guides will be circulated to six practitioners and consumers respectively, and their feedback discussed by telephone consultation. This will occur over November and December 2006. Following this, the content of the documents will be finalised and sent to an external design consultant.

Request for feedback on the public guide will specifically ask for responses to the following questions:

How useful would it have been when you first realised that you needed help?

How useful is it now?

How useful would it be for your family, close friends or carer?

What information was most helpful?

What information was least helpful?

Is there anything that makes it difficult to understand the content?

Do you feel there are any gaps in the information?

Where would you expect to find a copy of this guide?

Both guides will be available for download or ordered as hard copies via ACPMH's website. The companion documents will include an acknowledgement page that describes the focus testing that has been undertaken.

ACPMH made various submissions for funding to support the development of the guidelines and specifically to engage an external consultant to undertake the systematic review of the literature. In May 2005, \$100K funding from Emergency Management Australia Research & Innovation Program was secured.

Terms of Reference for the development of practice guidelines for ASD and PTSD

Section 1: Project Terms of Reference

1.1 Aim

To develop evidence-based recommendations to guide health practitioners in effectively helping adults who, following exposure to traumatic events, have developed or are at risk of developing forms of distress that are generally consistent with the criteria for Acute Stress Disorder (ASD) and Posttraumatic Stress Disorder (PTSD).

1.2 Target groups

The guidelines are intended to influence the care of all adult Australian men and women, across the full range of populations, who develop or are at risk of developing these forms of distress following traumatic events. The guidelines are intended to include the care of older adults who do not have significant age-related comorbidity

1.3 Credibility and broad influence

The guidelines will be developed according to the requirements of NH&MRC using a process and format designed to maximise support for their implementation. For mental health clinicians their influence is intended to support the implementation of the main guideline recommendations; for primary care and general health and welfare workers their influence is intended to promote awareness of the guidelines that pertain to specialist mental health interventions and to guide primary care interventions.

1.4 Limitations

The guidelines are principally limited to forms of distress consistent with the constructs of ASD and PTSD. They do not seek to address the full range of possible responses to traumatic exposure, including those known as Complex PTSD or Disorders of Extreme Stress Not Otherwise Specified (DESNOS).

The guidelines are limited to adults and do not, at this stage, include children or adolescents.

1.5 Practitioners

The guidelines are intended to be used by a range of health professionals in a way that is commensurate with their level of expertise. Thus it is intended that individual practitioners will deliver interventions within their area of expertise, and refer the client

to other appropriately qualified practitioners for interventions outside of their own expertise. There is insufficient evidence available in either the research or clinical practice literature to allow an authoritative specification of competencies required for particular interventions, and so the individual practitioner should be guided by his or her own professional code of conduct with regard to this issue.

1.6 Settings

The guidelines are targeted to intervention, support and care provided across the full range of settings including primary health care, community care, day programs, specialist outpatient, residential and inpatient settings. It will also consider implications for interventions in rural and remote settings.

1.7 Outcomes

The guidelines will identify key measures and processes for use in practice settings to monitor outcomes.

1.8 Research and competency development

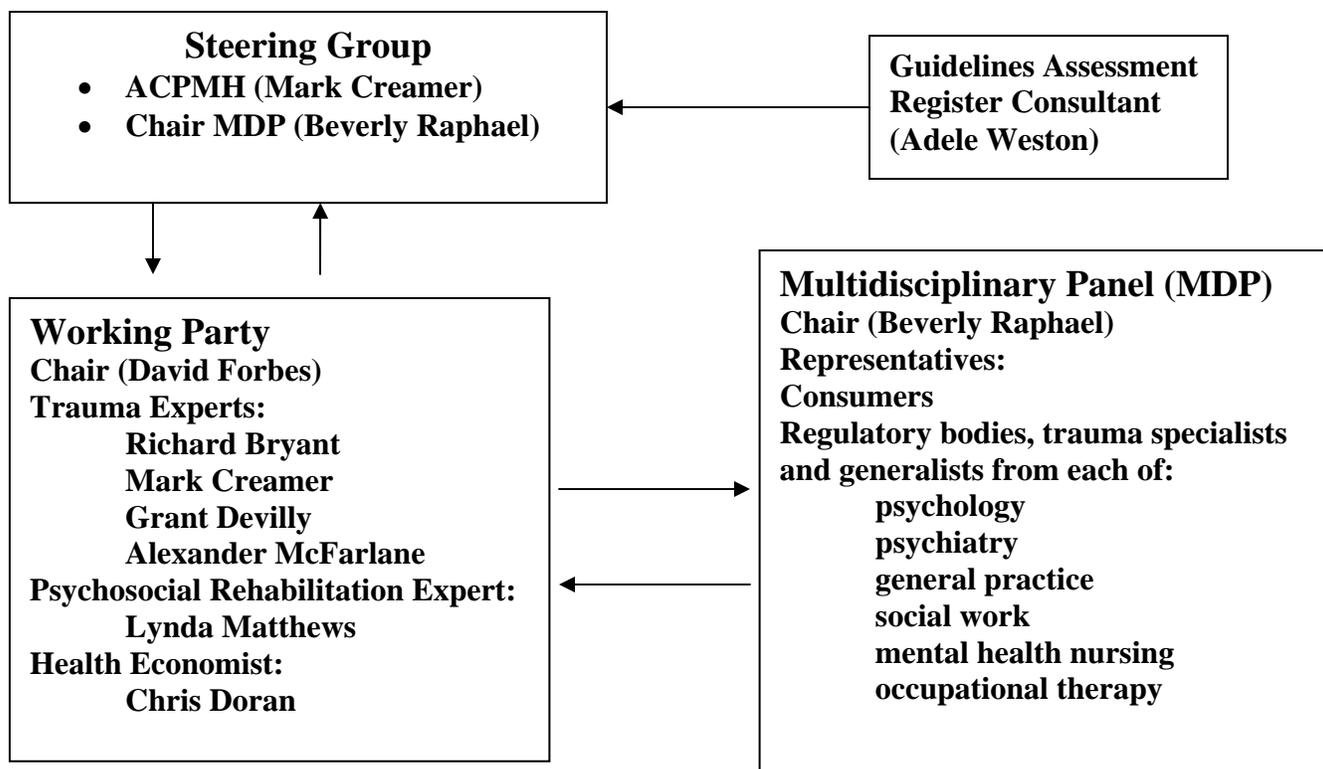
The guidelines will identify priority areas for future research and competency development required to address gaps in scientific evidence and inadequate practitioner knowledge and competency.

1.9 Future review

The guidelines will have a defined life and will be subject to review by 2010.

1.10 Organisational context

The guidelines will be developed within, and supported by, the following organisational structure.



Terms of reference for each of the Steering Group, Working Party and Multidisciplinary Panel are outlined in Sections 2, 3 and 4 below.

Section 2: Terms of Reference for the Steering Group

2.1 Steering Group Mission Statement

The Steering Group will direct and oversee the work of the Working Party, consider the advice of the Multidisciplinary Panel and have ultimate responsibility for the content and format of the Guidelines.

2.2 Problem Statement

Practitioners in the field of posttraumatic mental health operate across a diverse range of clients, trauma types and therapeutic paradigms. This diversity will be reflected in the composition of the multidisciplinary panel, creating a forum in which diverse views will be expressed and taken into consideration. Whilst representing a significant challenge, this forum importantly creates an opportunity to develop a set of treatment guidelines which are endorsed by that diverse range of practitioners, and subsequently used across settings and practitioners. The Steering Group will have a critical role in maintaining the focus on the broad objectives and having ultimate responsibility for any disputes which cannot be resolved at a lower level in the organisational structure of the Guideline Development team.

2.3 Boundaries

- The Steering Group has ultimate responsibility for the format and content of the Treatment Guidelines, and as such has the authority to make final decisions in their regard.
- Responsibility for the day to day work required in developing the Treatment Guidelines will be delegated to the Working Party.

2.4 Specific issues to be addressed

The Steering Group will approve the questions to be put to the systematic review, review the progress of MDP and WP through regular (3 monthly) reports from the Chair of both groups, review and direct modifications to drafts of the guidelines towards the end of the process and sign off on the final Guidelines.

2.5 Desired Outcomes

Each treatment guideline will accurately represent the best research evidence available, or in the absence of research evidence, expert consensus opinion. Each guideline will be written in a way that is easy to understand and implement. Overall, the guidelines will be presented in an organised and coherent manner, with appropriate linkages between items and advice to practitioners on how to use the guidelines to inform treatment planning and clinical decision making.

2.6 Persons Involved

The Steering Group will comprise Mark Creamer, ACPMH (the organisation with trauma expertise carrying responsibility for the Guideline development process) and Beverly

Raphael, Chair of the Multidisciplinary Panel (representing the range of consumers and practitioners who will use or benefit from the guidelines).

2.7 Project Administration

2.7.1 Time frames

International guidelines for the treatment of PTSD and ASD were released in November 2004 (U.S.) and February 2005 (U.K.). The Working Party now has access to the systematic reviews conducted in the development of these guidelines.

For a period of 2 months from February 2005, the systematic reviews will be examined to identify any gaps in the literature reviewed, with relevance to the scope of the Australian treatment guidelines. It is envisaged that a small number of additional questions will be generated by the Working Party, and, when endorsed by the MDP and Steering Group, submitted to a targeted systematic review.

From the end of July 2005, the Working party will oversee the targeted systematic review addressing gaps identified in existing guidelines, and at the same time begin to formulate draft treatment recommendations on the basis of the systematic reviews used in the U.S. and U.K. guidelines. Draft guidelines should be complete by the end of November 2005. Over the following six month period, in consultation with the multidisciplinary panel and key stakeholders, the content and presentation of the guidelines will be finalised. During the period November 2005 – May 2006, we envisage that the guidelines will pass back and forth between the Working Party and Multidisciplinary Panel, on 3 or 4 occasions, and be the subject of extensive consultation with key stakeholders. This consultation process will establish the infrastructure needed to support the forthcoming dissemination process.

The content of the guidelines will be finalised by the end of May 2006, and forwarded to NH&MRC. It is anticipated that dissemination will commence in June 2006.

2.7.2 Meetings

The MDP will generally communicate by telephone, email and telephone link up where necessary. Face-to-face meetings will be held only if required. Such meetings will be held in Melbourne, with travel and accommodation costs being met by ACPMH.

2.7.3 Resources

Members of the Steering Group will need to undertake work in their own time and using their own resources.

2.7.4 Reporting Guidelines

The Steering Committee will receive 3 monthly reports from the Chair of the Working Party and MDP.

2.7.5 Dispute Resolution

In the event of a dispute arising between members of the Multidisciplinary Panel or Working Party, the Chair of those respective groups will seek to resolve the dispute in the

first instance. If this is unsuccessful, the issue will be referred to the Steering Group for resolution.

In the event of a dispute arising between the MDP and Working Party, the matter will be referred to the Steering Group.

Section 3: Terms of Reference for the Working Party

3.1 Working Party Mission Statement

The Working Party will formulate guidelines for interventions for ASD and PTSD on the basis of evidence-based literature and in the absence of an evidence-base, expert consensus opinion.

3.2 Problem Statement

Significant variations in clinical practice are apparent across the range of settings and practitioners providing services to traumatised individuals. If consistency and quality of clinical practice is to be improved, practitioners must have ready access to guidelines for best practice interventions for ASD and PTSD, which are relevant and helpful in their daily clinical practice. To meet this aim, the guidelines must address the range of presenting problems associated with ASD and PTSD including common comorbid disorders, and to guide the clinician in tailoring recommended and acceptable treatments to clients.

The working party will develop the proposed Practice Guidelines for ASD and PTSD in Adults on the basis of a systematic review of the literature, building on the work previously done by U.K. National Institute for Clinical Excellence (2005), American Psychiatric Association (2004), US Veterans Affairs/Department of Defence (2003), International Society for Traumatic Stress Studies (2000) and Expert Consensus Guidelines, Journal of Clinical Psychiatry (1999).

3.3 Boundaries

- The Working Party will generate questions for the systematic review, oversee its conduct, and write treatment guidelines based on the outcome.
- Individual members of the Working Group will take responsibility for one or more questions.
- The allocation of questions to members will be made by the Chair of the Working Party, following expressions of interest and discussion with all members.
- The working group will consider feedback on the guidelines from the multidisciplinary panel.
- The Steering Group has authority to address disputes regarding content or format if they arise.

3.4 Specific issues to be addressed

Each member of the working party will be responsible for overseeing the conduct of the systematic review in relation to one or more question. Where questions are not adequately answered by review of the literature, expert opinion will be used through existing documentation or Delphi processes. When the review is complete the Working Party member will draft the treatment guideline/s in relation to that question/s and forward them to the Chair of the Working Party, who will forward them to other members of the Working Party. Each member of the Working Party will provide feedback and the individual member will consider that feedback in revising the guideline. As best as possible, consensus should be reached amongst members of the Working Party before the guidelines are forwarded to the MDP for comment. Should disagreements arise, the Chair will seek to resolve them, before referring the matter on to the Steering Group, if necessary.

Similarly, when the guidelines are circulated to members of the MDP for comment, individual members of the Working Party will be responsible for incorporating feedback into the draft guidelines where appropriate, and highlighting differences of opinion where consensus is not reached. These differences may be resolved at the level of the Steering Group, or may be documented as irreconcilable differences on the final Guideline document.

The Chair of the Working Party will be responsible for ensuring that panel members complete tasks within the time frame required and will provide a brief report to the Steering Group on a three monthly basis on the progress of the Working Party.

Should there be disagreements between the suggestions of the MDP and the WP, the WP will be responsive to the recommendations of the Steering Group. If major differences of opinion remain, consideration will be given to including a statement of dissenting views in the guidelines.

3.5 Desired Outcomes

Each treatment guideline will accurately represent the best research evidence available, or in the absence of research evidence, expert consensus opinion. Each guideline will be written in a way that is easy to understand and implement. Overall, the guidelines will be presented in an organised and coherent manner, with appropriate linkages between items and advice to practitioners on how to use the guidelines to inform treatment planning and clinical decision making.

3.6 Persons Involved

The Working Party will be chaired by ACPMH (delegated to David Forbes) and will comprise established experts in trauma research and practice from throughout Australia, an expert in psychosocial rehabilitation and a health economist.

The Chair of the Working Party will have the authority to accept or reject nominations for membership.

3.7 Project Administration

3.7.1 Time frames

International guidelines for the treatment of PTSD and ASD were released in November 2004 (U.S.) and February 2005 (U.K.). The Working Party now has access to the systematic reviews conducted in the development of these guidelines.

For a period of 2 months from February 2005, the systematic reviews will be examined to identify any gaps in the literature reviewed, with relevance to the scope of the Australian treatment guidelines. It is envisaged that a small number of additional questions will be generated by the Working Party, and, when endorsed by the MDP and Steering Group, submitted to a targeted systematic review.

From the end of July 2005, the Working party will oversee the targeted systematic review addressing gaps identified in existing guidelines, and at the same time begin to formulate draft treatment recommendations on the basis of the systematic reviews used in the U.S. and U.K. guidelines. Draft guidelines should be complete by the end of November 2005. Over the following six month period, in consultation with the multidisciplinary panel and key stakeholders, the content and presentation of the guidelines will be finalised. During the period November 2005 – May 2006, we envisage that the guidelines will pass back and forth between the Working Party and Multidisciplinary Panel, on 3 or 4 occasions, and be the subject of extensive consultation with key stakeholders. This consultation process will establish the infrastructure needed to support the forthcoming dissemination process.

The content of the guidelines will be finalised by the end of May 2006, and forwarded to NH&MRC. It is anticipated that dissemination will commence in June 2006.

3.7.2 Meetings

The Working Party will generally communicate by telephone, email and telephone link up where necessary. Face-to-face meetings may be held on 1 or 2 occasions over the 18 month period. In addition, members of the Working Party may be involved in a full day meeting with the Multidisciplinary Panel towards the end of the process. All meetings will be held in Melbourne, with travel and accommodation costs being met by ACPMH.

3.7.3 Resources

External funding has been sought to cover the cost of the systematic reviews and project coordination. Members of the Working Party however, will need to undertake work in their own time and using their own resources. With the exception of the consumer representatives, this also applies to the members of the MDP. A sitting fee will be provided to consumer representatives in line with Commonwealth Government recommendations. The cost of this will be met by ACPMH.

3.7.4 Reporting Guidelines

Members of the Working Party will report to the ACPMH delegated Chair David Forbes, who in turn will report to the Steering Group.

3.7.5 Dispute Resolution

Any difficulties or disputes which arise should be directed in the first instance to the Chair of the Working Party, who may act to resolve the difficulty or dispute, or may refer the matter on to the project Steering Group.

Section 4: Terms of reference for the Multidisciplinary Panel

4.1 Multidisciplinary Panel Mission Statement

The multidisciplinary panel will review the Guidelines in the process of their development, and provide advice to the Working Party on the Guideline relevance and utility for the target audience of service providers and recipients who will use and/or benefit from the Guidelines.

4.2 Problem Statement

The assessment and intervention for problems consistent with ASD and PTSD is undertaken by a diverse range of mental health and general health practitioners, across different trauma types and health care settings. The success of the Guidelines will be determined by the extent to which they are adopted across those diverse contexts, and ultimately the extent to which they result in improvement in the assessment and interventions for clients/patients with ASD and PTSD. The guidelines therefore need to be written and presented in a way which is accessible to a diverse range of health care professionals and is of practical value across clinical settings. To achieve this, the advice of clinicians who work across those settings is essential. Similarly, consumer involvement is important to ensure that treatment recommendations meet the needs of consumers and that the guidelines will assist consumers in making informed choices about their treatment.

4.3 Boundaries

- The multidisciplinary panel will review and offer advice on the relevance of the Terms of Reference for the project.
- The multidisciplinary panel will review and offer advice on the set of questions to be put to the systematic review for the project.
- The multidisciplinary panel will review the draft Guidelines and offer advice on the way information is presented in terms of relevance and utility to the groups they represent.
- The multidisciplinary panel will not have authority or decision making power over how that advice is used.

4.4 Specific issues to be addressed

Contact with the members of the panel is anticipated to occur in two phases. The first phase will involve members receiving by mail/email, draft terms of reference for the

project and questions to be put to the systematic review. Their task will be to read the terms of reference and review questions and provide written feedback to the Chair of the MDP on the appropriateness and comprehensiveness of these documents.

The second phase, which is anticipated to occur approximately 6 months later, will involve members receiving by mail/email copies of the draft guidelines. Members' task will be to read the recommendations and provide written feedback to the Chair of the MDP on the guidelines, in terms of:

- Ease of reading and understanding
- Usefulness as a clinical tool
- Suggestions for improvement

The panel may be asked for feedback on the guidelines as they are progressively modified, on 2 or 3 occasions over a subsequent 3 – 4 month period. Feedback will be required within 2-3 weeks on each occasion.

Towards the end of this process, the multidisciplinary panel will meet, together with the Working Party for a final review and discussion of the guidelines. The degree to which the panel have reached consensus on the presentation of the guidelines, will be documented.

4.5 Desired Outcomes

The guidelines will be written and presented in a way that the multidisciplinary representative members of the panel believe will be accepted and used by those professionals they represent, and that the consumer representative believes will benefit consumers in terms of accessibility and quality of treatment provided.

4.6 Persons Involved

The multidisciplinary panel will be chaired by Professor Beverly Raphael and will comprise representatives from each of the following:

Mental health professional associations or regulatory bodies (APS, AASW, ANZCP, RACGP, RACN), multidisciplinary trauma specialists, multidisciplinary general mental health providers and consumers.

The Chair of the panel will have the authority to accept or reject nominations for panel membership.

4.7 Project Administration

4.7.1 Time frames

International guidelines for the treatment of PTSD and ASD were released in November 2004 (U.S.) and February 2005 (U.K.). The Working Party now has access to the systematic reviews conducted in the development of these guidelines.

For a period of 2 months from February 2005, the systematic reviews will be examined to identify any gaps in the literature reviewed, with relevance to the scope of the Australian treatment guidelines. It is envisaged that a small number of additional questions will be generated by the Working Party, and, when endorsed by the MDP and Steering Group, submitted to a targeted systematic review.

From the end of July 2005, the Working party will oversee the targeted systematic review addressing gaps identified in existing guidelines, and at the same time begin to formulate draft treatment recommendations on the basis of the systematic reviews used in the U.S. and U.K. guidelines. Draft guidelines should be complete by the end of November 2005. Over the following six month period, in consultation with the multidisciplinary panel and key stakeholders, the content and presentation of the guidelines will be finalised. During the period November 2005 – May 2006, we envisage that the guidelines will pass back and forth between the Working Party and Multidisciplinary Panel, on 3 or 4 occasions, and be the subject of extensive consultation with key stakeholders. This consultation process will establish the infrastructure needed to support the forthcoming dissemination process.

The content of the guidelines will be finalised by the end of May 2006, and forwarded to NH&MRC. It is anticipated that dissemination will commence in June 2006.

4.7.2 Meetings

One face-to-face meeting will be held towards the end of this process. The meeting will be held in Melbourne and will probably take a full day. Travel and accommodation costs incurred by members of the panel will be met by ACPMH.

4.7.3 Resources

With the exception of consumer representatives, members of the multidisciplinary panel will need to undertake the work in their own time and using their own resources. A sitting fee will be provided to consumer representatives in line with Commonwealth Government recommendations. The cost of this will be met by ACPMH.

4.7.4 Reporting Guidelines

Members of the panel will report to the Chair Professor Beverly Raphael, who in turn will report to the Steering Group.

4.7.5 Dispute Resolution

Any difficulties or disputes which arise should be directed in the first instance to the Chair of the multidisciplinary panel, who may act to resolve the difficulty or dispute, or may refer the matter on to the project Steering Group.

APPENDIX E2: AHTA process report

There were nineteen research questions developed by the PTSD guidelines Working Party. Of these, eleven questions were originally addressed by the NICE or VA/DOD guidelines and so, therefore, the literature only required updating to August 2005 (the end-search date for these guidelines). One question was previously addressed by the NICE guidelines but no level II evidence was found, therefore lower levels of evidence were searched from 1966. Seven of the research questions were developed by the PTSD guidelines Working Party and therefore required a full literature search from 1966 to August 2005. One research question, regrading prognostic markers that predict response to treatment, was later excluded, leaving eighteen research questions.

The guideline developers searched for pertinent literature in various databases and sources. These are provided in Table 29, Table 30 and Table 31.

Search Strategy

Table 29 Bibliographic databases

Electronic database	Time period
Cochrane Library – including: Cochrane Database of Systematic Reviews(CDSR); Database of Abstracts of Reviews of Effects (DARE); the Cochrane Central Register of Controlled Trials (CENTRAL); the Health Technology Assessment Database (HTA); and the NHS Economic Evaluation Database (NHS EED)	1966 – 8/2005
Cumulative Index to Nursing and Allied Health Literature (CINAHL)	1982 – 8/2005
Excerpta Medica Database (Embase)	1974 – 8/2005
Pre-Medline and Medline	1966 – 8/2005
PsycInfo	1983 – 8/2005
Dartmouth College Published International Literature on Traumatic Stress (PILOTS) catalogue	1966 – 8/2005
EconLit	
NHS Economic evaluation database	
Health economic evaluations database (HEED)	

Table 30 Other sources of evidence (1980-2005)

Electronic database	Time period
Current Controlled Trials metaRegister	http://controlled-trials.com/
Health Technology Assessment international	http://www.htai.org
International Network for Agencies for Health Technology Assessment	http://www.inahta.org/
National Library of Medicine Health Services / Technology Assessment Text	http://text.nlm.nih.gov/
UK National Research Register	http://www.update-software.com/national/
Google Scholar	http://www.scholar.google.com/
<i>Hand Searching (Journals from 2004)</i>	
PTSD Research Quarterly	Electronic access
<i>Expert Clinicians</i>	
Any information provided by expert clinicians associated with this review will be assessed as to whether it meets the inclusion criteria (including <i>In Press</i> articles)	Working Party
<i>Pearling</i>	
All included articles will have their reference lists searched for additional relevant source material	

Table 31 Specific internet sites searched for relevant literature

Health Technology Assessment/Systematic Review Sites	
AUSTRALIA	Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) http://www.surgeons.org/open/asernip-s.htm
	Health Economics Unit, Monash University http://chpe.buseco.monash.edu.au
	Centre for Clinical Effectiveness, Monash University http://www.med.monash.edu.au/healthservices/cce/evidence/
AUSTRIA	Institute of Technology Assessment / HTA unit http://www.oeaw.ac.at/ita/e1-3.htm
CANADA	Agence d’Evaluation des Technologies et des Modes d’Intervention en Santé (AETMIS) http://www.aetmis.gouv.qc.ca/fr/
	Alberta Heritage Foundation for Medical Research (AHFMR) http://www.ahfmr.ab.ca/publications.html
	Canadian Coordinating Office for Health Technology Assessment (CCHOTA) http://www.ccohta.ca/entry_e.html
	Centre for Health Economics and Policy Analysis (CHEPA), McMaster University http://www.chepa.org
	Canadian Health Economics Research Association (CHERA/ACRES) – Cabot database http://www.mycabot.ca
	Centre for Health Services and Policy Research (CHSPR), University of British Columbia http://www.chspr.ubc.ca
	Health Utilities Index (HUI) http://www.fhs.mcmaster.ca/hug/index.htm
	Institute for Clinical and Evaluative Studies (ICES) http://www.ices.on.ca
DENMARK	Danish Institute for Health Services Research (DSI) http://www.dsi.dk/engelsk.html
	Danish Institute for Health Technology Assessment (DIHTA) http://www.dihta.dk/publikationer/index_uk.asp
FINLAND	FINOHTA http://www.stakes.fi/finohta/e/
FRANCE	L’Agence Nationale d’Accréditation et d’Evaluation en Santé (ANAES) http://www.anaes.fr/

GERMANY	German Institute for Medical Documentation and Information (DIMDI) / HTA http://www.dimdi.de/en/hta/index.html
THE NETHERLANDS	Health Council of the Netherlands Gezondheidsraad http://www.gr.nl/adviezen.php
NEW ZEALAND	New Zealand Health Technology Assessment (NZHTA) http://nzhta.chmeds.ac.nz/
NORWAY	Norwegian Centre for Health Technology Assessment (SMM) http://www.oslo.sintef.no/smm/Publications/Engsmdrag/FrameSetPublications.htm
SPAIN	Agencia de Evaluación de Tecnologías Sanitarias, Instituto de Salud "Carlos III"/Health Technology Assessment Agency (AETS) http://www.isciii.es/aets/
	Catalan Agency for Health Technology Assessment (CAHTA) http://www.aatrm.net/html/en/dir393/doc7921.html
SWEDEN	Center for Medical Health Technology Assessment http://www.cmt.liu.se/English/Engstartsida.html
	Swedish Council on Technology Assessment in Health Care (SBU) http://www.sbu.se/www/index.asp
SWITZERLAND	Swiss Network on Health Technology Assessment (SNHTA) http://www.snhta.ch/
UNITED KINGDOM	Health Technology Board for Scotland http://www.htbs.org.uk/
	National Health Service Health Technology Assessment (UK) / National Coordinating Centre for Health Technology Assessment (NCCHTA) http://www.hta.nhsweb.nhs.uk/
	National Institute for Clinical Excellence (NICE) http://www.nice.org.uk
	University of York NHS Centre for Reviews and Dissemination (NHS CRD) http://www.york.ac.uk/inst/crd/
UNITED STATES	Agency for Healthcare Research and Quality (AHRQ) http://www.ahrq.gov/clinic/techix.htm
	Harvard School of Public Health – Cost-Utility Analysis Registry http://www.hsph.harvard.edu/cearegistry/
	U.S. Blue Cross/ Blue Shield Association Technology Evaluation Center (TEC) http://www.bcbs.com/tec/index.html
Specialty/Topic-specific Sites	
AUSTRALIA	Australian Psychological Society http://www.psychology.org.au
UNITED STATES	American Psychiatric Association http://www.psych.org/
GENERAL	Gateway for Post Traumatic Stress Disorder information http://www.ptsdinfo.org/
	International Society for Traumatic Stress Studies http://www.istss.org/
	National Centre for Post Traumatic Stress Disorder (NCPTSD) http://www.ncptsd.va.gov
	The Posttraumatic Stress Disorder (PTSD) Alliance http://www.ptsdalliance.org

The keywords and indexing terms utilised for searching the above databases and literature sources are provided – or similar to those provided – below. Table 32 outlines the terms developed for searching the PubMed platform.

Table 32 Search terms utilised for intervention questions for PTSD and ASD review

Area of inquiry	Search terms
All intervention searches	<p>MeSH Stress disorders, Traumatic</p> <p>Text words Posttraumatic stress disorder*; posttraumatic stress disorder*; ptsd; traumatic neurosis; acute stress disorder*; asd; critical incident stress; combat AND (neuros* OR syndrome); concentration camp syndrome</p>
Study design*	<p>MeSH Clinical trials; random allocation; single-blind method; double-blind method; epidemiological studies; intervention studies; control groups; cross-over studies; matched-pair analysis; meta-analysis; drug evaluation</p> <p>Text words Clinical trials; cross-over studies; random allocation; randomisation; randomisation; single-blind method; double-blind method; triple-blind; systematic review; cohort study; case-control; before-and-after studies; epidemiological studies; intervention studies; control groups; cross-over studies; matched-pair analysis; meta-analysis; drug evaluation</p>
Limits	English; Human

And

Psychological interventions (Questions 1-7, 15-17)	<p>MeSH Psychotherapy; cognitive therapy; behaviour therapy</p> <p>Text words Psychotherapy; (cognitive OR behaviour OR behaviour OR exposure OR hypnotic) AND (therapy OR intervention OR treatment); hypnosis; interapy; EMDR; eye movement desensitization; eye movement desensitization; counsel*; debrief*; psychodynamic; critical incident stress management; cism; tft; thought field therapy; emotional freedom techniques; eft; traumatic incident reduction; tapas acupressure; visual kinaesthetic disassociation; be set free fast</p>
Pharmacological intervention (Questions 8-11, 15-17)	<p>MeSH Psychopharmacology; drug therapy; benzodiazepines; antidepressive agents; hypnotics and sedatives</p> <p>Text words Psychopharmacology; drug therapy; pharmacolog* AND (intervention OR therapy OR treatment); pharmacother*; medication; SSRI*; benzodiazepine*; antidepressant*; hypnotic*; sympatholog*; antipsychotic*; tca</p>
Psychosocial rehabilitation (Questions 12-13, 16-17)	<p>MeSH Activities of daily living; mental health services; socioenvironmental therapy; rehabilitation, vocational</p> <p>Text words (psychosocial OR vocational) AND rehabilitation; self-care; supported housing; family skills; social skills training; case management; activities of daily living; mental health services; socioenvironmental therapy; rehabilitation, vocational</p>
Exercise therapy and Physical therapies (Question 14)	<p>MeSH Exercise movement techniques; exercise; swimming, walking, jogging, yoga Physical therapy (specialty); Physical therapy techniques; Complementary therapies; Musculoskeletal manipulations; Electroconvulsive therapy</p> <p>Text words Exercise movement techniques, exercise, swimming, walking, jogging, yoga Physical therapy (specialty); Physical therapy techniques; Complementary therapies; Musculoskeletal manipulations; massage, acupuncture, acupressure, reiki, transcranial magnetic stimulation, electroconvulsive therapy</p>

Comorbidities (Question 18*)	MeSH Comorbidity; depression; personality disorders; pain; substance-related disorders; phobic disorders; panic disorder; Text words Comorbid*; traumatic grief; depression; personality disorder*; pain; substance use; phobi*; gad; anxiety; panic; co-occurring; concurrent
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* Question 19 was renumbered question 18 after question 18 was removed

Study selection

Study selection followed the process outlined in Figure 1. Table 3 provides a breakdown of the study selection process in terms of the number of literature citations or articles retrieved and retained from each phase of the process. Any doubt concerning inclusions at Phase 4 was resolved by group consensus. The criteria for including studies to answer specific research questions are provided below.

Figure 1 Study selection process

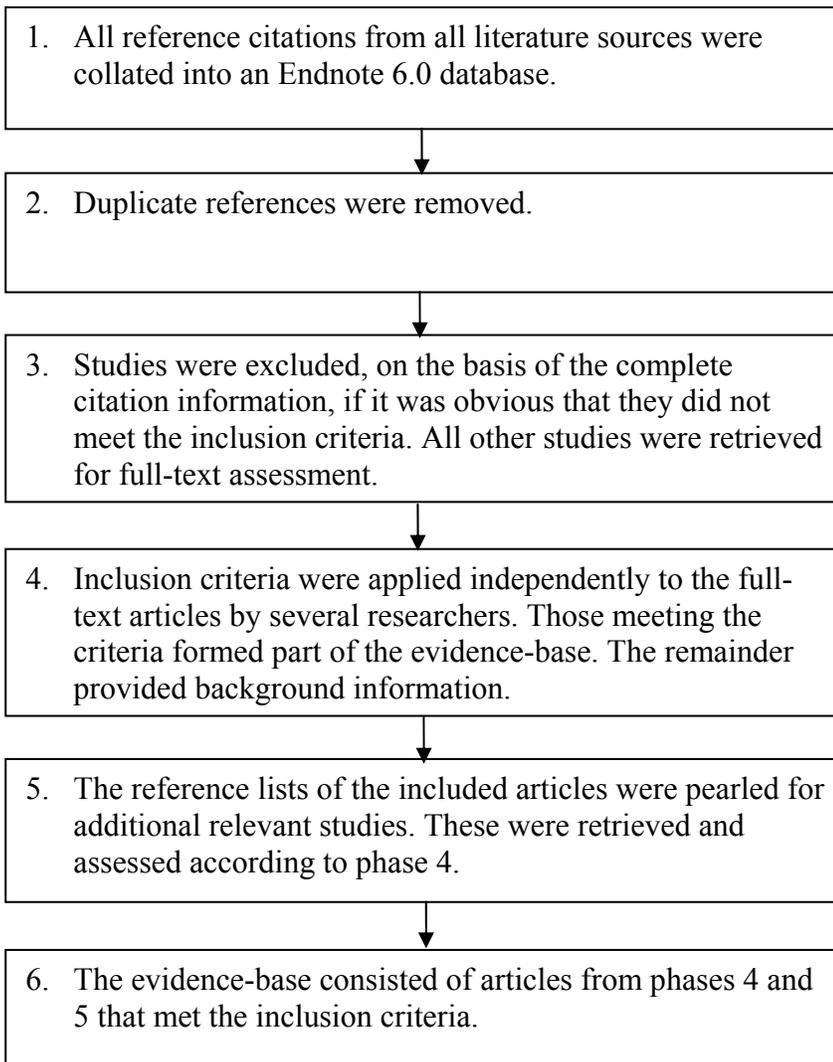


Table 33 Number of citations initially retrieved and then retained at each phase

	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5	Phase 6
Psychological	6068	5688	465 ASD 172 Q1& 2 39 Q15 98 PTSD 378 Q3& 4 69 Q5& 6 62 Q7 14 Q16 16 Q17 6			Q1 1 Q2 0 Q3 6 Q4 4 Q5 0 Q6 0 Q7 1
Pharmacological	2414		ASD PTSD			Q8 0 Q9 0 Q10 5 Q11 2
Psychosocial	3278					Q12 0 Q13 0
Physical therapies and exercise	413					Q14 0
Combined						Q15 5 Q16 6 Q17 1
Prognosis*	1051					Q18 11
Comorbidities	6199	5819	PTSD Q19 11			Q19 1
Total	19423					All 43

* not systematic and the research question was later excluded

Inclusion criteria

Studies were included for each research question if they addressed the population, therapy, comparator, outcomes, study design, search period and language delineated in Box 14 to Box 31.

In order to ensure that the selection of studies to answer specific research questions is not biased, these criteria are delineated prior to collating the literature. The type of patient Population, Intervention (treatment), Comparator (against which the treatment’s effectiveness is measured), and Outcomes of interest are made explicit – these are known as the PICO criteria and they relate directly to the research question that is being addressed. Additional limits to the literature search are also made clear ie restricting the search to studies of a certain research

design(s) (eg likely to provide unbiased or more reliable results), to a certain search period or language.

Studies were excluded from this review when they:

- did not meet the inclusion criteria;
- could not provide adequate data on the outcomes eg in graphical format, missing information, format or type of data were unable to be used;
- were updated by the same research group on the same research question for the same patients, with no different information provided;
- could not be located; or
- used an analogue for a traumatic event.

Studies were included if:

- PTSD symptoms were measured;
- the main target of the treatment was ASD or PTSD or preventing the development of these disorders;
- (for questions pertaining to PTSD) at least 70 percent of the participants had PTSD, and the remaining participants had symptoms of PTSD following a traumatic event;
- participants were over 16 years old; or
- at least 50 percent of the intent-to-treat sample were assessed at the relevant time point.

Psychological interventions

Box 14 Study selection criteria for research question 1

Research Question	
1. For adults exposed to trauma, do early psychological interventions improve outcomes compared to no intervention?	
Selection criteria	Inclusion criteria
Population	Adults exposed to trauma, including the subgroup of patients with ASD
Intervention	Early psychological intervention (eg debriefing, trauma-focused counselling, education, performed within one month of trauma)
Comparator	No intervention (eg assessment only)
Outcome	Primary outcomes: symptoms of ASD and PTSD Secondary outcomes: symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2004-8/2005*
Language	English

* Question answered by NICE systematic review with search period up until 2004 (National Institute for Clinical Excellence, 2005)

Box 15 Study selection criteria for research question 2

Research Question

2. For adults exposed to trauma, does any early psychological intervention confer any advantage over other early psychological interventions?

Selection criteria

Inclusion criteria

Population	Adults exposed to trauma, including the subgroup of patients with ASD
Intervention	Early psychological intervention (eg debriefing, trauma-focused counselling, education, performed within one month of trauma)
Comparator	Other early psychological intervention
Outcome	Primary outcomes: symptoms of ASD and PTSD Secondary outcomes: symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2004-8/2005*
Language	English

* Question answered by NICE systematic review with search period up until 2004 (National Institute for Clinical Excellence, 2005)

Box 16 Study selection criteria for research question 3

Research Question

3. For adults with PTSD do psychological interventions improve outcomes compared to no intervention?

Selection criteria

Inclusion criteria

Population	Adult patients with PTSD
Intervention	Psychological intervention (eg trauma-focused CBT, stress management therapy, EMDR, narrative exposure therapy, supportive counselling, interapy, thought field therapy)
Comparator	No intervention (eg assessment only)
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2004-8/2005*
Language	English

* Question answered by NICE systematic review with search period up until 2004 (National Institute for Clinical Excellence, 2005); CBT = cognitive behavioural therapy; EMDR = eye movement desensitization and reprocessing

Box 17 Study selection criteria for research question 4**Research Question**

4. For adults with PTSD, does any psychological intervention confer any advantage over other psychological interventions?

Selection criteria**Inclusion criteria**

Population	Adult patients with PTSD
Intervention	Psychological intervention (eg trauma-focused CBT, stress management therapy, EMDR, narrative exposure therapy, supportive counselling, interapy, thought field therapy)
Comparator	Other psychological intervention
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2004-8/2005*
Language	English

* Question answered by NICE systematic review with search period up until 2004 (National Institute for Clinical Excellence, 2005); CBT = cognitive behavioural therapy; EMDR = eye movement desensitization and reprocessing

Box 18 Study selection criteria for research question 5**Research Question**

5. Is individual therapy more effective than group therapy for PTSD?

Selection criteria**Inclusion criteria**

Population	Adult patients with PTSD
Intervention	Individual therapy (eg psychodynamic psychotherapy, individual cognitive behavioural therapies, EMDR, narrative exposure therapy, image rehearsal therapy, supportive counselling, hypnosis)
Comparator	Group therapy (eg supportive therapy, psychoeducation, psychodynamic therapy, group CBT such as anxiety management, stress inoculation, assertiveness training, prolonged exposure, cognitive restructuring)
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2002-8/2005*
Language	English

* Question answered by VA/DoD systematic review with search period up until 2002 (Department of Veterans Affairs/Department of Defence, 2004); EMDR = eye movement desensitization and reprocessing; CBT = cognitive behavioural therapy

Box 19 Study selection criteria for research question 6

Research Question

6. For adults with PTSD, is the combination of individual therapy and group therapy more effective than either alone?

Selection criteria

Inclusion criteria

Population	Adult patients with PTSD
Intervention	Individual therapy <u>and</u> group therapy (See Box 18 for examples)
Comparator	Individual therapy <u>or</u> group therapy (See Box 18 for examples)
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	1966-8/2005*
Language	English

*New review

Box 20 Study selection criteria for research question 7

Research Question

7. Are established interventions for PTSD effective when self-delivered without face-to-face practitioner support?

Selection criteria

Inclusion criteria

Population	Adult patients with PTSD
Intervention	Self-delivered psychological intervention without face-to-face practitioner support (eg web-based interapy or telephone support)
Comparator	(1) Practitioner delivered psychological intervention (2) No-treatment (eg assessment only)
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	1966-8/2005*
Language	English

* New review

Pharmacological interventions

Box 21 Study selection criteria for research question 8

Research Question

8. For adults exposed to trauma, do early pharmacological interventions improve outcomes compared to no intervention?

Selection criteria

Inclusion criteria

Population	Adults exposed to trauma, including the subgroup of patients with ASD
Intervention	Early pharmacological intervention, (eg imipramine, propranolol, benzodiazepines, other sympatholytics, other antidepressants, anticonvulsants, antipsychotics, chloral hydrate, given within one month of trauma)
Comparator	No intervention (eg assessment only)
Outcome	Primary outcomes: symptoms of ASD or PTSD Secondary outcomes: symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2004-8/2005*
Language	English

* Question answered by NICE systematic review with search period up until 2004 (National Institute for Clinical Excellence, 2005)

Box 22 Study selection criteria for research question 9

Research Question

9. For adults exposed to trauma, does any early pharmacological intervention confer any advantage over other early pharmacological interventions?

Selection criteria

Inclusion criteria

Population	Adults exposed to trauma, including the subgroup of patients with ASD
Intervention	Early pharmacological intervention (eg imipramine, propranolol, benzodiazepines, other sympatholytics, other antidepressants, anticonvulsants, antipsychotics, chloral hydrate, given within one month of trauma)
Comparator	Other early pharmacological intervention
Outcome	Primary outcomes: symptoms of ASD and PTSD Secondary outcomes: symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	1966-8/2005*
Language	English

* NICE systematic review had identical question, but no randomised controlled trials were found, so lower levels of evidence will be searched (National Institute for Clinical Excellence, 2005)

Box 23 Study selection criteria for research question 10**Research Question**

10. For adults with PTSD, do pharmacological interventions improve outcomes compared with placebo?

Selection criteria**Inclusion criteria**

Population	Adult patients with PTSD
Intervention	Pharmacological intervention (eg SSRIs, other second-generation antidepressants, tricyclic antidepressants, monoamine oxidase inhibitors, benzodiazepines, mood stabilisers, anti-convulsants, and some non-benzodiazepine hypnotics and anti-anxiety medications)
Comparator	Placebo
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2004-8/2005*
Language	English

* Question answered by NICE systematic review with search period up until 2004 (National Institute for Clinical Excellence, 2005); SSRIs = selective serotonin reuptake inhibitors

Box 24 Study selection criteria for research question 11**Research Question**

11. For adults with PTSD, does any pharmacological intervention confer any advantage over other pharmacological interventions?

Selection criteria**Inclusion criteria**

Population	Adult patients with PTSD
Intervention	Pharmacological intervention (eg SSRIs, other second-generation antidepressants, tricyclic antidepressants, monoamine oxidase inhibitors, benzodiazepines, mood stabilisers, anti-convulsants, and some non-benzodiazepine hypnotics and anti-anxiety medications)
Comparator	Other pharmacological intervention
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression/ anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2004-8/2005*
Language	English

* Question answered by NICE systematic review with search period up until 2004 (National Institute for Clinical Excellence, 2005)

Psychosocial rehabilitation for PTSD

Box 25 Study selection criteria for research question 12

Research Question

12. For adults with PTSD, does psychosocial rehabilitation improve outcomes compared to no intervention?

Selection criteria**Inclusion criteria**

Population	Adult patients with PTSD
Intervention	Psychosocial rehabilitation (eg teaching self-care and independent living skills techniques, providing supported housing, marital/family skills training, social skills training, vocational rehabilitation and case management)
Comparator	No intervention
Outcome	Primary outcome: functional improvement, quality of life Secondary outcomes: resolution of symptoms of PTSD, depression, anxiety and substance misuse/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	1966-8/2005*
Language	English

* New review

Box 26 Study selection criteria for research question 13

Research Question

13. For adults with PTSD, does psychosocial rehabilitation confer an advantage over any other psychological or pharmacological interventions?

Selection criteria**Inclusion criteria**

Population	Adult patients with PTSD
Intervention	Psychosocial rehabilitation (eg teaching self-care and independent living skills techniques, providing supported housing, marital/family skills training, social skills training, vocational rehabilitation and case management)
Comparator	Any other psychological or pharmacological intervention (eg trauma-focused CBT, stress management therapy, EMDR, narrative exposure therapy, supportive counselling, interapy, SSRIs, other second-generation antidepressants, tricyclic antidepressants, monoamine oxidase inhibitors, benzodiazepines, mood stabilisers, anti-convulsants, and some non-benzodiazepine hypnotics and anti-anxiety medications)
Outcome	Primary outcome: functional improvement, quality of life Secondary outcomes: resolution of symptoms of PTSD, depression, anxiety and substance misuse/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	1966-8/2005*
Language	English

* New review

Exercise and physical therapies

Box 27 Study selection criteria for research question 14

Research Question	
14. For adults with ASD or PTSD, do physical interventions or exercise confer an advantage over psychological or pharmacological intervention?	
Selection criteria	Inclusion criteria
Population	Adult patients with ASD or PTSD
Intervention	(1) Physical therapy (eg electroconvulsive therapy, transcranial magnetic stimulation, massage, acupuncture, acupressure, Healing Touch, CranioSacral therapy) (2) Exercise therapy (eg yoga, T'ai Chi, movement-to-music, rhythm activities, competitive sports, walking, jogging, swimming)
Comparator	Any psychological or pharmacological intervention (eg trauma-focused CBT, stress management therapy, EMDR, narrative exposure therapy, supportive counselling, interapy, SSRIs, other second-generation antidepressants, tricyclic antidepressants, monoamine oxidase inhibitors, benzodiazepines, mood stabilisers, anti-convulsants, and some non-benzodiazepine hypnotics and anti-anxiety medications)
Outcome	Primary outcome: resolution of symptoms of ASD or PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ functional improvement/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	1966-8/2005*
Language	English

* New review; CBT= cognitive behavioural therapy; EMDR = eye movement desensitization and reprocessing; SSRIs = selective serotonin reuptake inhibitors

Combining Interventions

Box 28 Study selection criteria for research question 15

Research Question	
15. For people exposed to trauma, is a single early intervention more effective than multiple early interventions?	
Selection criteria	Inclusion criteria
Population	Adult exposed to trauma, including the subgroup of patients with ASD
Intervention	Single early psychological or pharmacological intervention
Comparator	Early combined psychological or combined pharmacological interventions or combined psychological and pharmacological interventions
Outcome	Primary outcomes: symptoms of ASD or PTSD Secondary outcomes: symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ side-effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	1966-8/2005*
Language	English

* New review

Box 29 Study selection criteria for research question 16

Research Question	
16. For adults with PTSD, is a single intervention more effective than multiple interventions?	
Selection criteria	Inclusion criteria
Population	Adults patients with PTSD
Intervention	Single psychological or pharmacological intervention or psychosocial rehabilitation strategy
Comparator (1)	Combined psychological interventions or combined pharmacological interventions or combined psychological and pharmacological interventions
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Comparator (2)	Combined psychological intervention and psychosocial rehabilitation (eg teaching self-care and independent living skills techniques, providing supported housing, marital/family skills training, social skills training, anger management, vocational rehabilitation and case management) or combined pharmacological intervention and psychosocial rehabilitation
Outcome	Primary outcome: resolution of symptoms of PTSD, social and occupational function, quality of life Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2002-8/2005*
Language	English

* Question answered by VA/DoD systematic review with search period up until 2002 (Department of Veterans Affairs/Department of Defence, 2004))

Box 30 Study selection criteria for research question 17

Research Question	
17. For adults with PTSD, is an initial pharmacotherapy more effective than initial psychotherapy?	
Selection criteria	Inclusion criteria
Population	Adult patients with PTSD
Intervention	Initial pharmacological intervention
Comparator	Initial psychological intervention
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ social and occupational function/ quality of life/ treatment refusal/ dropout over 12 months/ side effects/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2002-8/2005*
Language	English

* Question answered by VA/DoD systematic review with search period up until 2002 (Department of Veterans Affairs/Department of Defence, 2004)

Prediction of treatment response

A comprehensive review of the evidence was not performed for question 18 and the question was later excluded from the systematic review.

Comorbidities

Box 31 Study selection criteria for research question 18^a

Research Question	
18. In the context of PTSD and comorbidity, is sequencing of intervention per diagnosis more effective than simultaneous interventions for both diagnoses?	
Selection criteria	Inclusion criteria
Population	Adult patients with PTSD and comorbidity (eg grief, depression, personality disorder, pain and substance misuse)
Intervention	Sequenced psychological or pharmacological intervention per diagnosis ie treatment for PTSD and then comorbidity or vice versa
Comparator	Simultaneous psychological and/or pharmacological interventions for both diagnoses
Outcome	Primary outcome: resolution of symptoms of PTSD Secondary outcomes: resolution of symptoms of depression, anxiety and substance misuse/ social and occupational function / quality of life / treatment refusal/ dropout over 12 months/ posttraumatic growth
Study design	Systematic reviews of randomised controlled trials, randomised controlled trials, pseudo-randomised controlled trials, non-randomised controlled trials, cohort studies, before-and-after controlled studies, case-control studies.
Search Period	2002-8/2005*
Language	English

* Question answered by VA/DoD systematic review with search period up until 2002 (Department of Veterans Affairs/Department of Defence, 2004) ; ^are-numbered as question 18, after question 18 was removed

Validity Assessment

Individual studies that were included in the review were critically appraised – in terms of internal and external validity - and the statistical and clinical relevance and applicability of results were determined utilising the NHMRC dimensions of evidence (NHMRC, 2000a, 2000b) and the recently developed NHMRC interim levels and grades of evidence.

The NHMRC dimensions of evidence (Table 34) consider three main aspects that are critical to an assessment of evidence: strength of the evidence, size of the effect and relevance of the evidence. The first domain is derived directly from the literature identified as informing a particular intervention. The last two require expert clinical input as part of their determination.

Table 34 Evidence dimensions

Type of evidence	Definition
Strength of the evidence	
Level	The study design used, as an indicator of the degree to which bias has been eliminated by design.*
Quality	The methods used by investigators to minimise bias within a study design.
Statistical precision	The <i>p</i> -value or, alternatively, the precision of the estimate of the effect. It reflects the degree of certainty about the existence of a true effect.
Size of effect	The distance of the study estimate from the “null” value and the inclusion of only clinically important effects in the confidence interval.
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

*See Table

Strength of evidence

Three subdomains (level, quality and statistical precision) are collectively a measure of the strength of the evidence.

Level of evidence

The research design of each study included in the systematic review is assessed according to its place in a hierarchy. The hierarchy reflects the effectiveness of the study design to answer a particular research question. Effectiveness is based on the probability that the design of the study has reduced or eliminated the impact of bias on the results. The NHMRC levels of evidence for intervention studies, together with the new ‘interim’ levels of evidence for questions on diagnosis, prognosis, aetiology and screening are provided in Table (NHMRC, 2005a). Only the highest level of evidence was reported for each clinical research question.

Quality of evidence

Each study included in the systematic review was critically appraised as to its methodological quality. The study was assessed according to the likelihood that bias, confounding and/or chance had influenced the results. Potential confounders included comorbidities, type of trauma and the duration of the intervention. Treatments other than the target intervention were recorded where possible and noted when not mentioned.

Critical appraisal of the included systematic reviews, randomised and non-randomised trials occurred using the NHMRC quality criteria provided in the checklists below (NHMRC, 2000a).

Statistical precision

Statistical precision was determined using standard statistical principles. The primary outcomes of each included study were critically appraised to determine whether the effect was ‘real’ as opposed to being due to chance. Small confidence intervals and *p*-values give an indication as to the probability that the reported effect is real.

Size of effect

For intervention studies it is important to assess whether statistically significant differences are also clinically important. The size of the effect needs to be determined, as well as whether the 95% confidence interval includes only clinically important effects.

Relevance of evidence

Similarly, the outcome being measured should be appropriate and clinically relevant. Inadequately validated (predictive) surrogate measures of a clinically relevant outcome should be avoided (NHMRC, 2000b). Checklists assessing the clinical importance and relevance of results from each study were utilised and are provided below.

This dimension assesses the relevance of the results of each individual study with respect to:

- a. Outcomes: the appropriateness of the outcomes. Are they relevant to the patient?
- b. Population: are the outcomes of the study based on a similar population and therefore generalisable or applicable to the population of interest?
- c. Intervention: are the outcomes of the study a consequence of a similar intervention and therefore generalisable or applicable to the intervention of interest?

Levels and grades of evidence

Table 35 Designations of levels of evidence* according to type of research question (including tablenotes) (NHMRC, 2005a)

Level	Intervention §	Diagnosis **	Prognosis	Aetiology †††	Screening
I *	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, §§ among consecutive patients with a defined clinical presentation ††	A prospective cohort study ***	A prospective cohort study	A randomised controlled trial
III-1	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, §§ among non-consecutive patients with a defined clinical presentation††	All or none §§§	All or none §§§	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> • Non-randomised, experimental trial † • Cohort study • Case-control study • Interrupted time series with a control group 	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst untreated control patients in a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: <ul style="list-style-type: none"> • Non-randomised, experimental trial • Cohort study • Case-control study
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> • Historical control study • Two or more single arm study ‡ • Interrupted time series without a parallel control group 	Diagnostic case-control study ††	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: <ul style="list-style-type: none"> • Historical control study • Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard) ††	Case series, or cohort study of patients at different stages of disease	A cross-sectional study	Case series

Tablenotes

* A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those studies are of level II evidence.

§ Definitions of these study designs are provided on pages 7-8 *How to use the evidence: assessment and application of scientific evidence* (NHMRC, 2005b).

† This also includes controlled before-and-after (pre-test/post-test) studies, as well as indirect comparisons (ie. utilise A vs B and B vs C, to determine A vs C).

‡ Comparing single arm studies ie. case series from two studies.

** The dimensions of evidence apply only to studies of diagnostic accuracy. To assess the effectiveness of a diagnostic test there also needs to be a consideration of the impact of the test on patient management and health outcomes. See *MSAC (2004) Guidelines for the assessment of diagnostic technologies*. Available at: www.msac.gov.au .

§§ The validity of the reference standard should be determined in the context of the disease under review. Criteria for determining the validity of the reference standard should be pre-specified. This can include the choice of the reference standard(s) and its timing in relation to the index test. The validity of the reference standard can be determined through quality appraisal of the study. See Whiting P, Rutjes AWS, Reitsma JB, Bossuyt PMM, Kleijnen J. The development of QUADAS: a tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews. *BMC Medical Research Methodology* 2003, 3: 25.

†† Well-designed population based case-control studies (eg. population based screening studies where test accuracy is assessed on all cases, with a random sample of controls) do capture a population with a representative spectrum of disease and thus fulfil the requirements for a valid assembly of patients. However, in some cases the population assembled is not representative of the use of the test in practice. In diagnostic case-control studies a selected sample of patients already known to have the disease are compared with a separate group of normal/healthy people known to be free of the disease. In this situation patients with borderline or mild expressions of the disease, and conditions mimicking the disease are excluded, which can lead to exaggeration of both sensitivity and specificity. This is called spectrum bias because the spectrum of study participants will not be representative of patients seen in practice.

‡‡ Studies of diagnostic yield provide the yield of diagnosed patients, as determined by an index test, without confirmation of the accuracy of this diagnosis by a reference standard. These may be the only alternative when there is no reliable reference standard.

*** At study inception the cohort is either non-diseased or all at the same stage of the disease.

§§§ All or none of the people with the risk factor(s) experience the outcome. For example, no smallpox develops in the absence of the specific virus; and clear proof of the causal link has come from the disappearance of small pox after large-scale vaccination.

††† If it is possible and/or ethical to determine a causal relationship using experimental evidence, then the 'Intervention' hierarchy of evidence should be utilised. If it is only possible and/or ethical to determine a causal relationship using observational evidence (ie. cannot allocate groups to a potential harmful exposure, such as nuclear radiation), then the 'Aetiology' hierarchy of evidence should be utilised.

Note 1: Assessment of comparative harms/safety should occur according to the hierarchy presented for each of the research questions, with the proviso that this assessment occurs within the context of the topic being assessed. Some harms are rare and cannot feasibly be captured within randomised controlled trials; physical harms and psychological harms may need to be addressed by different study designs; harms from diagnostic testing include the likelihood of false positive and false negative results; harms from screening include the likelihood of false alarm and false reassurance results.

Note 2: When a level of evidence is attributed in the text of a document, it should also be framed according to its corresponding research question eg. level II intervention evidence; level IV diagnostic evidence; level III-2 prognostic evidence.

The quality of the evidence included in this systematic review was assessed using the following checklists:

Critical Appraisal Checklists

Checklist for appraising the quality of intervention studies

Source: (NHMRC, 2000a)

1. Method of treatment assignment

- a. Correct, blinded randomisation method described OR randomised, double-blind method stated AND group similarity documented
- b. Blinding and randomisation stated but method not described OR suspect technique (eg allocation by drawing from an envelope)
- c. Randomisation claimed but not described and investigator not blinded
- d. Randomisation not mentioned

2. Control of selection bias after treatment assignment

- a. Intention to treat analysis AND full follow-up
- b. Intention to treat analysis AND <15% loss to follow-up
- c. Analysis by treatment received only OR no mention of withdrawals
- d. Analysis by treatment received AND no mention of withdrawals OR more than 15% withdrawals/loss-to-follow-up/post-randomisation exclusions

3. Blinding

- a. Blinding of outcome assessor AND patient and care giver
- b. Blinding of outcome assessor OR patient and care giver
- c. Blinding not done

4. Outcome assessment (if blinding was not possible)

- a. All patients had standardised assessment
- b. No standardised assessment OR not mentioned

Checklist for the critical appraisal of systematic reviews

Source: (NHMRC, 2000b).

1. Was an adequate search strategy used?
2. Were the inclusion criteria appropriate and applied in an unbiased way?
3. Was a quality assessment of included studies undertaken?
4. Were the characteristics and results of the individual studies appropriately summarised?
5. Were the methods for pooling the data appropriate?
6. Were the sources of heterogeneity explored?

Checklist for assessing clinical importance of benefit and harm

Source: (National Health and Medical Research Council, 2000)

Title of review:

Title of study:

Author(s):

Year:

Comparators:

Clinically important effect:

Rank Score : /4

Ranking	Clinical importance of benefit/harm
1	A clinically important benefit for the full range of plausible estimates. The confidence limit closest to the measure of no effect (the 'null') rules out a clinically unimportant effect of the intervention.
2	The point estimate of effect is clinically important BUT the confidence interval includes clinically unimportant effects.
3	The confidence interval does not include any clinically important effects.
4	The range of estimates defined by the confidence interval includes clinically important effects BUT the range of estimates defined by the confidence interval is also compatible with no effect, or a harmful effect.

Checklist for assessing the relevance of outcomes

Source: (National Health and Medical Research Council, 2000)

Title of review:

Title of study:

Author(s):

Year:

Comparators:

Rank Score : /5

Ranking	Relevance of the evidence
1	Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.
2	Evidence of an effect on a surrogate outcome that has been shown to be predictive of patient-relevant outcomes for the same intervention.
3	Evidence of an effect on proven surrogate outcomes but for a different intervention.
4	Evidence of an effect on proven surrogate outcomes but for a different intervention and population.
5	Evidence confined to unproven surrogate outcomes.

Grading the body of evidence

Once each included study is assessed according to the three dimensions of evidence, an evidence-based recommendation can be formulated based on the body of evidence answering the research question. A grade can then be appended to each recommendation.

- NHMRC grades of recommendation [NHMRC 2005, #38] are provided to assist users of the clinical practice guideline in making clinical judgements and indicate the strength of the recommendation. Grade A and B recommendations are generally based on a body of evidence which can be trusted to guide clinical practice, whereas Grade C and D recommendations must be applied carefully to individual clinical and organisational circumstances and should be followed with care.

Grade of recommendation	Description
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution

- ### How to assess the body of evidence and formulate recommendations

The application of a grade to a recommendation is based on an assessment of all the included studies for that recommendation (the ‘body of evidence’). The five components that are considered in judging the body of evidence are:

- *volume* of evidence (which includes the number of studies sorted by their methodological quality and relevance to patients)
- *consistency* of the study results
- the potential *clinical impact* of the proposed recommendation (including the balance of risks and benefits, the relevance of the evidence to the clinical question, the size of the patient population and resource issues)
- the *generalisability* of the body of evidence to the target population for the guideline
- the *applicability* of the body of evidence to the Australian healthcare context.

The Australian Guidelines for the Treatment of Adults with Acute Stress Disorder and Posttraumatic Stress Disorder

1. INTRODUCTION

The Australian Centre for Posttraumatic Mental Health (ACPMH) has developed Australian Guidelines for the Treatment of Adults with Acute Stress Disorder and Posttraumatic Stress Disorder ('the Guidelines'), in collaboration with Australian experts in the field of posttraumatic mental health. The Guidelines will help health practitioners, policy makers and the public make appropriate decisions around screening, assessment and treatment for Acute Stress Disorder (ASD) and Posttraumatic Stress Disorder (PTSD).

This plan details how ACPMH will promote and distribute:

- The Guidelines
- Practitioner guide
- Guide for the public
- Promotional brochure

This plan draws on recommendations and case studies available in the NHMRC's *How to put the evidence into practice: implementation and dissemination strategies* (2000). It covers the period from November 2006 to the end of 2007 and summaries the minimum range of activities that ACPMH will undertake within its available budget. The activities may be broadened in scope if ACPMH is successful in obtaining external funding to support this dissemination plan.

The focus will be on reaching health professionals through influential advocates and their professional organisations. The main events include the recent symposium at the Australasian Society for Traumatic Stress Studies (ASTSS) conference (September 2006), a briefing for the Guidelines Multidisciplinary Panel (MDP), and a launch of the Guidelines at the Centre's proposed Trauma and Mental Health Forum in March or April 2007.

2. SITUATIONAL ANALYSIS

2.1 Background

Exposure to a traumatic event is unfortunately not an uncommon experience. A recent survey of the Australian population found that 64 per cent of Australian men and 50 per cent of women have experienced a traumatic event in their lives such as major disaster, war, sexual or physical assault and motor vehicle accidents. Furthermore, with increased global instability and the heightened threat of terrorism, the community may be considered more at risk of trauma exposure in the course of their daily lives than has previously been the case.

Almost anyone who goes through such a traumatic event will be emotionally affected in some way. Although most will recover with the support of family and friends, others will develop mental health problems and may benefit from professional help. Posttraumatic stress disorder (PTSD) is one of the more common

mental health conditions, with other anxiety disorders, depression, traumatic grief and substance misuse also relatively common following trauma.

Rates of PTSD vary depending on the nature of the traumatic event. In a national Australian survey, the highest 12-month prevalence rate of PTSD was associated with sexual assault (around 10 per cent) and the lowest rate was associated with natural disasters (less than 1 per cent). On average, about 260,000 Australian may experience PTSD in any one year.

PTSD can be a chronic and debilitating condition, causing disruption and instability in relationships, work, study and daily life. It carries a higher suicide risk than any other anxiety disorder². PTSD also brings considerable financial costs to individuals, communities, government and third-party insurers.

For people who develop PTSD and need help in their recovery, these Guidelines show practitioners the best way to help them. The Guidelines will also assist practitioners to decide when and how to step in and help someone who is experiencing psychological problems in the early days and weeks after a traumatic event.

Only in the last decade has there been an emerging consensus on the best treatment approaches for ASD and PTSD and so it has only recently been possible to develop evidence based clinical practice Guidelines for these conditions. Both the United Kingdom National Institute for Clinical Excellence (NICE, 2005) and the United States (APA, 2004; Veterans Affairs/ Department of Defence: VA/DoD, 2004) have published treatment Guidelines for PTSD. However, there remained a need to develop Guidelines tailored to Australian needs and our health care system. By setting treatment standards, the Guidelines are a critical part of Australia's constructive response to the psychological impact of trauma.

2.2 Opportunities and Challenges for Communication and Dissemination

This new set of Australian Guidelines will be released into a receptive environment – witness the COAG Mental Health Package and the \$1.9 billion of additional mental health funding announced in the 2006-07 federal budget. These and other initiatives promote and are in response to increased community awareness of mental health problems.

Not only do the Guidelines provide advice about the best way to treat a debilitating mental health disorder, but they also recommend treatment approaches that will minimise the health cost associated with long-term disability that can accompany PTSD. In fact, there is evidence that current treatment practices for PTSD are not cost-effective and that providing optimum treatment for PTSD will result in economic savings. This is an important message to convey in briefing sessions about the Guidelines.

Regardless of these savings, potential cost barriers to uptake of evidence-based treatment remain. For example, the Guidelines recommend 90 minutes for a

² <http://www.mhca.org.au/Resources/index.html>

consultation for some treatments, an increase on the current standard of one hour. It is also expensive for organisations to invest in training for practitioners.

Effective treatments for PTSD involve directly confronting the traumatic memory and yet most mental health practitioners, even those who specialise in working with traumatised people, do not use this approach. As such, the Guidelines clearly address a gap between treatment that has been proved to be effective and common treatment practices. Potential reasons for the poor uptake of trauma-focussed treatment need to be addressed upfront when promoting the Guidelines. In this regard, the Centre's communication about the Guidelines will need to challenge the commonly held myth that talking about the traumatic experience will only make things worse. The Centre will also need to allay any fears practitioners may have about managing the distress associated with trauma focused work.

Response to the Guidelines may be varied. These include some practitioners' concern that cognitive behaviour therapy (CBT) will dominate recommendations, that 'real clients' rarely conform to clear-cut diagnostic categories, and that the Guidelines will undermine the value of clinical judgement and may be interpreted by service planners as overly prescriptive. The Centre has been conscious of these concerns while developing the Guidelines. Key messages about the Guidelines will emphasise that they are only one component of good decision-making, and they recommend, not mandate, specific approaches.

The Guidelines are effectively asking many practitioners to change their behaviour in how they treat PTSD and ASD. Additional barriers to individual learning/change process could also include:

Tradition and training: practitioners adhere to what they learnt in their training and have used in practice

Art versus science: some practitioners may resist following evidence-based treatment recommendations because they believe they ignore the creativity needed in therapy.

Eclectic practice: some practitioners are used to picking and choosing treatments based on their own experience or perception of client need.

Scepticism of research: many practitioners are dubious about the ability of research to fit the real world of clinical practice.

Other challenges to effective dissemination can be further explained by various models of behavioural change.

The change process: behavioural change is complex and difficult. People's receptiveness to innovation and change is described differently in a variety of behavioural change models. People can be happily unaware and uninformed; interested and ready to be informed; prepared to try the new idea or behaviour; try it out; see and believe that the new behaviour 'works' and continue to maintain the change in their behaviour or practice. Communication and health promotion clearly demonstrate that different strategies and tools are needed for the different stages of change.

In broader terms, new ideas are usually taken up most quickly by the 'early adopters'. Their example is usually followed later by the 'early majority', after they hear about it from a trustworthy source. As 'new' practice becomes more widely accepted, the 'late majority' adopt it, once they see local proof. At the end of the spectrum are the 'traditionalists' who only grudgingly adopt the practice, long after it has become commonplace. The late majority and traditionalists account for approximately 60 per cent of any audience^[1].

In addition to this, the Guidelines will be competing for practitioners' notice with an overwhelming amount of information and resources they receive from government, community and commercial organisations. The Guidelines are about best-practice but will have little or no impact on practitioners' remuneration.

As such, the Centre plans to promote and disseminate the Guidelines with other mental health resources, as well as through existing and proposed mental health training for practitioners. Both resources and training are likely to increase in line with commonwealth and state government funding commitments. The challenge will be identifying and staying in touch with new resources and training initiatives. The Centre will need the support of Guidelines advocates and influencers (see page 7) to meet this challenge and facilitate opportunities to integrate the Guidelines.

Busy and overworked practitioners may not regard PTSD as a priority in their clinical practice. Key messages should therefore highlight the commonality and seriousness of trauma, the impact of PTSD and the proven benefits of treatment. Care will be taken to convey messages about resilience, spontaneous recovery from trauma and PTSD, so that practitioners and their patients get the full picture.

While complex and challenging, ACPMH will endeavour to take advantage of the potential opportunities and address the described barriers when targeting dissemination and training activities.

3. RESEARCH

A Guidelines multidisciplinary panel (MDP) has reviewed the Guidelines and the practitioner and public guides. MDP members represent the public, regulatory bodies, trauma specialists and generalists from a range of health professions including:

- psychology;
- psychiatry;
- general practice;
- social work;
- mental health nursing; and
- occupational therapy.

Dr Elana Newman, *Challenges of Implementing Evidence-Based Practice in Community Based Health Care*, ASTSS-ACPMH Joint Annual Conference, Adelaide, September 2006

The comprehensive consultation with the MDP has ensured that the Guidelines are high-quality, are based on existing evidence and are likely to be useful to health professionals. The Centre will also test information to promote the Guidelines with the MDP and seek their advice on this dissemination plan.

The Centre will therefore focus on evaluating the effectiveness of this dissemination plan, with surveys of advocates and professional organisations, analysis of ordering data, and website and newsletter monitoring.

In addition, a reply-paid feedback form will be investigated for inclusion in the practitioner guide, giving practitioners an opportunity to self-report on their use of the Guidelines and their effectiveness. If external funding is obtained, the Centre will also survey approximately 600 health professionals who were sent or ordered the practitioner guide and the guide for the public, asking them to self-report on their use of the Guidelines and their perceived efficacy. Further details are provided in the evaluation section (page 17).

4. GOAL

To encourage more health practitioners to use the best treatment for ASD and PTSD.

The communication goal is to raise awareness of the Guidelines among health practitioners, policy makers and people experiencing ASD or PTSD.

5. COMMUNICATION OBJECTIVES

Communication objectives that support this goal are to:

1. Win the support of advocates from the trauma, mental health and medical fields, and from the MDP to promote the Guidelines. This will be demonstrated by their reporting that, by December 2007, they have personally distributed the practitioner guide to ten colleagues, and promotional material to other groups and in other forums.

2. Win the support of professional bodies and community organisations to promote the Guidelines to their members. This will be demonstrated by their reporting in a telephone or email survey that they have distributed brochures and information through mailouts, newsletters, websites, meetings and training forums, from February 2007.

3. Generate interest in the Guidelines so that by December 2007, health professionals' organisations report that their members are aware of the Guidelines, know that the Guidelines recommend the best practice treatment and intend to use the Guidelines. This self-reporting will be in response to a telephone or email survey.

4. Generate interest in the Guidelines so that by December 2007, 2,000 practitioner guides and 300 public guides have been ordered from ACPMH, either by organisations or individuals.

5. Increase awareness among non-mental health practitioners about the psychological impact of trauma and the Guidelines, so that, by December 2007, up to 10 per cent of orders for the practitioner guide are from this group.

6. Integrate information about the Guidelines into the relevant mental health information and training initiatives of COAG, individual government agencies, training bodies, hospitals, academic, community and veteran organisations by the end of 2007.

7. Demonstrate the practical application of the Guidelines in policy, clinical and training sessions at the launch, briefing and training sessions, so that participants report, in a follow up survey or telephone call, that they can share the information with their organisations and/or members.

8. Ensure key messages for relevant audiences are reflected in all information about the Guidelines, as measured through ongoing monitoring of materials.

9. 80 per cent of health practitioners who were provided with the Guidelines by ACPMH or advocates self-report that they are using the Guidelines and that they are effective. This will be demonstrated through a feedback mechanism provided in the practitioner guide or a self-report survey of 600 practitioners who received the Guidelines. This survey can only be conducted if external funding is obtained.

6. AUDIENCES

The Centre will tailor its promotion of the Guidelines to reflect the different requirements of health practitioners working in primary, secondary and tertiary health services.

Primary

1. Multidisciplinary practitioners planning treatment across clinical settings including:

- Psychologists
- Psychiatrists
- Counsellors
- Mental health nurses
- General practitioners
- Occupational therapists
- Medical, psychology and psychiatry clinical course coordinators (via professional accrediting bodies and universities)

2. Funding bodies making service purchasing decisions, such as:

- Department of Health and Ageing – including Office for Aboriginal and Torres Strait Islander Health (negotiate with OATSIH on reaching Aboriginal Medical Services)
- Departments of Health (states) – including Victoria’s Mental Health Project officers
- Departments of the Attorney-General and Justice (Commonwealth and State)

- Third-party insurers (states)
- Emergency services organisations (police, fire, ambulance – all states)
- Department of Defence (Director of Mental Health and Centre for Occupational Health) and treatment arms of the Department
- Department of Veterans' Affairs – includes Vietnam Veterans Counselling Service (VVCS)

Secondary

3. People experiencing ASD or PTSD, and their families or carers, who are making decisions about their treatment.

Advocates and influencers

4. Guidelines Working Party and MDP members
5. Opinion leaders in trauma, mental health and medical fields
6. Professional organisations or distribution avenues including:
 - Australian Psychological Society (APS)
 - Royal Australian and New Zealand College of Psychiatrists (RANZCP)
 - Australian Association of Social Workers (AASW)
 - Australian College of Rural and Remote Medicine (ACRRM)
 - [The Australian & New Zealand College of Mental Health Nurses Inc](#) (ANZCMHN)
 - Royal Australian College of General Practitioners (RACGP)
 - Australian Divisions of General Practice (ADGP – specifically mental health coordinators in Divisions)
 - Rural Doctors Association of Australia (RDAA)
 - VVCS National Director and Directors
 - OT Australia
 - Australian Centre for the Study of Sexual Assault
 - State government sexual assault centres (c70)
 - Trauma/torture organisations (numbers TBC)
 - Australian Network for Promotion, Prevention and Early Intervention for Mental Health (Auseinet)
 - [Workplace counselling programs](#)
 - [The Australian Guidance and Counsellors Association](#) (AGCA, 1,000 members)
 - Primary Mental Health Care Resource Centre (PARC)
 - Primary Health Care Research and Information Service
 - Mental Health Council of Australia
 - National Mental Health Consumer and Carer Forum³
 - Community groups including ex-service organisations and support groups
 - National Mental Health and Wellbeing Forum (DVA)

7. KEY MESSAGES

Why the Guidelines/what's the problem they address?

³ <http://www.mhca.org.au/Resources/index.html>

In Australia, up to 64 per cent of men and almost 50 per cent of women experience a traumatic event some time in their lives, such as:

- an accident;
- sexual assault;
- violence;
- a natural disaster, like bushfires, floods and cyclones;
- war; or
- torture.

Almost anyone who goes through such a traumatic event will be emotionally affected in some way. Although most will recover with the support of family and friends, others will develop mental health problems and may benefit from professional help. Posttraumatic stress disorder (PTSD) is one of the more common mental health conditions, with other anxiety disorders, depression, traumatic grief and substance misuse also relatively common following trauma.

Rates of PTSD vary depending on the nature of the traumatic event. In a national Australian survey, the highest 12-month prevalence rate of PTSD was associated with sexual assault (around 10 per cent) and the lowest rate was associated with natural disasters (less than 1 per cent). On average, about 260,000 Australian may experience PTSD in any one year.

PTSD can be a chronic and debilitating condition, causing disruption and instability in relationships, work, study and daily life. It carries a higher suicide risk than any other anxiety disorder.⁴

PTSD can cause disruption and instability, in relationships, work, study and daily life. People with PTSD may:

- not be able to get the incident out of their mind;
- sleep badly;
- feel irritable with themselves and the world in general;
- have trouble concentrating;
- abuse alcohol or drugs to block out memories;
- become unusually busy to avoid dealing with the issues;
- struggle with uni, school or work;
- have trouble connecting with others; and/or
- feel depressed, panicky or anxious.

PTSD can affect anybody from any culture - men and women, young people and children.

The longer PTSD lasts, the greater the chance that the person will develop other mental health conditions – depression, anxiety, and alcohol and drug misuse.

Effective treatments for ASD and PTSD are available.

The key distinguishing feature between Acute Stress Disorder (ASD) and PTSD is the duration of symptoms required for the diagnosis to be made

⁴ Kessler, R.C., *Posttraumatic Stress Disorder: The Burden to the Individual and to Society*, *Journal of Clinical Psychiatry* 2000; 61, p8

Posttraumatic mental health problems can be difficult for both practitioners and the people affected. They may both be unsure about how to deal with it.

Only 40 per cent of people identified as having PTSD as their primary diagnosis had consulted a health professional in the 12 months prior to the 1997 Australian National Survey of Mental Health and Well-being survey. Of these, approximately two-thirds received treatment considered to be effective.

Although there has been growing consensus about the treatment of ASD and PTSD in recent years, approaches are varied and there is still a gap between proven treatments and routine clinical care. The guidelines aim to bridge this gap by promoting evidence-based interventions such as trauma-focussed therapies.

What the Guidelines do

The Guidelines will help health practitioners, policy makers and the public make appropriate decisions around screening, assessment and treatment for ASD and PTSD.

Practitioners who implement the recommendations from the Guidelines whether in regard to screening, assessment or treatment, can be confident that their intervention is based on best practice.

Importantly, the Guidelines are only one component of good decision-making, and they recommend, not mandate, specific approaches.

Specifically, the Guidelines:

- Translate the current body of knowledge around ASD and PTSD into recommendations for actual clinical practice.
- Address the gap between best practice and current treatment of ASD and PTSD in Australia.
- Help reduce the unintended negative effects of some aspects of treatment for ASD and PTSD.
- Improve consistency and quality of specialist and routine clinical practice with people affected by trauma.
- Improve awareness in the primary health sector and provide better tools to screen for PTSD.
- Contribute to the capacity of Australia's health services, as well as high-risk occupations such as emergency services and the military, to respond effectively to psychological trauma in an era of increased global instability.

Extensive consultation with practitioners from a range of different specialities, as well as with people affected by trauma, has resulted in practical recommendations which are applicable across the range of service settings and geographical locations.

The Guidelines provide information that may be helpful in addressing psychological trauma in a range of different groups. These include Aboriginal and Torres Strait Islander peoples, and refugees and asylum seekers, as well as military and

emergency service personnel, traumatic injury survivors, victims of crime, sexual assault, natural disasters and terrorism.

Who are the Guidelines for?

The Guidelines are for:

- Practitioners from a range of health disciplines supporting people who have experienced a traumatic event or treating those who have gone on to develop mental health problems as a result.
- Organisations and funding bodies making decisions about health service purchasing and programs to help people after accidents, sexual assault, crime or torture; emergency workers; veterans and the military.
- People experiencing ASD or PTSD, and their families or carers, who are making decisions about their treatment.

The full version of the Guidelines is available from the National Health and Medical Research Council's website (nhmrc.gov.au) and www.acpmh.unimelb.edu.au.

A free practitioner guide for practitioners can be downloaded or ordered via www.acpmh.unimelb.edu.au or by calling the Centre on (03) 9496 2922.

This practitioner guide outlines the key recommendations made in the guidelines. It aims to help practitioners identify posttraumatic mental health problems early and become aware of best practice in the field so they can refer or treat people affected by trauma appropriately.

A free guide to treatment for people diagnosed with ASD or PTSD, their carers and families can be downloaded or ordered via www.acpmh.unimelb.edu.au or by calling the Centre on (03) 9496 2922.

This guide for the public will help people affected by trauma, their family and carers to recognise the onset of posttraumatic mental health disorders, make informed decisions about seeking help and actively participate in their treatment. It aims to give them tools to improve their ability to gain access to resources and to quality, evidence-based interventions.

Organisations and health practitioners can contact the Centre to discuss briefings and training about the Guidelines.

About the Guidelines

The Guidelines have been designed by the Australian Centre for Posttraumatic Mental Health in collaboration with experts in the field of posttraumatic mental health and in consultation with a multidisciplinary panel of health practitioners, and people who have experienced PTSD or ASD.

The National Health and Medical Research Council has endorsed⁵ the Guidelines, which are based on a systematic literature review of outcome research.

⁵ Please note that this statement is in anticipation of NHMRC approval.

While US and UK Guidelines exist, this is the most current set of Guidelines and the only ones applicable to Australia's healthcare system.

The Guidelines were developed as recommended by the National Health and Medical Research Council's *A Guide to the Development, Implementation and Evaluation of Clinical Practice Guidelines* (1999) and will be reviewed in 2008.

Professor Mark Creamer, Director of ACPMH and Professor Beverley Raphael, Director of Disaster Management Australia and Chair of the multidisciplinary panel formed the steering committee responsible for overseeing the development of the Guidelines.

ACPMH is an internationally recognised centre of excellence at the University of Melbourne, specialising in trauma-related research, policy advice, service development and education.

8. COMMUNICATION ACTIVITIES AND CHANNELS

Guidelines Resources and Promotional Materials

This dissemination plan covers the promotion and distribution of, at a minimum:

1. The Guidelines (150 copies for ACPMH distribution) – the full Guidelines including systematic review of the literature.
2. Practitioner guide (3,500 copies) – a brief reference tool for practitioners, with limited background information and treatment recommendations.
3. Guide for the public (2,600 copies) – a brief summary of the Guidelines.
4. Promotional brochure (10,000)⁶

Resources, promotional and support materials are detailed overleaf:

⁶ Final numbers to be confirmed once products developed, additional copies of each can be printed if external funding obtained.

Resource	Audience	For	Format	Available from
Guidelines resources				
Full guidelines	Researchers; organisations; profs bodies	reference	Online Print: A4 'textbook'	NHMRC <i>print & online</i> ACPMH <i>ltd print copies, online only, inc. separate PDF of 'special groups'</i>
Practitioner guide	Practitioners	clinical use	user-friendly booklet	ACPMH web
Public guide	People with ASD/PTSD, families & carers	information	user-friendly booklet	ACPMH web
PTSD Tips	Practitioners	clinical use	On-line PDF, <i>print if budget allows</i>	ACPMH web
Promotional & support material				
Brochure	Practitioners, health services	encourage orders	A5 or DL design	ACPMH print & online
Info sheet	potential funders & training partners	staff & advocates to promote Guidelines	Word doc	ACPMH print & online
Talking points	All audiences	staff & advocates use at meetings & presentations	internal use & emailed to advocates	ACPMH team
Power point	Potential funders, training partners, practitioners	staff & advocates use at meetings & presentations	CD & emailed to advocates	ACPMH team
Journal articles	Practitioners	Aust psychiatry & psychology publications	Authors submit to editorial board	ACPMH web
General articles & announcements	Members, practitioners, staff of different organisations	Newsletters <i>prof bodies, comm. gps, organisations ACPMH</i>	PDF emailed to editors	ACPMH web
Website icon & blurb	Members, practitioners, staff of different organisations	Newsletters <i>prof bodies, comm. gps, organisations, ACPMH</i>	Blurb and link to resources emailed to website coords	ACPMH web
Letter(s)	Guideline & brochure recipients	mail out of resources & broch, introduce & encourage support	ACPMH letterhead	n/a
Media release (TBC)	Medical media, poss. mainstream	Publicise the launch (if appr)	ACPMH media release	ACPMH web

Guidelines advocates

ACPMH will seek to win the support of opinion leaders in the trauma, mental health and medical fields, and of members of the MDP to promote the Guidelines to their colleagues and professional organisations. ACPMH will invite Beverly Raphael, Chair of the MDP, to host a function to thank members for their significant contribution. Members will be provided with copies of the Guidelines and promotional information at this function, so that they can easily promote the Guidelines.

Advocates will be encouraged to personally distribute practitioner guides and guides for the public to other influential practitioners, and promotional material in training forums, at conferences and meetings. Recipients are likely to respond more positively to and use a resource provided to them from a credible source, such as a colleague whose judgement they trust. ACPMH may also need their support when approaching relevant professional organisations. ACPMH will provide each advocate with a supply of the shorter versions for distribution, and a promotional package to facilitate their support. ACPMH will ask advocates to keep a record of their activities and to self-report on their distribution and promotional efforts via a telephone or email survey.

Guidelines Symposium

Members of the Guidelines Working Party (Mark Creamer, Lynda Matthews, Richard Bryant, Grant Devilly and Alexander McFarlane), Chair of the Working Party, Associate Professor David Forbes, and Chair of the MDP Beverly Raphael presented a symposium on the Guidelines at the Australasian Society for Traumatic Stress Studies (ASTSS) conference in September 2006. The symposium aimed to prepare key mental health practitioners about the Guidelines, as well as identify and facilitate promotional and training partnerships for implementation in 2007. ACPMH invited participants to provide their email address so they can be informed when the Guidelines are available. At this point, ACPMH will also seek their assistance in personally distributing the Guidelines to up to 10 of their colleagues once released.

Launch

The Centre proposes to launch the Guidelines at its inaugural Trauma and Mental Health Forum, to be held in Melbourne in March or early April 2007. The Centre will demonstrate the practical application of the Guidelines to Forum participants for policy, program, training and clinical settings. Forum participants will include decision-makers from funding bodies and mental health services, as well as opinion leaders in the areas of mental health, health, emergency and disaster management, sexual assault, crime and torture. The launch will be supported by simultaneous promotion of the Guidelines in peak bodies newsletters and websites, as detailed below. Briefings and training activities will follow the launch, pending the available budget.

Promotional avenues

Components of the above information will be distributed to Guidelines advocates and those organisations listed as influencers (see page 7) for use in their mail outs, newsletters, meetings, workshops, conferences and training forums. Health practitioners who attend any briefings and training forums will be asked to distribute the practitioner guide to a small number of their colleagues (5 to 10)

personally. Medical media opportunities will be investigated in preference to mainstream media.

Mail out of Guidelines and promotional materials

ACPMH will distribute a set of Guidelines materials (full version, practitioner and public guides and promotional brochure) to all funding bodies and influencers (see page 7). Numbers provided to each will vary. Each mail out will include a cover letter to introduce the Guidelines and asking for their support in promoting them to their providers or members.

ACPMH will follow up this initial mail out with key organisations, to ascertain their interest in a broader mail out of the brochure to their members. ACPMH will also send the brochure to selected practitioners as per the table below. Practitioners will only receive the Guidelines directly from a Guidelines advocate or by ordering copies from ACPMH. External funding will allow for a more comprehensive mail out, including mental health and other providers for DVA and TAC, for example.

Recipient	full version	Pract. guide	Public guide	brochure/promo info
Funding bodies (DVA, ADF, TAC, VTF)	√	√	√	√ only if requested for their mail out
Influencers (pg 6)	√	√	√	√ only if requested for their mail out
GPs (Better MH Outcomes reg'd) 4,580				√
ACPMH mailing list 2,500 (avoid duplication with mail out to funding bodies)				√

Website

The Guidelines' appendixes make the final product too unwieldy to be of practicable use in a clinical setting. Hard copies of the full version will only be distributed as per the table above. It will be available for order from the NHMRC website (www.nhmrc.gov.au), with a PDF available on ACPMH's website. The majority of potential readers will be most interested in the practitioner guide and the guide for the public. Both will be available in PDF form on ACPMH's website, to complement the limited number of printed copies. The promotional brochure and a PTSD Tip sheet will also be available on the Centre's website.

Briefings

Depending on the available budget, ACPMH will organise and lead a limited number of briefings for relevant politicians, service managers and opinion leaders in the areas of mental health, health, emergency and disaster management, sexual assault, crime and torture. Similar to the launch, the Centre will demonstrate the practical application of the Guidelines for policy, program, training and clinical settings.

Training

At a minimum, health practitioners who attend any briefings and training forums will be asked to personally distribute the Guidelines to a small number of their colleagues (5 to 10). ACPMH will follow up with them to monitor distribution, and through contacting recipient directly, endeavour to gauge the uptake of the guidelines through self-reporting by practitioners.

If sufficient external funding is obtained, ACPMH will develop a comprehensive training strategy to encourage positive changes to clinical practice. ACPMH will identify training partnerships with the assistance of the previously mentioned advocates, to facilitate the Guidelines' inclusion in mental health initiatives of government agencies, training bodies, academic and community organisations. This will involve the Centre taking the lead in delivering training and possibly develop train-the-trainer programs, accrediting key representatives to deliver training about the Guidelines.

9. BUDGET

ACPMH has allocated funds to support the minimum dissemination activities outlined in this plan and is currently exploring funding opportunities to expand these activities.

10. TIMELINE

Activity	Timing
Identify and source funding	July-Dec 2006
ASTSS symposium	Sept 2006
Anticipated approval of the Guidelines	Dec 2006
Design Guidelines, practitioner guide & public Guide	Oct-Jan 2007
Develop & design promotional materials	Oct-Jan 2007
Printing of Guidelines & promotional materials	February 2007
Organise training & dissemination partnerships	Nov 06-July 2007
Organise briefings	Nov 06-Dec 2007
MDP function	February 2007
Guidelines on website	March 2007
Guidelines mail outs (3 x versions)	March 2007
Pitch and distribute promotional materials	Nov 06-June 2007
Launch at the Trauma and Mental Health Forum	March/April 2007
Hold briefings & training	March-Dec 2007
Evaluation	Dec 2007
Ongoing distribution, briefings	June-Dec 2007

11. EVALUATION

As mentioned previously, the Centre will focus on evaluating the effectiveness of this dissemination plan, using its own resources. If external funding is obtained, the Centre will be able to consider a self-report survey of health practitioners and possibly, other evaluation tools.

The effectiveness of this dissemination plan will be measured against its objectives so that, by December 2007:

Guidelines advocates report that they have personally distributed the Guidelines directly to 10 colleagues and promotional material to other groups, via a telephone or email survey.

Professional and peak bodies report in a telephone or email survey that they have distributed brochures and information to their members through mailouts, newsletters, websites, meetings and training forums. This will also be measured through monitoring of their communication avenues.

Professional organisations report in a telephone or email survey that their members are aware of the Guidelines, know that the Guidelines recommend the best practice treatment and intend to or are using the Guidelines.

2,000 practitioner guides and 300 guides for the public have been ordered from ACPMH, either by organisations or individuals.

Up to 10 per cent of orders for the practitioner guide are from non-mental health practitioners.

Health practitioners who attend Guidelines briefings or training sessions report that they have personally distributed the Guidelines to up to 10 of their colleagues.

Information about the Guidelines is included in the mental health information and training initiatives of COAG, individual government agencies, training bodies, academic, community and veteran organisations, as demonstrated through monitoring and self-reporting via telephone calls.

Participants at briefings and training sessions report that they can share the information about how to apply the Guidelines with their colleagues or members, via follow-up telephone calls or email survey.

In addition:

Participants at the launch request copies of the Guidelines and subsequent briefing/training sessions for their organisations.

ACPMH receives a 20 per cent increase in contact from identified target audiences in relation to the Guidelines (website and telephone), the majority of who order a version of the Guidelines, as evidenced through website and telephone monitoring.

The reach of promotional material will be measured by the number of brochures mailed out, either directly by ACPMH or via professional and other organisations.

All briefings, training sessions, printed and website information contain relevant key messages and ACPMH branding and NHMRC endorsement.

In terms of use of the Guidelines:

80 per cent of health practitioners who received a copy of the Guidelines self-report that they are using the Guidelines and that they are effective. This will be demonstrated through a feedback mechanism provided in the practitioner guide, and potentially, a self-report survey of 600 practitioners who received the Guidelines. Note that the survey, and additional evaluation, can only be conducted if external funding is obtained.

Public consultation on the draft guideline was advertised in the Australian on 15th September 2006, with a 30 day period to respond. Over this period the guideline was available for download from the Australian Centre for Posttraumatic Health website, together with a pro forma for written submissions. This document presents the submissions received and Working Party responses.

SUBMISSION 1

Treatment of Post Traumatic Stress Disorder

On reading the guidelines for adults for treatment of Post Traumatic Stress Disorder (PTSD) there are some issues that I would like to raise with you. While I haven't had the opportunity to read all 488 pages as yet, in my early reading I make two points, one in relation to diagnosis, and the second in relation to recovery.

Diagnosis

One of the issues, after seeing over 3,000 police and an enormous number of veterans which I have failed to keep count of, as well as normal every day victims of crime, hostages, victims of hold-ups, rapes, etc, it is certainly self evident to me that there're are significant differences in the presentation of post trauma pathology. In fact, the optimistic outcome for a person who has been through a single incident such as a bank robbery I believe is quite positive. I refer to of course those other people who suffer from PTSD of a complex nature, and of course, a word that has crept into the psychiatric nomenclature in the last ten years. It implies that there can be an affect of an accumulation of trauma that makes the presentation of PTSD quite different from a single event. You are more than aware of the literature and perhaps the even controversial nature of this matter (Lindahl 2004).

As you would also be aware, in the DSM-IV we have just one schemata for PTSD, and I feel that so often doctors, as well as mental health professionals try to push all cases into that any patient that even vaguely looks like they suffer from PTSD. This has caused a devaluing, and perhaps even some cynicism with regard to this condition.

None the less, it needs to be recognised that in diagnosing PTSD there are some substantial differences between say a 30 year veteran police officer and a civilian who experienced a single event. While they may have some symptoms in common, there is a large variance in the presentation, but more importantly, the chronic nature of such a condition. I would be interested in your thoughts on the matter and maybe how you intend to develop the more general guidelines. I can't see for instance in the draft that I have questions about complex PTSD, are not discussed you clearly cover issues such as co-morbid conditions.

Working party response:

This issue is considered in various places throughout the guideline:

Section 1.4 Scope of the guidelines paragraph 4; Section 2.3.4 Associated features;

Section 4.1.1.5 Psychological treatment summary of evidence paragraph 5;
Section 7 Specific populations and trauma types: issues for consideration in the application of the guidelines

The second matter is one of recovery. Like others, I am regularly frustrated by comments received by some members of the mental health profession that sees PTSD more as a transient condition rather than the so often chronic condition. For instance, I had a psychiatrist recently reply to a report that I had completed in relation to a police officer's fitness for work. This was a 55 year old male veteran's for some 28 years who had been exposed to multiple traumas, and undoubtedly had had PTSD, a matter that a psychiatrist did not argue with. However, what was clear is that following his six months of therapy, his retirement from police work, he was taking Effexor, an SSRI, approximately 125mls, and a hypnotic (Stilnox). He was currently residing on the coast with a substantial pension. The psychiatrist said the client was now recovered from PTSD and that they were fit to work. These are the kinds of dangerous opinions that I think stem from the idea that PTSD can be cured rather than managed. I make the point that in some cases, if a person is "cured" it may be that they had not have suffered from PTSD in the first place. However, it is clear to me and others that this ex-police officer had re-gained some stability because he had reduced all the major stressors in his life, including not re-facing traumatic circumstance, taking a retirement option which secured him financially, then basically living in a fairly protected manner, as or as he described it, his "cacoan". His wife complained that he still rarely liked to go out, but he was easier to live with. He also pointed out that if he ceased medication he would find many of the symptoms that he had previously would re-occur.

In one respect therapeutically I think that the mental health professional treating him and his general practitioner had done a good job. However, his remission was and continues to be only possible because of the strategies that have not only been psychotherapeutic than psycho-pharmacologically, but also his lifestyle. What the good doctor was trying to say was that he has now recovered (cured) and he can return to work as a police officer. I would think that given the evidence this is nonsense. However, my point is that I think that too often there is this idea that a person suffers PTSD then simply recovers, and that is what is regarded as a cure. I consider PTSD typically has the cycle of relapse, recovery, remission. There is some hope that the remission will remain permanent but I consider the patient is always at risk.

Moreover, as you point out in the guidelines, quite often PTSD is accompanied by other psycho-pathology or is the trigger for it. I refer of course to depression, as well as other anxiety based conditions including alcohol abuse. That being the case, these conditions, to use a more colloquial term, "get a life of their own". While we might see that the original symptoms of PTSD remit, in fact, the primary presentation may be something difference, such as I say, depression.

I suppose my point is here that in reading the guidelines and in mixing the complex with the simple, and only having one diagnostic criteria provided by the DSM-IV, confuses the picture making treatment more complex.

I guess my question to you is "how do you feel about the comments made here?" I have purposely avoided the arguments such as the neurophysiologic arguments raised by

people like Basil Van de Kolk and George Everly. I have restricted myself to just two clinical issues as a scientist practitioner.

I look forward to any comments you might have and would hope that these comments are in some way helpful feedback in respect to what I consider your guidelines are an outstanding contribution to the treatment of this puzzling and at times vexing condition.

Working party response:

We agree that PTSD is often a chronic condition without treatment (Section 2.3.7) and sometimes a chronic condition with treatment (see Section 2.5.1. Factors influencing treatment outcome, Section 2.5.2 Treatment goals and Section 4.1.9.6 Psychosocial rehabilitation recommendations).

An explicit statement about the rates of recovery with effective treatment has been added to Section 2.3.7 The course of PTSD

SUBMISSION 2

Section 2.5.2

Psychosocial rehabilitation is important as you indicate, and should be an essential component from the start.

Working party response:

No further comment required

Section 2.4.2

Where assessment is discussed on page 44 there is a need to identify past history and personal history more clearly, not just past trauma. Here and elsewhere physical health issues need to be integrated; from issues related to any injury arising from the incident to health behaviour change, to concurrent or developing physical health problems. This would also be relevant with respect to potential medications and the interaction of any pharmacotherapy etc with them.

Working party response:

Notes to this effect added to section 2.4.2 comprehensive assessment and section 4.1.5.5 Pharmacological treatments summary of evidence.

Section 2.4.4

The issue of bereavement complicating trauma, or trauma complicating bereavement, needs to be considered a bit more carefully. For instance the distress of trauma vs. separation distress, and the importance of mitigating traumatic aspects by supportive processes of viewing and saying goodbye to deceased, fulfilling critical religious rituals etc.

Working party response:

This issue is now addressed in section 2.4.4

Section 2.4.6

The issue of malingering is discussed. Prolonged symptoms may arise from many causes not just possible financial gain. Secondary gains related to the sick role may be much more powerful, as may other sources contributing to disability. It would be useful to mention these issues.

Working party response:

Discussion of these additional factors that may contribute to prolonged symptoms has been added to section 2.4.6.

Section 4.1.9.6.7

On page 166 [4.1.9.6.7.] it could be useful to mention post traumatic growth.

Working party response:

Mention of posttraumatic growth has been added here and included in the glossary.

Section 4.1.11.5

On page 174 where depression and comorbidity with PTSD are discussed it would be useful to mention the potential suicide risk in the first paragraph, as this is an urgent component of assessment and can be present whether or not the depression is there, and or obvious. Safety assessment is also a key component elsewhere.

Working party response:

Note made to this effect in section 4.1.11.5.

Section 7

The summaries of the literature are very useful at the end of each section before the recommendations and in general are put together in a positive and valuable way.

Working party response:

No further comment required

Section 7

With respect to the specific population sections it should be emphasised that these sections each represent broad comment.

Working party response:

“broad comment” noted in introductory paragraph.

Section 7.3

I am surprised that there was not more comment on the Military and Emergency Services etc.

Working party response:

No further comment required

Section 7.7 and 7.8

It should be reiterated for disaster and terrorism however that these are not guidelines to apply and that there is a national consensus process through the National Mental Health Disaster Response Committee which informs planning, preparation, rescue and response as well as the recovery period in terms of mental health. I could provide brief comment on this for both those sections if you wish, because as they stand they do not represent Australian guidelines for the structure of response in which PTSD sits. However I realise detail may not be appropriate so just some indication of the process would be helpful. As there is extensive Australian research, but little on intervention there is not a strong evidence base, although some useful work from other settings or in process. I am not suggesting that this detail should be included, but there is clear evidence of PTSD appearing after natural and other disasters. It is also an issue to be addressed with terrorism where it could also be advised that the issues of a coordinated response are considered.

Working party response:

Note to this effect is made in the introduction to natural disasters and terrorism sections with reference source provided.

SUBMISSION 3

Section 7.2

Working with interpreters. I think more comprehensive attention should be given to the issue of working with interpreters.

- Perceptions of confidentiality. In small migrant communities, interpreters are frequently educated members of a small community, often community leaders. Clients may perceive their confidentiality is compromised by disclosures made through known members of their own community.
- Interpreter Training. Interpreters need to understand the rationale, aims and strategies involved, particularly in Imaginal Exposure techniques, so that Therapist response to the client is not compromised.
- Vicarious traumatization of Interpreter. There is the possibility that the client experience may reflect the interpreter's experience. Interpreter may be traumatized by participation in the telling of client's narrative.

Reference: Lipton, G., Arends, M., Bastian, K., Wright, B. and O'Hara, P. (2002). The Psychosocial Consequences Experienced by Interpreters in Relation to Working with Torture and Trauma Clients: A West Australian Pilot Study.

<http://www.mmha.org.au/MMHAPublications/Synergy/2002Winter/PsychosocialConsequencesInterpreters>

Working party response:

These issues have been included in Section 7.2 and reference made to them, in Section 2.5.3 Cultural and linguistic diversity.

Psychological Research, and in particular, research in Australia suggests very strongly that Australia's policies of mandatory detention and temporary refugee protection have adverse effects on asylum seekers' mental health. Both the experience of detention and the conditions of the temporary protection visa are implicated as predictors of PTSD in refugees in Australia. The prevalence of PTSD in detained refugees is alarmingly high. Steel and his colleagues (2004) found that 50% of children and 86% of adults in their study met the diagnostic criteria for PTSD.

Similarly in 2006, Steel and his colleagues (2006) reported extremely high incidence of PTSD in temporary visa holders.

Clinical experience of working with asylum seekers who have experienced immigration detention and who are holders of any form of temporary visa indicates that such people have much difficulty in engaging in therapy to address their trauma. Their trauma experience is prolonged and multi-faceted. They progress through a continuing passage of traumatizing experiences. Most have a history of pre-migration trauma, frequently, imprisonment and physical torture. Their flight to safety has been difficult, dangerous and traumatizing. The fact of detention in penal-like institutions is traumatic. Nested within that are the traumatizing experiences that Steel and his colleagues list (Steel et al, 2004). The limitations of the temporary visas (reduced access to settlement services and welfare benefits) cause severe distress to many. Some visa conditions do not allow the visa holder to work, to access welfare support or to access a Medicare card, conditions which provoke extreme levels of anxiety. During their time as temporary visa holders, they face further traumatic events – The interviews to apply for permanent protection, the frequent rejections of their application, the appeals to the Refugee Review tribunal and other courts of appeal. Clinical interviews also indicate that the trauma experienced by temporary visa holders is not consigned to past experiences but pervades their present lives and their futures. Many report that their intense intrusive and disturbing thoughts and nightmares are about being arrested by detention guards and returned to detention or being deported – they experience 'flash-forwards.' McInerney and Kaye (2006) argue that standard diagnostic categories and individual therapy in these conditions may be inadequate to address these complexities that have such a devastating impact on asylum seekers' lives.

References

McInerney, D. and Kaye, J. (2006). Asylum Seekers, therapy and ethics. *Critical Psychology* 2006; 16: 166 – 179.

Steel, Z., Momartin, S., Bateman, C., Hafshejani, A., Silove, D., Everson, N., Roy, K., Dudley, M., Newman, L., Blick, B. and Mares, S. (2004). Psychiatric status of asylum seeker families held for a protracted period in a remote detention centre in Australia. *Aust. NZ J Public Health* 2004; 28 (6): 23 – 32.

Steel, Z., Silove, d., Brooks, R., Momartin, S., Alzuhairi, B. and Susljik, I. (2006) Impact of immigration detention and temporary protection on the mental health of refugees. *British Journal of Psychiatry* 2006: 188: 58 – 64.

Working party response:

These issues and references have been included in Section 7.2

SUBMISSION 4

Section 7.2

1. The limited evidence-base in the field both for direct clinical trauma work and more general psychosocial interventions.
2. The recent evidence from the IRCT published (from memory) in the Journal of Nervous and Mental Disease about fairly mixed outcomes in a naturalistic follow-up of refugees with traumatic stress in a clinic in Copenhagen - presumably who received multimodal sorts of interventions.
3. Growing but as yet small number of studies suggesting that culturally-adapted CBT (including exposure) may be effective for refugees with trauma-related disorders (four studies we have discussed),
4. The need to define more clearly who needs specific psychological (specifically CBT) interventions and/or pharmacological interventions over and above the general psychosocial assistance and counselling that is given in contemporary programs provided by torture and trauma services.

Working party response:

Points 1, 3 and 4 have been included. The paper cited in point 2 found poor outcomes for refugees following a routine rehabilitation program (psychotherapy, physiotherapy, social counselling and medical help). However it was published after the cut-off for the systematic review and has not been included.

SUBMISSION 5

Section 7.4

I was wondering if the special population group titled Motor Vehicle Accidents should be extended to Injury populations. The rationale for this is that most of the studies that have examined MVA samples have recruited from hospitals (hence have been injured). That is, I suggest that the MVA group is a subset of the larger injury group. By making Injury as a special population (rather than MVA) would increase the amount of published data available to review.

Working party response:

The section has been relabeled Motor Vehicle Accident and other injury survivors, but to retain its relevance to MVA survivors without serious injury, explicit reference to MVA survivors with soft tissue injuries added

Appendix F Evidence tables

Explanatory Notes for the evidence tables used for individual study data extraction are provided below.

STUDY DETAILS

Enter the following details into the table as indicated:

- [1] Full reference citation details
- [2] Details of how the study was funded or other relevant affiliations of the authors (designed to expose potential conflicts of interest, such as drug company funding for the drug being trialed)
- [3] The study type (eg RCT, case-control study, cohort study), with additional detail where relevant
- [4] As per the NHMRC levels of evidence, provided at pg-8 of the NHMRC toolkit publication: How to use the evidence: assessment and application of scientific evidence
- [5] Country/setting (eg hospital, primary care, hospice)
- [6] Provide detail on the intervention. This will generally be a therapeutic procedure such as treatment with a pharmaceutical agent, surgery, a dietary supplement, a dietary change or psychotherapy. Some other interventions are less obviously categorised as interventions, such as early detection (screening) and patient educational materials. The key characteristic is that a person or their environment is manipulated in the hope of benefiting that person or reducing harm. Particular reference should be made to any differences from Australian current practice.
- [7] Number of participants enrolled in the intervention/treatment group
- [8] The intervention (eg drug, therapy, placebo) used as a comparison in the study. There may be more than one comparator. Particular reference should be made to any differences from Australian current practice.
- [9] Number of participants enrolled in the comparison/control group(s)
- [10] Any factors that may confound/influence the results and/or the external validity (see below) of the results (eg age, sex, comorbidities, obesity, existing medications, previous surgery)
- [11] Length of follow-up of the participants
- [12] The outcomes studied (list all outcomes in terms of primary and secondary outcomes). Indicate which outcomes are relevant to the review/guidelines inclusion criteria

INTERNAL VALIDITY (QUALITY ASSESSMENT)

Enter the following details about the study:

- [13] The method used to assign patients to treatment or control groups (eg coin toss, random number table, computer-generated random numbers, sealed envelopes). Also indicate whether the allocation list was concealed (eg computerised random number generation, administered from a central trial office, assigned locally)
- [14] The results of the group analysis, noting any clinically or statistically significant differences between the groups at study inception
- [15] Whether the participants, outcome assessors and (if different) investigators were blinded to the group allocation
- [16] Indicate whether, aside from the experimental treatment, the groups were treated and measured the same
- [17] The proportion of participants that were followed up and whether all participants were analysed according to the group to which they were initially allocated, regardless of whether or not they dropped out, fully complied with the treatment, or crossed over and received the other treatment ('intention to treat analysis' - ITT)

[18] Describe your assessment (in words) of the overall quality of the study. Is the study quality good enough that you have confidence in the results?

RESULTS

Allowing one row for each relevant outcome, enter the following data from the results of the trial:

[19] The outcome relevant for this entry in the database (Note: more than one table may be required if there are several outcomes relevant to different clinical questions/guidelines)

[20] For binary outcomes, show numbers of patients with the outcome. For continuous outcomes, show means \pm standard deviations; or medians and interquartile ranges

[21] For binary outcomes, show numbers of patients with the outcome. For continuous outcomes, show means \pm standard deviations; or medians and interquartile ranges. Add number of columns as needed (eg 3-arm trials)

[22] Absolute and relative measures of effect and measure of variability eg risk differences (absolute risk reduction or absolute risk increase), mean differences, relative risk, odds ratio

[23] A measure of benefit, when the treatment increases the probability of a good event. The number needed to treat to benefit (NNT) = the number of participants who must receive the treatment to create one additional improved outcome in comparison with the control treatment; calculated as $1/\text{absolute benefit increase}$, rounded up to the next highest whole number

[24] A measure of harm, when the treatment increases the risk of specified adverse outcomes of a condition or reduces the probability of a good event. The number needed to treat to harm (NNH) = the number of patients who, if they receive the treatment, would lead to one additional person being harmed compared with patients who receive the control treatment; calculated as $1/\text{absolute risk increase}$, rounded up to the next highest whole number

[25] 95% confidence interval (CI) for all measures, if available, otherwise use P-value (be explicit on what comparison the P-value relates to)

[26] Insert the words corresponding to the appropriate rating from the scale provided at pg-23 of the NHMRC toolkit publication: *How to use the evidence: assessment and application of scientific evidence*

[27] Insert the words corresponding to the appropriate rating from the scale provided at pg-28 of the NHMRC toolkit publication: *How to use the evidence: assessment and application of scientific evidence*

[28] Information on any adverse events mentioned in the study

EXTERNAL VALIDITY

Include a brief discussion of the following questions:

[29] Are the patients in the study so different from those being considered for the guideline that the results may not be applicable to them?

[30] Will the potential benefits outweigh any potential harms of treatment in the guideline population?

[31] Add your overall comments regarding the interpretation or implications of this study

Question 1

STUDY DETAILS				
Reference [1] (Gamble, 2005)				
Affiliation/source of funds [2] Queensland Nursing Council and scholarship from Faculty of Nursing & Health, Griffith University, Qld, Australia				
Study design [3] Randomised controlled trial	Level of evidence [4] II	Location/setting [5] Antenatal clinics in 3 maternity hospitals in Brisbane, Qld, Australia		
Intervention [6] Counselling integrating elements of Critical Incident Stress debriefing (CISD)		Comparator(s) [8] Standard postnatal care		
Sample size [7] 50		Sample size [9] 53		
Population characteristics [10] Women who experienced traumatic childbirth Intervention group – as above Comparator group(s) – as above				
Length of follow-up [11] 3 months		Outcome(s) measured [12] PTSD, depression (measured by EPDS), depression (measured by DASS), anxiety (measured by DASS), stress (measured by DASS)		
INTERNAL VALIDITY				
Allocation [13] Computer randomised and sealed opaque envelopes	Comparison of study groups [14] No significant differences at inception	Blinding [15] Follow-up assessor was blinded, counsellor was not	Treatment/ measurement bias [16] Minimal difference	Follow-up (ITT) [17] 102/103 patients minimum
Overall quality assessment (descriptive) [18] Was not double-blind due to method of intervention, but overall a good study				
RESULTS				
Outcome [19]	Intervention group [20]	Control group [21]	Measure of effect/effect size [22] RR (95% CI) [25]	Benefits (NNT) [23] 95% CI [25]
PTSD at 4-6 wks	17/49	16/53	1.15 (0.66, 2.02)	
PTSD at 3 mo	3/50	9/53	0.35 (0.10, 1.23)	
EPDS score >12 at 4-6 wks	16/50	18/50	0.96 (0.56, 1.67)	
EPDS score >12 at 3 mo	4/50	17/53	0.25 (0.09, 0.69)	4 (3,11)
DASS-depression (>13) at 3 mo	3/50	14/53	0.23 (0.07, 0.76)	5 (3,15)
DASS-anxiety (>9) at 3 mo	1/50	6/53	0.18 (0.02, 1.45)	-
DASS-stress (>19) at 3 mo	7/50	17/53	0.46 (0.20, 0.96)	6 (3,44)
		Clinical importance (1-4) [26] 4		Relevance (1-5) [27] 1 (patient-relevant outcomes)
Any other adverse effects [28] None listed				
EXTERNAL VALIDITY				

Generalisability [29] High
Applicability [30] High
Comments [31] Australian based study that shows positive benefits of single face-to-face counselling session

Question 2

STUDY DETAILS				
Reference [1] Bryant 2005				
Affiliation/source of funds [2] School of Psychology, University of New South Wales, Sydney, Australia/ supported by the National Health and Medical Research Council				
Study design [3] Randomised controlled trial	Level of evidence [4] II		Location/setting [5] Patients referred to the Westmead Hospital PTSD Unit	
Intervention [6] Cognitive behavioural therapy		Comparator [8] Supportive counselling		
Sample size [7] 33		Sample size [9] 24		
Population characteristics [10] Civilian trauma survivors following nonsexual assault or motor vehicle accident who met the criteria for ASD . Intervention group – as above Comparator group(s) – as above				
Length of follow-up [11] 6 months		Outcome(s) measured [12] CAPS-2 Intensity, CAPS-2 Frequency, IES-Intrusion, IES-Avoidance, BAI, Beck Depression Inventory		
INTERNAL VALIDITY				
Allocation [13] Process of minimisation stratified on gender, trauma types and ASDI total score using a random numbers system. Each month the key researcher amended allocation to ensure that gender, trauma type, and PTSD severity were balanced across groups.	Comparison of study groups [14] No differences in age, time since trauma, National Adult Reading Test, Stanford Hypnotic Susceptibility Scale, Acute Stress Disorder Scale.	Blinding [15] Clinicians who conducted assessments did not have access to a) participant notes, b) treatment allocation of participants, or c) supervision discussion of therapy sessions.	Treatment/ measurement bias [16] No other differences in treatment apart from the interventions were apparent. Two independent clinicians conducted 20% of initial ASD assessments with interrater reliability of 100%.	Follow-up (ITT) [17] 6 months 9/33 of the CBT and 2/24 of the supportive counselling groups dropped out.
Overall quality assessment (descriptive) [18]. The study had similar populations in the two interventions, although blinding of patients was not possible. Full randomisation did not occur and lack of allocation concealment means bias in patient allocation was possible.				
RESULTS				
Outcome [19]	Intervention group [20] CBT	Control group [21] Supportive counselling	Measure of effect size [22] 95% CI [25]	NR*

PTSD ITT				
Posttreatment	36%	50%		
Follow-up	42%	58%		
<u>Treatment completer</u>				
Posttreatment	13%	46%		
Follow-up	21%	59%		
Total IES <12				
ITT				
Follow-up	24%	12%		
<u>Treatment completer</u>				
Follow-up	33%	13%		
	Clinical importance (1-4) [26] 2- some clinically important differences		Relevance (1-5) [27] 1- patient relevant outcomes	
Any other adverse effects [28] No adverse events reported.				
EXTERNAL VALIDITY				
Generalisability [29] The study population is from Australia and relevant to the wider Australian population.				
Applicability [30] Some benefits and no harms were reported in the study.				
Comments [31] Used MANCOVA analysis for both ITT and completer data on CAPs-2 intensity, CAPS-2 frequency, IES-Intrusion, IES-Avoidance, BAI and Beck depression inventory-2 for posttreatment and follow-up scores that controlled for initial symptom severity and trauma type. Hence, simple before-after within scale p values or comparisons were not reported.				

*NR=not relevant because only continuous data is reported

Question 3

STUDY DETAILS		
Reference [1] (Basoglu, 2005)		
Affiliation/source of funds [2] The researchers were based at the Section of Trauma Studies, Institute of Psychiatry, King's College, University of London, London, England. Also at the Istanbul Center for Behavior Research and Therapy (ICBRT), Istanbul, Turkey.		
Study design [3] Randomised controlled trial	Level of evidence [4] II	Location/setting [5] Two housing sites set up after the earthquake that occurred in Turkey on August 17, 1999.
Intervention [6] Single-session modified behaviour treatment (SSBT) based on CBT-explanation of treatment rationale, focusing on reduction of fear and avoidance, shifting focus from habituation to anxiogenic stimuli to enhancement of sense of control over traumatic stressors	Comparator(s) [8] Waiting list (WL)	Sample size [9] 28
Sample size [7] 31	Population characteristics [10] Earthquake victims with PTSD (N = 59). The mean time since the earthquake was 3 years (<i>SD</i> = 0.3) at first assessment. Mean age 36.3 (<i>SD</i> 11.5). 50 (84.7%) female, 9 (15.3%) male. Exclusion criteria – drug or alcohol dependence, severe depression with suicidal intent, psychotic illness, predominating grief, use of benzodiazepines, use of a stable dose of antidepressants for less than 2 months at the time of assessment, and previous CBT for earth-quake related traumatic stress.	
Intervention group – as above		
Comparator group(s) – as above		
Length of follow-up [11] 6 weeks	Outcome(s) measured [12] Clinician-Administered PTSD Scale (CAPS), Fear and Avoidance Questionnaire (FAQ), Beck Depression Inventory (BDI), Work and Social Adjustment Scale (WSA)	
INTERNAL VALIDITY		

<p>on [13] Random allocation conducted according to a computer-generated randomisation list. Blocking was used to ensure approximately equal cell sizes. The participants were recruited into the study by four independent assessors, who did not have access to the random assignment schedule. The latter was implemented by the project coordinator (E.S.), who did not take part in the assessments at any stage during the trial.</p>	<p>Comparison of study groups [14] The treatment conditions were similar in every baseline variable except gender; there were fewer men in the WL condition, $\chi^2(1, N=59)=4.04, p<.05$. In total, 50 (84.7%) of the participants were female. According to the researchers, this reflected the fact that the rates of PTSD in the community were three times higher in women than in men. In addition, recruitment was conducted in daytime, when most men were at work.</p>	<p>Blinding [15] The outcome assessors were blinded. However, 11 (19%) participants revealed their treatment condition. Also, when the outcome assessors were tested, they were able to guess the treatment condition correctly 83.3-88.5% of the time.</p>	<p>Treatment/ measurement bias [16] No difference in treatment aside from type of intervention was reported.</p>	<p>Follow-up (ITT) [17] <i>6 weeks</i> 10 participants were lost to the first assessment after trial entry. The breakdown of these 10 participants across treatment group was not mentioned.</p>
<p>Overall quality assessment (descriptive) [18] 1a, 2c, 3c (blinding done but as outlined above, not achieved) 4a.- average quality</p>				
<p>RESULTS</p>				
<p>Outcome [19]</p>	<p>Intervention group [20] SSBT</p>	<p>Control group [21] WL</p>	<p>Measure of effect/effect size [22]</p>	
<p><u>CAPS</u> <u>Treatment Completer</u> Pretreatment Posttreatment <u>FAQ</u> <u>Treatment Completer</u> Pretreatment Posttreatment <u>BDI</u> <u>Treatment Completer</u> Pretreatment Posttreatment <u>WSA</u> <u>Treatment Completer</u> Pretreatment Posttreatment</p>	<p>67.8 (SD 16.5) 44.4 (SD 25.0) 58.3 (SD 19.7) 32.7 (SD 24.5) 22.0 (SD 9.8) 15.1 (SD 11.4) 3.9 (SD 1.9) 2.4 (SD 2.4)</p>	<p>60.5 (SD 14.1) 54.7 (SD 21.4) 59.4 (SD 18.1) 48.7 (SD 18.) 18.6 (SD 8.8) 16.1 (SD 9.5) 3.2 (SD 1.9) 2.7 (SD 1.6)</p>	<p> F(1,57)=14.0, p<.001 F(1,57)=8.7, p<.01 F(1,57)=4.8, p<.05 F(1,57)=4.0, p<.05</p>	

	<p>Clinical importance (1-4) [26] 1 A clinically important benefit for the full range of plausible estimates for CAPS (primary outcome) and FAQ outcomes. Effect for BDI and WSA outcomes statistically significant but not clinically important</p>	<p>Relevance (1-5) [27] 1 Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.</p>
<p>Any other adverse effects [28] No adverse events reported.</p>		
<p>EXTERNAL VALIDITY</p>		
<p>Generalisability [29] The study population were Turkish earthquake survivors. The findings may be applicable to an Australian population.</p>		
<p>Applicability [30] Some benefits and no harms were reported in this study.</p>		
<p>Comments [31]</p>		

STUDY DETAILS																	
Reference [1] (Ehlers, 2005)																	
Affiliation/source of funds [2] The researchers were based at the Department of Psychology, King's College London, London, UK. Also at the Department of Psychiatry, Oxford University, UK.																	
Study design [3] Randomised controlled trial.	Level of evidence [4] II	Location/setting [5] Outpatient clinic-consecutive referrals London, UK															
Intervention [6] Cognitive therapy (CT) - modify excessively negative appraisals of the trauma and its sequelae, imaginal exposure, cognitive restructuring, wide range of behavioural and cognitive maintaining strategies Sample size [7] 14	Comparator(s) [8] Waiting list (WL) Sample size [9] 14																
Population characteristics [10] PTSD diagnosed by DSM-IV (SCID), 18-65 years, PTSD linked to discrete traumatic event in adulthood, time since trauma >6 months. Exclusion criteria - unconsciousness for >15 minutes or no memory of trauma, history of psychosis, current alcohol or drug dependence, borderline personality disorder, severe depression needing immediate treatment, assessment and treatment could not be conducted without interpreter.																	
<table style="width: 100%; border: none;"> <thead> <tr> <th style="text-align: left;"><u>Sample characteristics</u></th> <th style="text-align: left;"><u>Comorbidities</u></th> <th style="text-align: left;">(%)</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>28</td> <td>Anxiety Disorder 20</td> </tr> <tr> <td>Mean age</td> <td>36.6</td> <td>Current depression 20</td> </tr> <tr> <td>% male</td> <td>46.4</td> <td>Past depression 15</td> </tr> <tr> <td></td> <td></td> <td>Dysthymia 5</td> </tr> </tbody> </table>			<u>Sample characteristics</u>	<u>Comorbidities</u>	(%)	N	28	Anxiety Disorder 20	Mean age	36.6	Current depression 20	% male	46.4	Past depression 15			Dysthymia 5
<u>Sample characteristics</u>	<u>Comorbidities</u>	(%)															
N	28	Anxiety Disorder 20															
Mean age	36.6	Current depression 20															
% male	46.4	Past depression 15															
		Dysthymia 5															
Intervention group – as above																	
Comparator group(s) – as above																	
Length of follow-up [11] 3 months for waitlist 6 months for intervention group	Outcome(s) measured [12] <u>Primary</u> • PTSD symptoms (Posttraumatic Diagnostic Scale (PDS), Clinician Administered PTSD Scale (CAPS-SX)) <u>Secondary</u> • Functioning (Sheehan Disability Scale, CAPS-SX) • Depression (BDI) • Anxiety (BAI)																
INTERNAL VALIDITY																	

<p>on [13] Random allocation, though method not stated.</p>	<p>Comparison of study groups [14] The treatment groups were comparable in demographic characteristics (including gender, age, type of traumatic event, time in months since traumatic event, marital status, education, exams passed, current employment, profession) and trauma characteristics (SCID ratings for severity of PTSD). Self-reported symptom severity was also similar on all measures. However, independent assessors rated the CT group as more severe on the CAPS-SX, CAPS-frequency ($F(1, 26)=10.55, p=.003$), CAPS-intensity ($F(1,26)=4.92, p=.036$) and overall CAPS-severity ($F(1,26)=10.55, p=.008$). There was also a trend for a greater proportion of patients with comorbid anxiety disorders in the CT group, 4 (43%) vs 2 (14%), $\chi^2(1,28), p=.094$. Seven of the CT patients (50%) and 4 of the waitlist patients (29%) met diagnostic criteria for current major depression, and further 4 (29%) of the CT patients and 3 (21%) of the waitlist patients reported a history of major depression.</p>	<p>Blinding [15] Independent assessors (trained psychologists) who were not aware of the treatment condition gave the CAPS-SX. The remaining questionnaires were self-report and details were not given as to whether the assessors that administered them were blinded.</p>	<p>Treatment/measurement bias [16] No difference apart from type of intervention was apparent.</p>	<p>Follow-up (ITT) [17] No patient dropped out.</p>
<p>Overall quality assessment (descriptive) [18] Average quality Assignment c Selection bias a Blinding b Outcome a</p>				
<p>RESULTS</p>				
<p>Outcome [19]</p>	<p>Intervention group [20] CT</p>	<p>Control group [21] WL</p>	<p>Measure of effect/effect size [22]</p>	
<p><u>PDS (original scale)</u> Pretreatment 3 month follow-up <u>PDS (distress scale)</u> Pretreatment 3 month follow-up <u>CAPS (frequency)</u> Pretreatment 3 month follow-up</p>	<p>32.4 (SD 6.5) 10.3 (SD 8.9) 33.8 (SD 7.1) 9.7 (SD 10.1) 42.0 (SD 8.5) 16.0 (SD 15.3) 11.4 adj. M*</p>	<p>31.2 (SD 6.3) 29.8 (SD 8.4) 34.4 (SD 7.1) 30.5 (SD 9.3) 31.6 (SD 8.4) 35.5 (SD 11.4) 34.2 adj. M*</p>	<p>p<.0005 p<.0005 p<0.0005 *as there was a significant baseline difference between the CT and the waitlist on the CAPS, adjusted means were reported at 3 months</p>	

<u>CAPS (intensity)</u> Pretreatment 3 month follow-up	36.5 (SD 9.4) 13.7 (SD 13.4) 10.4 adj. M*	29.0 (SD 8.5) 30.9 (SD 9.6) 34.2 adj. M*	p<.0005 * as there was a significant baseline difference between the CT and the waitlist on the CAPS, adjusted means were reported at 3 months)
<u>Sheehan Disability Scale</u> Pretreatment 3 month follow-up 6 month follow-up	7.6 (SD 1.9) 3.0 (SD 2.6)	6.7 (SD 1.9) 6.3 (SD 1.8)	p<.0005
<u>Disability (CAPS)</u> Pretreatment 3 month follow-up	3.1 (SD 0.6) 1.4 (SD 1.1)	2.4 (SD 0.6) 2.5 (SD 0.7)	p<.0005
<u>BDI</u> Pretreatment 3 month follow-up	23.7 (SD 9.0) 10.6 (SD 8.6)	23.2 (SD 8.0) 19.3 (SD 7.2)	p=.003
<u>BAI</u> Pretreatment 3 month follow-up	24.1 (SD 11.1) 8.2 (SD 10.8)	19.2 (SD 7.2) 21.2 (SD 11.2)	P<.0005
Clinical importance (1-4) [26] 1 A clinically important benefit for the full range of plausible estimates for the primary outcomes	Relevance (1-5) [27] 1 Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.		
Any other adverse effects [28] No adverse events reported.			
EXTERNAL VALIDITY			
Generalisability [29] The study population were civilian trauma survivors recruited from referrals from General Practitioners and Community Mental Health teams. The findings may be generalisable to the wider Australian civilian trauma survivor population.			
Applicability [30] Some benefit and no harms were reported in this study.			
Comments [31]			

STUDY DETAILS				
Reference [1] Kubany (2004)				
Affiliation/source of funds [2] Researchers based at National Center for Posttraumatic Stress Disorder, Dept of Veterans Affairs, Honolulu, Hawaii				
Supported by a grant from the TriService Nursing Research Group, Department of Defenses				
Study design [3] Randomised controlled trial	Level of evidence [4] II		Location/setting [5] Outpatient clinic. Referred from victim services agency.	
Intervention [6] Cognitive trauma therapy for battered women (CTT-BW) including trauma history exploration, PTSD education, stress management, exposure to abuse and abuser reminders, self-monitoring of negative talk, cognitive therapy for guilt, modules on self-advocacy, assertiveness and how to identify perpetrators Twice weekly sessions, individual format, 8-11 sessions Sample size [7] 63			Comparator(s) [8] Waiting list Sample size [9] 62	
Population characteristics [10] Met criteria for partner abuse-related PTSD, had been out of abusive relationship for 30 days and no intention of reconciling, had not been physically or sexually abused or stalked by anyone for at least 30 days. Exclusion criteria - Currently abusing alcohol or drugs. Have schizophrenia or bipolar disorder. Age range=18-70, mean=42.2±10.1 Intervention group –as above Comparator group(s) –as above				
Length of follow-up [11] 6 weeks		Outcome(s) measured [12] PTSD symptoms (CAPS) Depression (BDI)		
INTERNAL VALIDITY				
Selection [13] During initial screening, every 2 consecutive women determined to be eligible were randomly assigned either to one of the two treatment conditions.	Comparison of study groups [14] No differences in age, education, ethnicity, medication use, concomitant therapy, or number or types of traumatic events reported, were found.	Blinding [15] The assessors were blind to participant's allocation condition assignments, and none served as therapists in the study. (Note: In the articles it was clear that this procedure was followed for the CAPS. However, it was unsure whether this procedure was followed in the other outcome assessments.)	Treatment/ measurement bias [16] No differences apart from type of intervention were apparent.	Follow-up (ITT) [17] 14/125 who passed the initial phone interview did not qualify for participation on the basis of the full assessment. 4/63 assigned to the CTT-BW condition dropped out before beginning treatment. 13/63 participation in the CTT-BW condition dropped out before completing treatment. 20/62 participating in the WL condition did not complete their second assessment.

Overall quality assessment (descriptive) [18] 1b, 2c, 3b, 4a. – average quality			
RESULTS			
Outcome [19]	Intervention group [20] CTT-BW	Control group [21] Waiting list	Measure of effect/effect size [22] 95% CI [25]
<u>CAPS</u> <u>ITT</u> Pretreatment Posttreatment	74.4 (SD 19.9) 33.3 (SD 32.8)	78.0 (SD 20.5) 74.1 (SD 21.9)	NS. M-W U = 0.85, p<.001 (two-tailed)
<u>Treatment Completer</u> Pretreatment Posttreatment	72.9 (SD 18.4) 15.8 (SD 14.4)	77.5 (SD 21.9) 71.9 (SD 23.8)	NS
<u>BDI</u> <u>ITT</u> Pretreatment Posttreatment	26.9 (SD 10.1) 12.0 (SD 14.2)	27.4 (SD 11.0) 28.7 (SD 10.5)	NS M-W U = 0.83, p<.001 (two-tailed)
<u>Treatment Completer</u> Pretreatment Posttreatment	25.1 (SD 8.9) 4.6 (SD 5.3)	25.3 (SD 10.8) 27.2 (SD 10.5)	NS
Clinical importance (1-4) [26] 1 A clinically important benefit for the full range of plausible estimates.		Relevance (1-5) [27] 1 Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.	
Any other adverse effects [28] No adverse events reported.			
EXTERNAL VALIDITY			
Generalisability [29] The sample of formerly battered women, referred by victim service agencies that serve battered women in Hawaii. The findings may be generalisable to victims of domestic violence and sexual abuse in Australia.			
Applicability [30] Some benefits and no harms were reported in this study.			
Comments [31]			

CAPS=Clinician Administered PTSD Scale; BDI=Beck Depression Inventory; ITT=intention-to-treat; SD=standard deviation; M-W U= Mann Whitney U-test; NS=not significant; WL=waitlist

STUDY DETAILS		
Reference [1] Lindauer (2005)		
Affiliation/source of funds [2] The researchers were based at the Academic Medical Centre, University of Amsterdam, at Graduate School Neurosciences, Amsterdam, at the Altrecht Institute for Mental Health Care, Utrecht, The Netherlands.		
Study design [3] RCT	Level of evidence [4] II	Location/setting [5] Outpatient clinic of the Academic Medical Centre, University of Amsterdam, The Netherlands
Intervention [6] Brief eclectic psychotherapy - single-session CBT (BEP) Sample size [7] 12	Comparator [8] Waitlist control (WL) Sample size [9] 12	
Population characteristics [10] Patients referred to the outpatient clinic of the Academic Medical Centre who satisfied the DSM-IV criteria as assessed by the SI-PTSD. Exclusion criteria – any current or past organic mental disorder, psychotic disorder, psychoactive substance use disorder, moderate and severe major depression, non-PTSD anxiety disorders and severe dissociative disorders. Further exclusion criteria were the use of psychiatric medication and language mastery problems. Intervention group – as above Comparator group(s) – as above		
Length of follow-up [11] 2 weeks after completion of treatment	Outcome(s) measured [12] Structured Interview for PTSD (SI-PTSD), Hospital Anxiety and Depression Scale (HADS), Structured Clinical Interview for DSM-IV (SCID-IV)	
INTERNAL VALIDITY		

<p>Allocation [13] A colleague who had done no assessments used a computer program to randomly assign 12 patients to each condition in a block design.</p>	<p>Comparison of study groups [14] No statistically significant differences between treatment groups were found with regards to age, years of education, years since trauma, number of prior traumas, rates of traumas attributed to interpersonal violence or to accident/disaster, gender, civil status, history of previous psychotherapy, comorbid mild major depression, change of work due to trauma, sick leave or relationship problems.</p> <p>However, upon further inspection of the baseline means, for the BEP condition an average of 2.7 (SD 2.5) years had occurred since the trauma, compared with an average of 6.1 (SD 9.4) years for the WL condition. 58.3% of the BEP participants were male, while 33.3% of the WL participants were male. 3/12 of the participants in the BEP condition showed comorbid mild major depression, compared with 0/12 in the WL condition.</p>	<p>Blinding [15] Outcomes were assessed by a researcher that was blind to the patient's treatment group.</p>	<p>Treatment/measurement bias [16] No differences in treatment apart from type of intervention were apparent. However, 2/12 participants in the BEP condition experienced a new physical threat during or shortly after the treatment and a re-emergence of DSM-IV PTSD symptoms before the post-test assessment.</p>	<p>Follow-up (ITT) [17] 1/12 from the WL condition was transferred to the treatment group because of work-related consequences. 2/12 from the BEP condition did not begin treatment for practical reasons – illness in family, work obligations. 3/12 left prematurely – 1/12 due to emigration, 1/12 whose PTSD had improved after imaginal exposure and 1/12 for whom imaginal exposure proved too difficult to endure. Hence 7/12 of the BEP participants and 1/12 WL participants dropped out before treatment completion. A further 3/12 in the BEP condition did not complete their posttreatment assessment.</p>
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Overall quality assessment (descriptive) [18].
1a, 2d 3b, 4a.- poor quality

RESULTS

Outcome [19]	Intervention group [20]	Control group [21]	Measure of effect size [22] 95% CI [25]
<p><u>SI-PTSD (Reexperiencing)</u> <u>ITT</u> Pre-test Post-test</p>	<p>3.4 (SD 0.9) 1.2 (SD 1.5)</p>	<p>3.9 (SD 0.8) 3.1 (SD 1.8)</p>	<p>F(1,22)=4.97, p<0.05</p>
<p><u>SI-PTSD (Avoidance)</u> <u>ITT</u> Pre-test Post-test</p>	<p>3.9 (SD 1.1) 1.6 (SD 2.2)</p>	<p>3.5 (SD 0.7) 3.2 (SD 1.7)</p>	<p>F(1,22)=3.60, not significant</p>
<p><u>SI-PTSD (Hyperarousal)</u> <u>ITT</u> Pre-test Post-test</p>	<p>3.8 (SD 0.9) 1.3 (SD 1.8)</p>	<p>3.8 (SD 1.0) 2.7 (SD 1.5)</p>	<p>F(1,22)=5.82, p<0.05</p>

<u>HADS (depressive subscore)</u>			
<u>ITT</u>			
Pre-test			
Post-test	11.8 (SD 4.3) 8.0 (SD 6.7)	9.0 (SD 3.5) 9.1 (SD 5.7)	F(1,22)=2.85, not significant
<u>HADS (anxiety subscore)</u>			
<u>ITT</u>			
Pre-test			
Post-test	13.1 (SD 3.2) 8.1 (SD 4.8)	11.3 (SD 3.3) 12.0 (SD 4.7)	F(1,22)=5.07, p<0.05
Clinical importance (1-4) [26] Unable to determine		Relevance (1-5) [27] 1 Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.	
Any other adverse effects [28] No adverse events reported.			
EXTERNAL VALIDITY			
Generalisability [29] The study population were civilian trauma survivors in the Netherlands. The findings may be generalisable to the wider Australian population.			
Applicability [30] Some benefits and no harms were reported in this study.			
Comments [31] Very small treatment group – only four participants completed the treatment and treatment outcome assessment.			

STUDY DETAILS		
Reference [1] Rothbaum (2005)		
Affiliation/source of funds [2] Not stated.		
Study design [3] Randomised controlled trial	Level of evidence [4] II	Location/setting [5] Not stated
Intervention [6] EMDR	Comparator(s) [8] Waiting list (WL)	
Sample size [7] 24	Sample size [9] 24	
<p>Population characteristics [10] Female victims of rape at least three months prior to study entry. The index must have been a rape in adulthood (age 12 or older) or a single incident of rape in childhood (ages 0-11) by either a family or non-family member. Participants were not excluded if they had other traumas including childhood sexual abuse. Rape was defined as any form of unwanted genital penetration including vaginal, anal, oral, and digital penetration. Fondling or touching through clothes were not included. Three participants who experienced life threatening events that included attempted rape without penetration as defined above were allowed to participate. If on psychotropic medication, participants were required to be stable on the medication at the same dosage for 30 days prior to study entry and to agree not to change medication or dosage for the duration of the study.</p> <p>Exclusion criteria included: History of schizophrenia or other psychoses; current suicidal risk or practiced self mutilation; illiterate and therefore unable to complete self-reports; current alcohol or drug dependence as determined by the SCID; blind or had a history of serious eye disease (e.g. detached retina) that would cause risk with rapid eye movement; use of cocaine in any form within 60 days of treatment administration; or in an ongoing threatening situation (e.g. domestic violence).</p> <p>Intervention group – as above</p> <p>Comparator group(s) – as above</p>		
Length of follow-up [11] Treatment length – 4-5 weeks	Outcome(s) measured [12] Clinician-Administered PTSD Scale (CAPS), Structured Clinical Interview for DSM-IV: Non-Patient Version (SCID), PTSD Symptom Scale Self-Report (PSS-SR), Impact of Event Scale-Revised (IES-R), Beck Depression Inventory (BDI), Dissociative Experiences Scale-II (DES-II), State-Trait Anxiety Inventory (STAI)	
INTERNAL VALIDITY		

on [13] Randomisation stated, though method not specified.	Comparison of study groups [14] No significant differences in age, ethnicity, marital status, number of children, employment, level of education or household income were found across treatment conditions.	Blinding [15] Blinding not mentioned.	Treatment/ measurement bias [16] No differences aside from type of intervention were apparent.	Follow-up (ITT) [17] Posttreatment 5/24 in the EMDR condition dropped out (4 before midpoint assessment). 4/24 in the WL condition dropped out.
Overall quality assessment (descriptive) [18] 1c, 2c, 3c (not mentioned), 4a				
RESULTS				
Outcome [19]	Intervention group [20] EMDR	Control group [21] WL	Measure of effect/effect size [22] 95% CI [25]	
CAPS SCID IV <u>Treatment completer</u> Posttreatment	In graphical format 5/20	In graphical format 18/20	RR 0.28 [95% CI 0.13 to 0.60] NNT 2 [95 % CI 1-2]	
IES-R	In graphical format	In graphical format		
PSS-SR	In graphical format	In graphical format		
<u>BDI</u> <u>Treatment Completer</u> Pretreatment Posttreatment	25.95 (SD 7.11) 10.70 (SD 11.45)	24.05(SD 10.50) 22.20(SD 10.55)		
<u>DES-II</u> <u>Treatment Completer</u> Pretreatment Posttreatment	18.68 (SD 12.67) 8.12 (SD 7.98)	12.53(SD 10.18) 12.36 (SD 8.51)		
<u>STAI-State</u> <u>Treatment Completer</u> Pretreatment Posttreatment	51.10 (SD 11.05) 32.60 (SD 11.62)	46.58(SD 13.48) 49.00(SD 13.73)		
<u>STAI-Trait</u> <u>Treatment Completer</u> Pretreatment Posttreatment	56.80 (SD 10.95) 41.10 (SD 14.48)	53.42(SD 13.07) 53.95(SD 13.01)		

Clinical importance (1-4) [26] 2	Relevance (1-5) [27] 1
Any other adverse effects [28] No	
EXTERNAL VALIDITY	
Generalisability [29] The results are likely to be generalisable to the PTSD population in Australia.	
Applicability [30] Some benefit and no harms were reported in this study.	
Comments [31]	

STUDY DETAILS				
Reference [1] Rothbaum (2005)				
Affiliation/source of funds [2] Not stated.				
Study design [3] Randomised controlled trial	Level of evidence [4] II	Location/setting [5] Not stated		
Intervention [6] Prolonged Exposure (PE)		Comparator(s) [8] Waiting list (WL)		
Sample size [7] 24		Sample size [9] 24		
<p>Population characteristics [10] Female victims of rape at least three months prior to study entry. The index must have been a rape in adulthood (age 12 or older) or a single incident of rape in childhood (ages 0-11) by either a family or non-family member. Participants were not excluded if they had other traumas including childhood sexual abuse. Rape was defined as any form of unwanted genital penetration including vaginal, anal, oral, and digital penetration. Fondling or touching through clothes were not included. Three participants who experienced life threatening events that included attempted rape without penetration as defined above were allowed to participate. If on psychotropic medication, participants were required to be stable on the medication at the same dosage for 30 days prior to study entry and to agree not to change medication or dosage for the duration of the study.</p> <p>Exclusion criteria included: History of schizophrenia or other psychoses; current suicidal risk or practiced self mutilation; illiterate and therefore unable to complete self-reports; current alcohol or drug dependence as determined by the SCID; blind or had a history of serious eye disease (e.g. detached retina) that would cause risk with rapid eye movement; use of cocaine in any form within 60 days of treatment administration; or in an ongoing threatening situation (e.g. domestic violence).</p> <p>Intervention group – as above</p> <p>Comparator group(s) – as above</p>				
Length of follow-up [11] Treatment length – 4-5 weeks		Outcome(s) measured [12] Clinician-Administered PTSD Scale (CAPS), Structured Clinical Interview for DSM-IV: Non-Patient Version (SCID), PTSD Symptom Scale Self-Report (PSS-SR), Impact of Event Scale-Revised (IES-R), Beck Depression Inventory (BDI), Dissociative Experiences Scale-II (DES-II), State-Trait Anxiety Inventory (STAI)		
INTERNAL VALIDITY				
Randomisation [13] Randomisation stated, though method not specified.	Comparison of study groups [14] No significant differences in age, ethnicity, marital status, number of children, employment, level of education or household income were found across treatment conditions.	Blinding [15] Blinding not mentioned.	Treatment/ measurement bias [16] No differences aside from type of intervention were apparent.	Follow-up (ITT) [17] Posttreatment 3/24 in the PE condition dropped out (2 before midpoint assessment). 4/24 in the WL condition dropped out.

Overall quality assessment (descriptive) [18] 1c, 2c, 3c (not mentioned), 4a						
RESULTS						
Outcome [19]	Intervention group [20] PE	Control group [21] WL	Measure of effect/effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25] Harms (NNH) [24] 95% CI [25]		
CAPS	In graphical format	In graphical format	RR 0.06 [95% CI 0.008 to 0.38]	NNT 1 [95 % CI 1-1]		
SCID-IV <u>Treatment completer</u> Posttreatment	1/20	18/20				
IES-R	In graphical format	In graphical format				
PSS-SR	In graphical format	In graphical format				
<u>BDI</u> <u>Treatment Completer</u> Pretreatment	16.70 (SD 8.18)	24.05(SD 10.50)				
Posttreatment	4.65 (SD 4.99)	22.20(SD 10.55)				
<u>DES-II</u> <u>Treatment Completer</u> Pretreatment	10.13 (SD 5.45)	12.53(SD 10.18)				
Posttreatment	4.84 (SD 4.65)	12.36 (SD 8.51)				
<u>STAI-State</u> <u>Treatment Completer</u> Pretreatment	43.33 (SD 12.59)	46.58(SD 13.48)				
Posttreatment	30.00 (SD 10.44)	49.00(SD 13.73)				
<u>STAI-Trait</u> <u>Treatment Completer</u> Pretreatment	48.72 (SD 8.62)	53.42(SD 13.07)				
Posttreatment	35.56 (SD 9.88)	53.95(SD 13.01)				
Clinical importance (1-4) [26] 2					Relevance (1-5) [27] 1	
Any other adverse effects [28] No						
EXTERNAL VALIDITY						
Generalisability [29] The results are likely to be generalisable to the PTSD population in Australia.						

Applicability [30] No harms were reported in this study.
Comments [31]

Question 4

STUDY DETAILS				
Reference [1] Blanchard (2004)				
Affiliation/source of funds [2] Supported by a grant from NIMH.				
Study design [3]: Randomised controlled trial	Level of evidence [4] II		Location/setting [5] Centre for stress and anxiety disorders, Albany, USA	
Intervention [6]: Cognitive behavioural therapy-CBT		Comparator(s) [8]: Supportive psychotherapy-SUPPORT		
Sample size [7] 28 patients		Sample size [9] 24 patients		
Population characteristics [10] Individual had been injured in a motor vehicle accident (MVA) & sought medical attention within 48 hrs of the MVA. There had to be at least 6 months but no more than 24 months had elapsed since the MVA and the individual met criteria for full PTSD or severe sub-syndromal PTSD. Intervention group –as above Comparator group(s) –as above				
Length of follow-up [11] One and two year follow-up		Outcome(s) measured [12] PTSD symptoms –CAPS, PTSD checklist-PCL, BDI, STAI-state, STAI-trait, Impact of event scale (IES)		
INTERNAL VALIDITY				
Randomisation [13] Not stated	Comparison of study groups [14] No differences were reported at baseline for treatment completers.	Blinding [15] Not stated	Treatment/ measurement bias [16] Appeared to be treated the same apart from the intervention.	Follow-up (ITT) [17] No ITT Follow-up on those who completed treatment
Overall quality assessment (descriptive) [18] The details of the study, such as randomisation, allocation concealment and blinding were not clearly stated. In addition no intention to treat analysis was carried out.				
RESULTS				
Outcome [19]	Intervention group [20] CBT	Control group [21] SUPPORT	Measure of effect/effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]

CAPS- 1 yr follow-up			Condition main effect: F[1,50]= 4.65 ^a p=0.036	Harms (NNH) [24] 95% CI [25] NC	
Pre treatment	64.4(24.0)	66.3(26.9)			
Posttreatment	23.2(26.1)	40.9(25.9)			
3 months follow-up	21.9(24.9)	40.0(30.3)			
12 months follow-up	21.3(28.4)	35.5(27.5)			
24 months follow-up	-	-			
CAPS- 2 yr follow-up					
Pre treatment	64.8(25.3)	64.4(29.6)			
Posttreatment	21.2(26.6)	41.2(29.0)			
3 months follow-up	-	-			
12 months follow-up	20.7(30.3)	33.3(24.7)			
24 months follow-up	20.1(25.0)	29.7(24.5)			
PTSD-1 yr follow-up					NS*
Pre treatment	52.1 (12.3)	56.3(14.4)			
Posttreatment	31.8(14.0)	44.2(13.9)			
3 months follow-up	33.1(13.1)	41.6(14.3)			
12 months follow-up	35.0(17.5)	39.2(14.9)			
24 months follow-up	-	-			
PTSD-2 yr follow-up					
Pre treatment	51.6(12.6)	55.7(14.9)			
Posttreatment	29.7(14.5)	45.5(15.7)			
3 months follow-up	-	-			
12 months follow-up	34.5(18.4)	39.6(15.3)			
24 months follow-up	30.6(14.3)	40.1(13.5)			
IES-1 yr follow-up			NS		
Pre treatment	38.1(13.7)	40.5(20.4)			
Posttreatment	13.1(15.3)	27.1(18.9)			
3 months follow-up	12.6(13.5)	24.3(19.6)			
12 months follow-up	14.2(17.5)	19.2(17.5)			
24 months follow-up	-	-			
IES-2 yr follow-up					
Pre treatment	38.2(11.3)	41.9(22.6)			
Posttreatment	13.0(16.9)	29.2(19.5)			
3 months follow-up	-	-			
12 months follow-up	14.2(18.0)	18.2(17.7)			
24 months follow-up	9.9(12.1)	22.1(19.0)			
BDI-1yr follow-up			p=0.07		
Pre treatment	22.8(11.4)	27.0(11.8)			
Posttreatment	11.8(12.6)	20.4(12.3)			
3 months follow-up	12.6(12.8)	18.8(13.4)			
12 months follow-up	13.8(14.2)	18.8(11.9)			
24 months follow-up	-	-			
BDI-2yr follow-up					
Pre treatment	22.8(12.2)	26.1(12.7)			
Posttreatment	11.5(13.1)	22.4(13.4)			
3 months follow-up	-	-			
12 months follow-up	14.6(15.7)	19.0(14.0)			
24 months follow-up	11.8(14.2)	17.4(15.0)			

STAI-state 1yr f up			Condition main effect F[1,50]=8.90 ^a p=0.004	
Pre treatment	53.9(14.0)	57.8(11.9)		
Posttreatment	39.5(13.1)	51.3(12.4)		
3 months follow-up	42.9(14.8)	50.9(14.6)		
12 months follow-up	38.0(12.3)	50.0(12.7)		
24 months follow-up	-	-		
STAI-state-2yr f up				
Pre treatment	55.8(15.5)	56.6(12.4)		
Posttreatment	38.4(14.1)	52.4(13.8)		
3 months follow-up	-	-		
12 months follow-up	38.0(13.7)	45.9(16.7)		
24 months follow-up	37.1(14.8)	45.9(16.7)		
STAI-trait 1yr f up			Condition main effect F[1,50]=3.98 ^a p=0.050	
Pre treatment	53.8(13.7)	56.4(10.1)		
Posttreatment	41.4(15.3)	52.3(11.6)		
3 months follow-up	41.6(14.7)	49.1(10.9)		
12 months follow-up	42.2(15.8)	49.4(12.9)		
24 months follow-up	-	-		
STAI-trait-2yr f up				
Pre treatment	53.3(15.2)	57.0(11.1)		
Posttreatment	40.1(16.8)	53.1(13.1)		
3 months follow-up	-	-		
12 months follow-up	41.5(17.9)	48.2(14.8)		
24 months follow-up	38.5(15.8)	46.8(17.0)		
	Clinical importance (1-4) [26] 2 The point estimate of the primary outcome (CAPs) is clinically important but the confidence interval includes clinically unimportant effects.		Relevance (1-5) [27] 1 Evidence of an effect on patient relevant clinical outcomes, including benefits and harms, and quality of life and survival.	
Any other adverse effects [28] Not stated				
EXTERNAL VALIDITY				
Generalisability [29]: The study population is relevant to MVA survivors in Australia.				
Applicability [30]: At the one year follow-up, CBT was more effective over SUPPORT for all outcome measures except BDI, which was not significantly different. The two year follow-up showed less significant effects of CBT over support however there was a 25% drop out rate which may have had an impact on the findings.				
Comments [31]				

*Not calculated because Blanchard et al (2004) only reported continuous data; NS=not significant

STUDY DETAILS				
Reference [1] McDonagh (2005)				
Affiliation/source of funds [2] National Institutes of Mental Health Grant and by the National Center for posttraumatic stress disorder.				
Study design [3] Randomised controlled trial-although process was changed when dropout for intervention group was higher.	Level of evidence [4] II		Location/setting [5]	
Intervention [6] Cognitive behavioural therapy (CBT) for 14 weeks	Comparator(s) [8] Present-centred therapy (PCT) for 14 weeks			
Sample size [7] 29 patients	Sample size [9] 22 patients			
Population characteristics [10] Women with histories of childhood sexual abuse (CSA) who met DMS-IV criteria for PTSD. Women needed one clear detailed memory of the CSA. Patients were excluded if they were pregnant, had used medication with significant autonomic nervous system effects, known cardiovascular disease, hypertension severe enough to require medication, current alcohol abuse, many many more???				
Intervention group –as above				
Comparator group(s) – as above				
Length of follow-up [11] Posttreatment, 3 months and 6 months	Outcome(s) measured [12] PTSD symptoms (CAPS), Depression (BDI), Anxiety (STAI), Quality of life (QOLI)			
INTERNAL VALIDITY				
Randomisation [13] Allocation concealment [14]	Comparison of study groups [14] No reported differences	Blinding [15] Outcome assessor was blinded	Treatment/ measurement bias [16] Appeared to be treated the same apart from the intervention.	Follow-up (ITT) [17] ITT was carried out as well as treatment completer analysis
Overall quality assessment (descriptive) [18] Proper randomisation did not occur and allocation concealment was unclear so there is a potential for bias in patient allocation. Despite this blinding was carried out and no differences were observed between groups.				
RESULTS				
Outcome [19]	Intervention group [20] CBT	Control group [21] PCT	Measure of effect/effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]
CAPS Pre-test Post-test	69.9 (SD 16.8) 53.1 (SD 28.8)	67.7 (SD 14.6) 47.2 (SD 22.4)	Effect sizes (ITT) CBT vs PCT: -0.22 Completer CBT vs PCT = 0.26	NC

BDI Pre-test Post-test	18.9 (SD 9.6) 12.9 (SD 12.5)	17.0 (SD 7.7) 10.8 (SD 9.5)	Effect sizes completer CBT vs PCT = 0.32	
QOLI Pre-test Post-test	36.1 (SD 15.9) 39.5 (SD 17.0)	35.2 (SD 15.3) 39.0 (SD 12.6)	NR	
STAI-state Pre-test Post-test	53.5 (SD 10.4) 46.2 (SD 13.9)	54.5 (SD 9.2) 46.4 (SD 12.2)	Effect sizes completer CBT vs PCT = 0.54	
		Clinical importance (1-4) [26] 3 The confidence interval does not include any clinically important effects	Relevance (1-5) [27] 1 Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival	
Any other adverse effects [28] None stated				
EXTERNAL VALIDITY				
Generalisability [29] The study population is relevant to childhood sexual abuse women in Australia.				
Applicability [30] CBT and PCT were both effective in reducing PTSD and anxiety symptom severity as well as reducing cognitive distortions. Therefore this study suggests that both treatments may be effective in treatment of CSA-related PTSD.				
Comments [31] Qulaity of life effect measure not reported because the pretreatment difference explained the effect rather than the treatment itself.				

NC=not calculated because all outcomes were represented by continuous data

STUDY DETAILS					
Reference [1] Marcus(2004) update of Marcus (1997)					
Affiliation/source of funds [2] Grant from Kaiser Permanente Kaiser Adult Psychiatry, Santa Clara					
Study design [3] Randomised controlled trial	Level of evidence [4] II		Location/setting [5] HMO psychiatric clinic (Health Maintenance Organisation) Santa Clara, California		
Intervention [6] EMDR 50 min sessions Sample size [7] : Not stated separately		Comparator(s) [8] Standard Care (Clinicians favoured method of treatment) 50 min sessions of individual psychotherapy, possible addition of 30-45 min medication visits or 90 min session group therapy Sample size [9]: Not stated separately			
Population characteristics [10] Intervention group – some taking medications Comparator group(s) – some taking medications					
Length of follow-up [11] 3 months and 6 months		Outcome(s) measured [12] Resolution of PTSD symptoms over time (PTSD scale) Depression (BDI), Anxiety (STAI) Functional improvement (SUD, Global assessment of functioning)			
INTERNAL VALIDITY					
Random assignment [13] Random assignment using block randomisation with blocks of four to either SC or EMDR	Comparison of study groups [14] Not reported but appears to differ in some of the post-test results	Blinding [15] Independent evaluator assessed and conducted interviews.	Treatment/ measurement bias [16] Appeared to be treated the same apart from the intervention.	Follow-up (ITT) [17] 44 (66% of original study) at 3 months 36 (54% % of original study) at 6 months	
Overall quality assessment (descriptive) [18] Randomisation was adequate and although study was not blinded due to interventions, the interviewer was independent to treatment allocation.					
RESULTS					
Outcome [19]	Intervention group [20]	Control group [21]	Measure of effect/effect size [22]		Benefits (NNT) [23] 95% CI [25]
	EMDR	SC	95% CI [25]		Harms (NNH) [24] 95% CI [25]
PTSD scale			EMDR	SC	NC
Post-test	24.50 (SD 21.30)	44.26(SD 30.02)	2.03*	1.13*	
3 months	17.25 (SD 21.08)	42.21(SD 27.19)	0.34*	0.07*	
6 months	15.95 (SD 17.79)	43.50(SD 35.12)	0.44*	0.02*	

BDI					NC
Post-test	8.36 (SD 8.31)	15.29(SD 12.86)	1.32*	0.47*	
3 months	8.10 (SD 10.39)	14.42(SD 11.35)	0.03*	0.07*	
6 months	6.90 (SD 8.79)	17.93(SD 16.06)	0.17*	-0.18*	
STAI-trait					NC
Post-test	38.08 (SD 11.19)	47.77(SD 13.43)	1.19*	0.59*	
3 months	34.72 (SD 13.66)	44.11(SD 12.31)	0.27*	0.28*	
6 months	33.59 (SD 11.61)	46.78(SD 16.23)	0.39*	0.07*	
STAI-state					NC
Post-test	38.04 (SD 15.15)	45.61(SD 14.78)	1.05*	0.67*	
3 months	34.79 (SD 14.29)	41.05(SD 14.56)	0.22*	0.31*	
6 months	31.68 (SD 12.14)	43.73(SD16.76)	0.46*	0.12*	
SUD					NC
Post-test	1.98 (SD 1.94)	5.30 (SD 3.40)	3.45*	1.26*	
3 months	2.16 (SD 2.27)	4.19 (SD 3.61)	-0.09*	0.32*	
6 months	1.45 (SD 1.90)	4.18 (SD 3.83)	0.28*	0.31*	
	Clinical importance (1-4) [26] 2 The point estimate of effect is clinically important BUT the confidence interval includes clinically unimportant effects.			Relevance (1-5) [27] 1 Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.	
Any other adverse effects [28] Not stated					
EXTERNAL VALIDITY					
Generalisability [29] The study population is relevant to trauma victims in Australia.					
Applicability [30] The EMDR treatment of PTSD shows a beneficial effect and one that improves over time.					
Comments [31]					

NC=not calculated because only continuous data were reported; * Effect sizes are calculated for within treatment group over time, not between group effect size.

STUDY DETAILS				
Reference [1] Rothbuam, Astin & Marsteller (2005)				
Affiliation/source of funds [2]				
Study design [3] Randomised controlled trial	Level of evidence [4] II		Location/setting [5]	
Intervention [6]: Prolonged exposure (PE)	Comparator(s) [8] Eye movement desensitization & reprocessing (EMDR)		Sample size [9]	
Sample size [7]				
<p>Population characteristics [10] Female victims of a rape at least 3 months prior to study entry. The rape must have been during adulthood (12 years or older) or a single incident during childhood, by either family or non-family member. Exclusions included a history of schizophrenia or other psychoses, current suicidal risk or practiced self mutilation, illiterate, dependent on alcohol or drugs, blind or had a history of eye disease, cocaine users, or in a current threatening situation. Intervention group –As above</p> <p>Comparator group(s) –As above</p>				
Length of follow-up [11] 6 month follow-up		Outcome(s) measured [12] PTSD symptoms- CAPS, Structured clinical interview for DSM-IV-SCID, PTSD symptom scale self-report, IES, BDI, DES-II, STAI		
INTERNAL VALIDITY				
Randomisation [13] Blinded	Comparison of study groups [14] There were baseline differences for some measures. CAPS identified EMDR participants to have significantly higher overall PTSD & intrusive symptoms as well as depression. This was controlled for in the analysis.	Blinding [15] Assessors were blinded to treatment condition.	Treatment/ measurement bias [16] Appeared to be treated the same apart from the intervention.	Follow-up (ITT) [17] ITT was claimed to be carried out and no differences were found so not reported.
Overall quality assessment (descriptive) [18] The study did not state their randomisation strategy or their allocation concealment. Their sample size was also relatively small.				
RESULTS				
Outcome [19]	Intervention group [20]	Control group	Measure of	

PTSD diagnosis	PE	[21] EMDR	effect/effect size [22]
Posttreatment		NS	NR
6 month follow-up Continued to receive PTSD diagnosis	5.6%	26.3% p=0.185	NR
Composite total score improvement change from pre to posttreatment		NS	NR
Symptom cluster changes		NS	NR
End state functioning Posttreatment 6 month follow-up		NS NS	NR
Depression Change from pre to posttreatment 6 months		NS NS	NR
Dissociative symptoms Change from pre to posttreatment 6 month follow-up		P<0.05 NS	NR
Anxiety Change from pre to posttreatment 6 month follow-up		NS NS	NR
Clinical importance (1-4) [26] Unable to determine	Relevance (1-5) [27] Unable to determine		
Any other adverse effects [28]Not reported			
EXTERNAL VALIDITY			
Generalisability [29] The study population is relevant to female victims of rape in Australia.			
Applicability [30] EMDR was found to be effective for dissociative symptoms posttreatment in comparison to PE therapy.			
Comments [31]			

NR=not reported

Question 5

No included studies

Question 6

No included studies

Question 7

No included studies

Question 8

No included studies

Question 9

No included studies

Question 10

STUDY DETAILS				
Reference [1] Brady et al 2005				
Affiliation/source of funds [2] Dept of Psychiatry, South Carolina/ supported by a National Institute on Alcohol Abuse and Alcoholism grant				
Study design [3] Randomised controlled trial		Level of evidence [4] II		Location/setting [5] America (South Carolina); outpatient
Intervention [6] Sertraline 150mg/ day (+ riboflavin 100mg tabs) Sample size [7] 49		Comparator(s) [8] Placebo (+riboflavin 100mg tabs) Sample size [9] 45		
Population characteristics [10] Intervention group – DSM-V criteria for current alcohol dependence (within last 3 months) and current PTSD (within the past 6 months) in response to civilian (sexual assault, physical assault, serious accident) trauma. Patients could also meet criteria for a depressive disorder and another anxiety disorder. 18-65 years of age. Comparator group(s) – DSM-V criteria for current alcohol dependence (within last 3 months) and current PTSD (within the past 6 months) in response to civilian (sexual assault, physical assault, serious accident) trauma. Patients could also meet criteria for a depressive disorder and another anxiety disorder. 18-65 years of age				
Length of follow-up [11] 12 weeks		Outcome(s) measured [12] CAPS (Clinician Administered PTSD Symptom Scale – assess and rates severity) ; HAM-D (Hamilton Depression Scale); Impact of Events Scale (assess self-report PTSD); alcohol intake; craving; urine sample		
INTERNAL VALIDITY				
Randomisation [13]	Comparison of study groups [14] No apparent differences between the groups	Blinding [15] “Double-blind”	Treatment/ measurement bias [16] No apparent differences in treatment or measurement	Follow-up (ITT) [17] 49/49 (100%) sertraline 45/45 (100%) placebo
Overall quality assessment (descriptive) [18] The study has a relatively small sample size and the report does not include a sample size calculation. Potential confounders are adequately dealt with through inclusion/ exclusion criteria and urn randomisation. There was 100% follow-up, although this only lasted for 12 weeks. The cluster analysis is not robust given: its post hoc nature; the primary results were not statistically significant; and the sample size was small. The results for sertraline vs placebo can be considered meaningful if the sample size is adequate. – Good quality				
RESULTS				
Outcome [19]	Intervention group [20]	Control group [21]	Measure of effect/effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25] Harms (NNH) [24] 95% CI [25]

CAPS total score (adjusted for baseline)	Trend toward lower total CAPS score F(2,68) = 2.68, p=0.08			NC
	Trend toward lower intrusion and hyperarousal symptoms respectively [F(2,68) = 2.49, p=0.09: F(2,68) = 2.85, p=0.07]			
% of drinking days	23.0	20.4		
Average no of drinks consumed pr day	2.0 (±2.9)	1.4 (±1.9)		
No of drinks consumed per drinking day	6.8 (±6.5)	6.3 (±7.8)		
No of heavy drinking days (≥5 for men; ≥4 for women)	10.4 (±2.3)	8.9 (±2.5)		
	Clinical importance (1-4) [26] 4		Relevance (1-5) [27] 1	
Any other adverse effects [28] Side effects were mild and self-limiting in both groups; no drop outs due to AE; separate details are not provided for sertraline and placebo group				
EXTERNAL VALIDITY				
Generalisability [29] Population generalisable; combat-related PTSD was not included in the study				
Applicability [30] There appear to be no potential benefits to the treatment				
Comments [31] Results are also provided by “clusters” which were post hoc analyses.				

NC=not calculated because author’s only reported

STUDY DETAILS				
Reference [1] Davidson et al 2005				
Affiliation/source of funds [2] Dept of Psychiatry & Behavioural Sciences, Duke University Medical Centre, Durham; Durham Vets Admin Medical Centre, Durham; Private Practice, Raleigh, NC/ supported by grant #R01 MH 56656/ the authors thanked Eli Lilly for providing the medication & placebo				
Study design [3] 6 month open-label period followed by 6 month randomised treatment	Level of evidence [4] II		Location/setting [5] America Durham, North Carolina Raleigh, North Carolina Outpatient clinic	
Intervention [6] Fluoxetine Sample size [7] 27	Comparator(s) [8] Placebo Sample size [9] 30			
Population characteristics [10] Intervention group – PTSD; discontinuation of psychotropic medication ≥ 2 weeks before open-label period; 18-70 years of age; nonpregnant; pts who had shown at least minimal improvement during the open label phase Comparator group – PTSD; discontinuation of psychotropic medication ≥ 2 weeks before open-label period; 18-70 years of age; nonpregnant; pts who had shown at least minimal improvement during the open label phase				
Length of follow-up [11] Total of 12 months Randomised period 6 months		Outcome(s) measured [12] Clinical Global Improvement Scale (CGI-1) (primary); Clinical Global Impressions of Severity (CGI-S); Short PTSD Rating Interview (SPRINT); Davidson Trauma Scale (DTS); self-rated Severity of Symptoms Scale for AE		
INTERNAL VALIDITY				
Allocation [13] Preassigned randomly generated set of study numbers	Comparison of study groups [14] Fluoxetine group had a higher proportion of “white” pts compared with placebo (66.7 vs 56.5 respectively); slight differences in DTS score (fluoxetine 53.8 \pm 37.7; placebo 46.2 \pm 37.2); some differences in trauma history	Blinding [15] Open label for initial 6 months then “double-blind” for remaining 6 months	Treatment/ measurement bias [16] Treatment and measurement appears the same for both groups during the randomised double-blind phase. Dose was titrated during the initial open label phase to a maximum of 60mg/ day unless patients experienced troublesome AE or achieved a score of ≥ 2 on the CGI-1	Follow-up (ITT) [17] 57/62 (92%) 27/ 30 (90%) fluoxetine 30/ 32 (94%) placebo
Overall quality assessment (descriptive) [18] There were less subjects recruited than in the sample size calculation reducing the power of the study and secondary outcomes were not reported. Overall, the study appears robust and the results reliable assuming the definition of relapse is acceptable.				
RESULTS				
Outcome [19]	Intervention group [20]	Control group [21]	Measure of effect/effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]

CGI-1 No of relapses	6/ 27 (22.2%)	15/ 30 (50.0%)	P = 0.029	NNT 4 [2-25]
			Relative risk for relapse placebo 1.55 (1.03, 2.35) fluoxetine 0.44 (0.2, 0.98)	
			Odds ratio 3.50	
	Clinical importance (1-4) [26] 2		Relevance (1-5) [27] 1	
Any other adverse effects [28] Only the most common adverse events were reported. AE for fluoxetine: nightmares (n=5), insomnia (n=5). AE for placebo: nightmares (n=6), insomnia (n=5), akathisia (n=4), heart racing (n=7), headaches (n=7), increased appetite (n=7) and weight gain (n=6).				
EXTERNAL VALIDITY				
Generalisability [29] The results are likely to be generalisable to the PTSD population in Australia.				
Applicability [30] The results would suggest that the potential benefits of continuing fluoxetine for a further 6 months treatment after an initial 6 months treatment in reducing the risk of relapse of PTSD outweigh any potential harms				
Comments [31] Relapse was defined as a CGI-I score which reverted back to no improvement relative to baseline or worse (ie scores of 4 or below) or which had increased by ≥2 points relative to improvement status at week 24, or an untoward clinical event occurred.				

STUDY DETAILS				
Reference [1] Davis et al 2004				
Affiliation/source of funds [2] VA Medical Centre, Tuscaloosa; University of Alabama, Birmingham; John Hopkins Medical Centre, Baltimore; VA Medical Centre, Omaha; Creighton University, Omaha/ partial funding through an unrestricted grant from Bristol-Myers Squibb				
Study design [3] Randomised controlled trial	Level of evidence [4] II	Location/setting [5] America Birmingham & Tuscaloosa VA Medical Centres, Dept of Psychiatry Clinical Research Clinic, University of Alabama.		
Intervention [6] Nefazodone (max dose of 600mg/ day) Sample size [7] 27	Comparator(s) [8] Placebo Sample size [9] 15			
Population characteristics [10] Intervention group – Diagnosis of chronic PTSD; 19-75 years of age; stable physical health; free of all psychotropic medication in the previous 2 weeks; negative urine drugs-of-abuse screen Comparator group(s) – Diagnosis of chronic PTSD; 19-75 years of age; stable physical health; free of all psychotropic medication in the previous 2 weeks; negative urine drugs-of-abuse screen				
Length of follow-up [11] 12 weeks	Outcome(s) measured [12] CAPS total score (primary) CAPS-B subscale; CAPS-C subscale; CAPS-D subscale; Ham-A; Ham-D; PTSD checklist (self-report); Clinician-Administered Dissociative States Scale; Global Assessment of Functioning Scale; Clinician Global Impression			
INTERNAL VALIDITY				
Randomisation [13] Randomisation log kept by the pharmacist	Comparison of study groups [14] Overall the groups were similar except for prior treatment	Blinding [15] Patient and investigators blinded	Treatment/ measurement bias [16] Treatment and measurement appears consistent across the two groups	Follow-up (ITT) [17] 26/ 27 (96%) nefazodone 15/15 (100%) Placebo LOCF
Overall quality assessment (descriptive) [18] The sample size is relatively small and a sample size calculation is not provided. The follow-up period is only 12 weeks and drop out rates were sizeable (46% nefazodone; 40% placebo), although LOCF was used in the analyses. The nefazodone group had a higher proportion of early dropout after the baseline visit than the placebo group. Given these high drop out rates it is difficult to have confidence in the results.- Average-to-good quality				
RESULTS				
Outcome [19]	Intervention group [20] Mean change from baseline	Control group [21] Mean change from baseline	Measure of effect/effect size [22] 95% CI [25]	
CAPS total	-19.1 ± 24	-13.5 ± 25	p = 0.04	
CAPS-B	-4.4 ± 8	-3.1 ± 9	NS	

CAPS-C	-7.7 ± 12	-6.1 ± 12	NS
CAPS-D	-7.1 ± 8	-4.2 ± 9	p = 0.007
Ham-D	-3.8 ± 8	-1.8 ± 6	p = 0.008
PTSD checklist	-7.0 ± 24	-2.9 ± 8	p = 0.08
Clinician-Administered Dissociative States Scale	-1.7 ± 13	-0.9 ± 7	p = 0.06
	Clinical importance (1-4) [26] 1	Relevance (1-5) [27] 1	
Any other adverse effects [28] Negative finding for Ham-A (absolute figures not reported); 4 pts in the nefazodone arm withdrew due to AE			
EXTERNAL VALIDITY			
Generalisability [29] Predominantly veteran population			
Applicability [30] The overall benefit from improvement in total CAPS score needs to be weighed against the negative finding on the Ham-A; there is insufficient detail provided to assess the Ham-A results. Given that: the CAPS score is the primary outcome; the study size is relatively small; and the study quality is reasonable, it is likely that the potential benefits of nefazodone will outweigh any potential harms in the guideline population.			
Comments [31]			

NB: the primary studies from this systematic review are before the time criteria for the current review

STUDY DETAILS				
Reference [1] (Mooney et al., 2004)				
Affiliation/source of funds [2] Forensic Mental Health Research Unit, Rampton Hospital, Retford, Nottinghamshire				
Study design [3] Systematic review (meta-analysis) of randomised controlled trials	Level of evidence [4] I		Location/setting [5] Details not provided.	
Intervention [6] Sertraline Sample size [7] n = 4 studies	Comparator(s) [8] Placebo Sample size [9] N = 4 studies			
Population characteristics [10] Intervention group – Patients with PTSD Comparator group(s) – Patients with PTSD				
Length of follow-up [11] 2-28 weeks		Outcome(s) measured [12] Leaving the study early; CAPS 2 change score at endpoint; IES change score at endpoint; IES change score at endpoint; CGI-S change score at endpoint		
INTERNAL VALIDITY				
Design [13] were RCT	Comparison of study groups [14] Some differences in severity of PTSD, proportion of females and trauma background.	Blinding [15] All trials were double-blind	Treatment/ measurement bias [16] Length of follow-up differed between trials; there were 32 outcomes reported across the trials but only two were measured in all four RCTs.	Follow-up (ITT) [17] Not reported
Overall quality assessment (descriptive) [18] The search strategy was comprehensive. However, there was no quality assessment of the four trials, no comparison of the populations and study design across the four trials, length of follow-up differed across the four trials, tests for heterogeneity were not reported and any reasons for heterogeneity were not explored. No justification was provided for selecting a random effects model. Overall, the results may not be robust given these limitations to the systematic review and meta-analysis.				
RESULTS				
Outcome [19]	Intervention group [20]	Control group [21]	Measure of effect/effect size [22] 95% CI [25]	
Leaving the study early (n = 4)			0.87 (0.55,1.35) z = 0.64; p = 0.5	
CAPS 2 change score at endpoint (n = 4)			-6.37 (-9.65, -3.10) z = 3.81; p = 0.0001	
IES change score at endpoint (n = 3)			-5.48 (-6.81, -4.15) z = 8.08; p = 0.00001	

CGI-S change score at endpoint (n = 3)			-0.51 (-0.81, -0.21) z = 3.37; p = 0.0008	
	Clinical importance (1-4) [26] 2		Relevance (1-5) [27] 1	
Any other adverse effects [28] The odds ration for leaving the study early favoured sertraline compared with placebo. However, the results was not statistically significant and the CI are wide.				
EXTERNAL VALIDITY				
Generalisability [29] The results appear to be generalisable to the Australian PTSD population.				
Applicability [30] The potential benefits of sertraline compared with placebo are difficult to analyse due to the absence of reporting of adverse events. If AE are mild and non serious then the potential benefits of sertraline may outweigh potential harms.				
Comments [31]				

STUDY DETAILS		
Reference [1] Reich et al 2004		
Affiliation/source of funds [2] McLean Hospital, Belmont; Department of Psychiatry, Harvard Medical School, Boston/ supported by a research grant from Janssen Pharmaceuticals		
Study design [3] Randomised controlled trial	Level of evidence [4] II	Location/setting [5] Outpatient setting; met with psychiatrist/ nurse weekly
Intervention [6] Risperidone 0.5mg qhs, increased to 1mg/ day after 3 days; dose increased weekly by up to 1mg per day per week to a target dose of 4mg/ day or relief of symptoms. Dose could be increased up to 8mg/day if necessary. Risperidone could be given in divided doses. Benzotropine could be prescribed for extrapyramidal SE of up to 2mg bd. Mean dose 1.41mg. Sample size [7] 12	Comparator(s) [8] Placebo Sample size [9] 9	
Population characteristics [10] Intervention group – English speaking females, 18-64 years of age with chronic PTSD from childhood physical, sexual, verbal or emotional abuse. ≥50 score on CAPS-1 (clinician-administered validated PTSD scale, 1 month version; provides a current and lifetime assessment of 17 DSM-III-R defined PTSD symptoms). Subjects could be taking 1 antidepressant (SSRI/ TCA/ MAOI/ bupropion/ venlafaxine, mirtazapine or serotonin antagonist reuptake inhibitor) &/or 1 hypnotic (benzodiazepine, zolpidem, trazodone, nefazodone or diphenhydramine). Dosages had to have been constant for ≥1 month before the study 5 patients were taking other psychiatric medication during the study (4 x SSRI, 1 x TCA, 2 x benzo) Comparator group – As above; 4 patients were taking other psychiatric medication during the study (2 x SSRI, 1 x TCA, 1 x benzo, 1 x trazodone).		
Length of follow-up [11] 8 weeks	Outcome(s) measured [12] Total, intrusive, avoidant and hyperarousal scores on CAPS-1 and CAPS-2 (as CAPS-1 only measured over a 1-week period and used to assess changes in symptom severity during treatment). CAPS-2 measured at baseline and weeks 1, 2, 4 and 8. CAPS-1 measured at baseline and week 8. Observed and reported AE.	
INTERNAL VALIDITY		

<p>on [13] only assigned” – no details of method provided</p>	<p>Comparison of study groups [14] Patients in the placebo group were younger (risp mean 30.6 [18-56]; placebo mean 24.2 [19-34]); abuse history varied between the groups; risperidone CAPS-1 baseline 65.5 (13.2), placebo 73.9 (10.4); risperidone CAPS-2 baseline 63.5 (17.4), placebo 65.6 (13.8)</p>	<p>Blinding [15] “double-blind” However, blinding unlikely to be maintained due to dose escalation and possible treatment with benzotropine due to extrapyramidal SE.</p>	<p>Treatment/ measurement bias [16] Benzotropine therapy could be prescribed for SE of risperidone. Study does not clarify if patients receiving placebo were given the same instructions regarding their dose. All other measurements and treatments were the same.</p>	<p>Follow-up (ITT) [17] Risperidone 9/12 (75%) Placebo 7/9 (78%)</p>
<p>Overall quality assessment (descriptive) [18]</p>				
<p>RESULTS</p>				
<p>Outcome [19]</p>	<p>Intervention group [20]</p>	<p>Control group [21]</p>	<p>Measure of effect/effect size [22] 95% CI [25]</p>	<p>Benefits (NNT) [23] 95% CI [25]</p>
	<p>Clinical importance (1-4) [26]</p>			<p>Harms (NNH) [24] 95% CI [25]</p>
	<p>Clinical importance (1-4) [26]</p>		<p>Relevance (1-5) [27]</p>	
<p>Any other adverse effects [28]</p>				
<p>EXTERNAL VALIDITY</p>				
<p>Generalisability [29]</p>				
<p>Applicability [30]</p>				
<p>Comments [31] “Subjects were instructed to maintain all other psychotropic medications at constant dosages during the study”</p>				

STUDY DETAILS				
Reference [1] Tucker et al 2004				
Affiliation/source of funds [2] Dept of Psychiatry & General Clinical Research Center, University of Oklahoma Health Sciences Center; Jim Thorpe Rehabilitation Center, Integris Health; Veterans Administration Hospital, Oklahoma; Dept of Medicine & Behavioural Medicine and Psychiatry, West Virginia University School of Medicine, West Virginia/ financial support provided by Forest Pharmaceuticals.				
Study design [3] Randomised controlled trial	Level of evidence [4] II		Location/setting [5] Outpatient Oklahoma & West Virginia, America	
Intervention [6] SSRIs Citalopram 20-50mg/ day (average end dose 36.2mg/ day) Sertraline 50-200mg/ day (end dose = 134.1mg/day) Sample size [7] 25 23		Comparator(s) [8] Placebo 1-4 tablets/ day (end dose = 2.1 tablets/ day) Sample size [9] 10		
Population characteristics [10] Intervention group – PTSD as determined by the Structured Clinical Interview for DSM-IV and Clinician Administered PTSD scale-I (CAPS-I), with CAPS score ≥ 50 (moderate-severe PTSD). Most of the subjects had additional Axis I diagnoses assessed as secondary to their PTSD. Comparator group(s) – PTSD as determined by the Structured Clinical Interview for DSM-IV and Clinician Administered PTSD scale-I (CAPS-I), with CAPS score ≥ 50 (moderate-severe PTSD). Most of the subjects had additional Axis I diagnoses assessed as secondary to their PTSD.				
Length of follow-up [11] 10 weeks		Outcome(s) measured [12] Interleukin 1 β levels; interleukin 2R levels, 8am and 4pm cortisol levels; CAPS and BDI totals		
INTERNAL VALIDITY				
Randomisation [13] "Randomly assigned"	Comparison of study groups [14] Differences in the M/F ratios between groups; higher proportion of non-Caucasians in the citalopram arm; difference in CAPS scores at baseline	Blinding [15] "double-blind"	Treatment/ measurement bias [16] All treatments and measurements appeared to be administered in a similar manner across the groups	Follow-up (ITT) [17] 19/25 (76%) citalopram 18/23 (78%) sertraline 7/10 (70%) placebo
Overall quality assessment (descriptive) [18] The sample size in each arm is small and a sizeable proportion of subjects withdrew during the study. Randomisation is not described and the CAPS score was not the primary outcome of interest in this study. Given these limitations, the results cannot be considered robust.- Average quality				
RESULTS				
Outcome [19]	Intervention group [20]	Control group [21]	Measure of effect/effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25] Harms (NNH) [24]

CAPS (change from baseline)	citalopram	sertraline	53.71 ± 22.60	NA	95% CI [25] NC
	38.68 ± 22.05	50.50 ± 18.81			
BDI	13.89 ± 10.38	14.67 ± 10.45	15.14 ± 16.18		
	Clinical importance (1-4) [26] 4			Relevance (1-5) [27] 1	
Any other adverse effects [28] No severe AE occurred during the study. Most AE were mild and consistent with SSRI treatment. Two patients who terminated treatment early indicated this was due to AE.					
EXTERNAL VALIDITY					
Generalisability [29] The study results are generalisable to the wider Australian population diagnosed with PTSD.					
Applicability [30] The SSRIs do not appear to offer any advantages over placebo in this study					
Comments [31]					

NC=not calculated because all continuous data; NA=not applicable

Question 11

STUDY DETAILS				
Reference [1] Chung et al 2004				
Affiliation/source of funds [2] Dept of Neuropsychiatry, Seoul Veterans Hospital, Seoul, Korea/ Organon & Janssen				
Study design [3] Open label randomised controlled trial	Level of evidence [4] II		Location/setting [5] Inpatient & outpatient Veterans Hospital, Seoul, Korea	
Intervention [6] Mirtazepine (average dose 34.1mg/ day) Sample size [7] 58		Comparator(s) [8] Sertraline (average dose 101.5mg/ day) Sample size [9] 55		
Population characteristics [10] Intervention group – Male veterans of the Korean or Vietnam war with PTSD as a primary diagnosis according to DSM-IV and CAPS-I criteria and possible comorbid major depression or dysthymia with symptoms of depression present for >3 months. Comparator group(s) – Male veterans of the Korean or Vietnam war with PTSD as a primary diagnosis according to DSM-IV and CAPS-I criteria and possible comorbid major depression or dysthymia with symptoms of depression present for >3 months.				
Length of follow-up [11] 6 weeks	Outcome(s) measured [12] Changes in clinical symptoms measured by clinician-administered PTSD scale (CAPS-2), the 17-item Hamilton depression scale (HAMD-17) and the clinical global impression scale (severity and improvement scale CGI-S and CGI-I); % response (response defined as a reduction of CAPS-2 total severity score by >30%, a reduction of HAMD-17 total score by >50% or a “much improved” score on the CGI			
INTERNAL VALIDITY				
Randomisation [13] “only assigned”	Comparison of study groups [14] Small difference in the % of comorbidities suffered between both groups	Blinding [15] Open label	Treatment/ measurement bias [16] Medications were titrated according to the clinical evaluation by the psychiatrist.	Follow-up (ITT) [17] 51/58 (88%) mirtazapine 49/55 (89%) sertraline
Overall quality assessment (descriptive) [18] This is an open label study with a relatively small sample size. Details of randomisation are not included and there was no placebo arm included in the study. There is a large standard deviation around the mean changes from baseline for both treatments. It is difficult to interpret the results given these limitations to the study design, although it would appear that mirtazapine is at least as effective as sertraline in reducing the CAPS-2, HAMD-17 and CGI-S scores in veterans with PTSD. – Poor-to-average quality				
RESULTS				
Outcome [19]	Intervention group [20] Change from baseline	Control group [21] Change from baseline	Measure of effect/effect size [22] 95% CI [25] Sertraline vs mirtazapine	Benefits (NNT) [23] 95% CI [25] Harms (NNH) [24] 95% CI [25]
CAPS-2	-44.8 ± 19.7	-33.2 ± 20.4	p=0.467	NC

HAMD-17	-14.1 ± 7.9	-11.7 ± 5.8	p=0.319	
CGI-S	-2.92 ± 0.9	-2.88 ± 0.9	p=0.809	
CAPS-2 responder	45 (88.2)	34 (69.4)	p=0.039	
HAMD-17 responder	38 (74.5)	38 (77.5)	p=0.903	
CGI-S responder	49 (96.1)	43 (87.8)	p=0.156	
	Clinical importance (1-4) [26] 3- no clinically important differences		Relevance (1-5) [27] 1 Patient relevant outcomes (but no difference that is relevant)	
<p>Any other adverse effects [28] AE reported for mirtazapine: dry mouth (19.6%), constipation (19.6%), somnolence (15.7%) and weight gain (2.0%). AE reported for sertraline: indigestion (14.3%), palpitation (6.1%), agitation (2.0%), epigastric soreness (2.0%) and sexual dysfunction (2.0%). There was a similar drop out rate for both groups.</p>				
EXTERNAL VALIDITY				
<p>Generalisability [29] The results are generalisable to the veteran population with PTSD in Australia.</p>				
<p>Applicability [30] The potential benefits of mirtazapine are unclear given the lack of placebo arm. The AE reported for mirtazapine were mild and non-serious.</p>				
<p>Comments [31]</p>				

NC=not calculated because all continuous data

STUDY DETAILS				
Reference [1] McRae et al 2004				
Affiliation/source of funds [2] Dept of Psychiatry & Behavioural Sciences, University of South Carolina, Charleston, South Carolina; Dept of Psychiatry, Dartmouth Medical School, Hanover, New Hampshire/ Bristol-Myers Squibb				
Study design [3] Randomised controlled trial	Level of evidence [4] II		Location/setting [5] Outpatient ;two academic medical centres, South Carolina & Hanover, New Hampshire ,America	
Intervention [6] Nefazodone – starting dose 50mg twice a day (average dose 463mg/ day) Sample size [7] 18		Comparator(s) [8] Sertraline – starting dose 25mg twice a day (average dose 153mg/ day) Sample size [9] 19		
Population characteristics [10] Intervention group – Male & female outpatients, aged 18-65 years who met the DSM-IV criteria for a principle diagnosis of PTSD as determined by CAPS-1 with a minimum duration of 3 months and total severity score ≥50 on CAPS-2 at the end of a 1-week placebo washout period. Comparator group(s) – Male & female outpatients, aged 18-65 years who met the DSM-IV criteria for a principle diagnosis of PTSD as determined by CAPS-1 with a minimum duration of 3 months and total severity score ≥50 on CAPS-2 at the end of a 1-week placebo washout period.				
Length of follow-up [11] 12 weeks	Outcome(s) measured [12] Primary - change from baseline in: 17-item total severity score of the CAPS-2; Clinical Global Impression-Improvement scale (CGI-I) Secondary – change in baseline in: 17-item Davidson Trauma Scale (DTS); a pt rated assessment of the 17 DSM-IV defined PTSD symptoms on frequency & severity; investigator-rated Montgomery-Asberg Depression Rating Scale (MADRS); investigator rated Hamilton Anxiety Scale (HAM-A); abbreviated investigator rated scale to assess PTSD symptoms (TOP-8); Pittsburgh Sleep Quality Index (PSQI)			
INTERNAL VALIDITY				
Randomly assigned [13] Treatment randomisation information was kept by a research pharmacist	Comparison of study groups [14] The time since trauma differed between the two groups (nefazodone 26.69 mean; sertraline mean 17.23) and the trauma background was slightly different.	Blinding [15] “double-blind”	Treatment/ measurement bias [16] All measurements were consistent between the groups. Treatment was titrated up based on response and tolerability to a target dose of 100mg twice a day for sertraline and 300mg twice a day for nefazodone. It is uncertain if blinding was maintained due to this titration.	Follow-up (ITT) [17] 13/18 (72%) nefazodone 13/19 (68%) sertraline
Overall quality assessment (descriptive) [18] Although the study is randomised and double-blind in design, the sample size is very small in the study and there is some uncertainty whether blinding was preserved throughout the study given the titration regimes. Nefazodone appears to have similar efficacy to sertraline in reduction of CAPS score, however, there is no placebo arm. Overall, the results will not be robust given these limitations. – Average-to-good quality				
RESULTS				

Outcome [19]	Intervention group [20] Mean score	Control group [21] Mean score	Measure of effect/effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]
				Harms (NNH) [24] 95% CI [25]
CAPS baseline endpoint	68.9 (7.7) 28.7 (22.2)	73.8 (16.4) 29.1 (25.4)	NS	NC
DTS baseline endpoint	73.5 (13.8) 33.3 (24.4)	67.3 (20.2) 35.9 (29.8)	NS	
HAM-A baseline endpoint	20.0 (6.2) 9.3 (7.1)	20.5 (9.3) 12.5 (12.2)	NS	
MADRAS baseline endpoint	22.9 (5.8) 9.9 (9.4)	21.9 (6.6) 10.7 (8.9)	NS	
TOP-8 baseline endpoint	16.2 (4.9) 5.5 (4.8)	17.5 (4.1) 5.6 (6.8)	NS	
CGI-I baseline endpoint	3.7 (0.8) 2.1 (1.3)	3.9 (0.7) 2.1 (0.9)	NS	
SHEEHAN baseline endpoint	19.4 (7.3) 11.7 (7.9)	17.8 (7.4) 10.6 (8.4)	NS	
PSQI baseline endpoint	11.9 (5.9) 6.8 (4.5)	12.3 (4.9) 7.0 (5.5)	NS	
	Clinical importance (1-4) [26] 3- No clinically important differences		Relevance (1-5) [27] 1- patient relevant outcomes	
Any other adverse effects [28] Both medications were well tolerated. The most common adverse events reported for nefazodone and sertraline respectively were: headache (26.3; 22.2), drowsiness (26.3; 27.8), insomnia (21.1; 16.7), restlessness (10.5, 11.1). Additional AE reported by >10% of subjects receiving sertraline were delayed ejaculation or anorgasmia (16.7%), fatigue (16.7%), nightmares (11.1%) and dry mouth (11.1%). Additional AE reported by >10% of subjects receiving nefazodone were dizziness/ light-headedness (21.1%), nausea (10.5%) and difficulty concentrating (10.5%).				
EXTERNAL VALIDITY				
Generalisability [29] The study results are generalisable to the Australian population with PTSD.				
Applicability [30] Potential benefits cannot be assessed in this trial due to the lack of placebo arm.				
Comments [31]				

NC=not calculated because all continuous data

Question 12

No included studies

Question 13

No included studies

Question 14

No included studies

Question 15

STUDY DETAILS				
Reference [1] Bryant 2005				
Affiliation/source of funds [2] School of Psychology, University of New South Wales, Sydney, Australia/ supported by the National Health and Medical Research Council				
Study design [3] Randomised controlled trial	Level of evidence [4] II		Location/setting [5] Patients referred to the Westmead Hospital PTSD Unit	
Intervention [6] Cognitive behavioural therapy		Comparator [8] Cognitive behavioural therapy plus hypnosis		
Sample size [7] 33		Sample size [9] 30		
Population characteristics [10] Civilian trauma survivors following nonsexual assault or motor vehicle accident who met the criteria for ASD . Intervention group – as above Comparator group(s) – as above				
Length of follow-up [11] 6 months		Outcome(s) measured [12] CAPS-2 Intensity, CAPS-2 Frequency, IES-Intrusion, IES-Avoidance, BAI, Beck Depression Inventory		
INTERNAL VALIDITY				
Allocation [13] Process of minimisation stratified on gender, trauma types and ASDI total score using a random numbers system. Each month RA amended allocation to ensure that gender, trauma type, and PTSD severity were balanced across groups.	Comparison of study groups [14] No differences in age, time since trauma, National Adult Reading Test, Stanford Hypnotic Susceptibility Scale, Acute Stress Disorder Scale.	Blinding [15] Clinicians who conducted assessments did not have access to a) participant notes, b) treatment allocation of participants, or c) supervision discussion of therapy sessions.	Treatment/ measurement bias [16] No other differences in treatment apart from the interventions were apparent. Two independent clinicians conducted 20% of initial ASD assessments with interrater reliability of 100%.	Follow-up (ITT) [17] 6 months 9/33 if the CBT and 7/30 of the CBP + hypnosis groups dropped out.
Overall quality assessment (descriptive) [18]. The study had similar populations in the two interventions, although blinding of patients was not possible. Proper randomisation did not occur and lack of allocation concealment means bias in patient allocation was possible.				
RESULTS				
Outcome [19]	Intervention group [20] CBT	Control group [21] CBT + hypnosis	Measure of effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]

IES-Intrusion <u>ITT</u> Pretreatment Posttreatment Follow-up <u>Treatment completer</u> Pretreatment Posttreatment Follow-up	27.12 (SD 7.46) 16.58 (SD 12.50) 16.97 (SD 11.80) 27.29 (SD 6.02) 12.79 (SD 11.01) 13.08 (SD 10.01)	24.73 (SD 8.06) 11.30 (SD 9.98) 13.57 (SD 9.52) 25.74 (8.41) 7.26 (SD 6.99) 11.17 (SD 9.13)	See comments	Harms (NNH) [24] 95% CI [25] NC
IES-Avoidance <u>ITT</u> Pretreatment Posttreatment Follow-up <u>Treatment completer</u> Pretreatment Posttreatment Follow-up	21.58 (SD 9.66) 11.06 (SD 12.23) 14.30 (SD 12.80) 20.92 (SD 6.02) 6.46 (SD 8.23) 10.92 (SD 11.17)	24.43 (SD 9.49) 15.03 (SD13.36) 16.30 (SD12.68) 22.00 (SD 7.76) 9.74 (SD 8.81) 11.39 (SD 8.48)	See comments	
Beck Anxiety Inventory <u>ITT</u> Pretreatment Posttreatment Follow-up <u>Treatment completer</u> Pretreatment Posttreatment Follow-up Beck Depression Inventory-2 <u>ITT</u> Pretreatment Posttreatment Follow-up <u>Treatment completer</u> Pretreatment Posttreatment Follow-up CAPS-2 Intensity <u>Treatment completer</u> Posttreatment Follow-up CAPS-2 Frequency <u>Treatment completer</u> Posttreatment Follow-up	24.39 (SD 11.23) 14.91 (SD 13.31) 15.67 (SD 13.21) 24.31 (SD 10.96) 11.17 (SD 11.73) 12.21 (SD 11.91) 19.97 (SD 10.01) 13.24 (SD 11.83) 14.61 (SD 12.31) 17.75 (SD 10.14) 8.50 (SD 9.54) 10.38 (SD 11.17) 10.88 (SD 8.27) 13.08 (SD 11.08) 12.08 (SD 9.41) 15.42 (SD 13.61)	27.27 (SD11.47) 15.47 (SD12.87) 17.07 (SD12.74) 27.35 (SD12.06) 11.70 (SD11.83) 14.04 (SD12.67) 18.40 (SD 8.39) 11.37 (SD 7.34) 13.57 (SD 8.78) 19.48 (SD 9.38) 10.30 (SD 8.04) 13.17 (SD 9.97) 10.83 (SD10.16) 14.09(SD11.52) 12.35 (SD11.86) 14.83 (SD13.22)	See comments	

PTSD ITT				
Posttreatment	36%	30%		
Follow-up	42%	40%		
<u>Treatment completer</u>				
Posttreatment	13%	9%		
Follow-up	21%	22%		
Total IES <12				
ITT				
Follow-up	24%	23%		
<u>Treatment completer</u>				
Follow-up	33%	30%		
	Clinical importance (1-4) [26] 2- some clinically important differences		Relevance (1-5) [27] 1- patient relevant outcomes	
Any other adverse effects [28] No adverse events reported.				
EXTERNAL VALIDITY				
Generalisability [29] The study population is from Australia and relevant to the wider Australian population.				
Applicability [30] Some benefits and no harms were reported in the study.				
Comments [31] Used MANCOVA analysis for both ITT and completer data on CAPs-2 intensity, CAPS-2 frequency, IES-Intrusion, IES-Avoidance, BAI and Beck depression inventory-2 for posttreatment and follow-up scores that controlled for initial symptom severity and trauma type. Hence, simple before-after within scale p values or comparisons were not reported.				

NC=not calculated because all continuous data

STUDY DETAILS				
Reference [1] Bryant 2005				
Affiliation/source of funds [2] School of Psychology, University of New South Wales, Sydney, Australia/ supported by the National Health and Medical Research Council				
Study design [3] Randomised controlled trial	Level of evidence [4] II		Location/setting [5] Patients referred to the Westmead Hospital PTSD Unit	
Intervention [6] Supportive counselling		Comparator [8] Cognitive behavioural therapy plus hypnosis		
Sample size [7] 24		Sample size [9] 30		
Population characteristics [10] .Civilian trauma survivors following nonsexual assault or motor vehicle accident who met the criteria for ASD . Intervention group – as above Comparator group(s) – as above				
Length of follow-up [11] ~6 months		Outcome(s) measured [12] CAPS-2 Intensity, CAPS-2 Frequency, IES-Intrusion, IES-Avoidance, BAI, Beck Depression Inventory		
INTERNAL VALIDITY				
Allocation [13] Process of minimisation stratified on gender, trauma types and ASDI total score using a random numbers system. Each month RA amended allocation to ensure that gender, trauma type, and PTSD severity were balanced across groups.	Comparison of study groups [14] No differences in age, time since trauma, National Adult Reading Test, Stanford Hypnotic Susceptibility Scale, Acute Stress Disorder Scale.	Blinding [15] Clinicians who conducted assessments did not have access to a) participant notes, b) treatment allocation of participants, or c) supervision discussion of therapy sessions.	Treatment/ measurement bias [16] No other differences in treatment apart from the interventions were apparent. Two independent clinicians conducted 20% of initial ASD assessments with interrater reliability of 100%.	Follow-up (ITT) [17] 6 months 2/24 of the SC and 7/30 of the CBP + hypnosis groups dropped out.
Overall quality assessment (descriptive) [18]. The study had similar populations in the two interventions, although blinding of patients was not possible. Proper randomisation did not occur and lack of allocation concealment means bias in patient allocation was possible.				
RESULTS				
Outcome [19]	Intervention group [20] Supportive counselling	Control group [21] CBT + hypnosis	Measure of effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]
Pretreatment to Posttreatment				

IES-Intrusion <u>ITT</u>				Harms (NNH) [24]
Pretreatment	24.58 (SD 8.21)	24.73 (SD 8.06)		95% CI [25]
Posttreatment	19.83 (SD 9.71)	11.30 (SD 9.98)	P<0.05	
Follow-up	20.21 (SD 9.96)	13.57 (SD 9.52)	P<0.05	NC
<u>Treatment completer</u>				
Pretreatment	24.45 (SD 8.57)	25.74 (8.41)		
Posttreatment	19.27 (SD 9.96)	7.26 (SD 6.99)	P<0.05	
Follow-up	19.68 (SD 10.25)	11.17 (SD 9.13)	P<0.05	
IES-Avoidance <u>ITT</u>				
Pretreatment	19.92 (SD 9.79)	24.43 (SD 9.49)		
Posttreatment	18.54 (SD 11.06)	15.03 (SD13.36)		
Follow-up	18.04 (SD 11.30)	16.30 (SD12.68)		
<u>Treatment completer</u>				
Pretreatment	19.55 (SD 10.09)	22.00 (SD 7.76)		
Posttreatment	18.05 (SD 11.37)	9.74 (SD 8.81)	P<0.05	
Follow-up	17.50 (SD 11.61)	11.39 (SD 8.48)	P<0.05	
Beck Anxiety Inventory <u>ITT</u>				
Pretreatment	28.67 (SD 13.45)	27.27 (SD11.47)		
Posttreatment	20.25 (SD 14.26)	15.47 (SD12.87)		
Follow-up	21.13 (SD 15.09)	17.07 (SD12.74)		
<u>Treatment completer</u>				
Pretreatment	29.23 (SD 13.74)	27.35 (SD12.06)		
Posttreatment	20.05 (SD 14.72)	11.70 (SD11.83)	P<0.05	
Follow-up	21.00 (SD 15.62)	14.04 (SD12.67)		
Beck Depression Inventory-2 <u>ITT</u>				
Pretreatment	22.04 (SD 11.77)	18.40 (SD 8.39)		
Posttreatment	14.96 (SD 10.92)	11.37 (SD 7.34)		
Follow-up	16.29 (SD 11.95)	13.57 (SD 8.78)		
<u>Treatment completer</u>				
Pretreatment	22.50 (SD 12.20)	19.48 (SD 9.38)		
Posttreatment	14.77 (SD 11.39)	10.30 (SD 8.04)		
Follow-up	16.23 (SD 12.49)	13.17 (SD 9.97)		
CAPS-2 Intensity <u>Treatment completer</u>				
Posttreatment	21.36 (SD 11.28)	10.83 (SD10.16)	P<0.05	
Follow-up	21.18 (SD 11.85)	14.09(SD11.52)	P<0.05	
CAPS-2 Frequency <u>Treatment completer</u>				
Posttreatment	23.59 (SD 13.29)	12.35 (SD11.86)	P<0.05	
Follow-up	23.23 (SD 14.64)	14.83 (SD13.22)	P<0.05	

PTSD <u>ITT</u>					
Posttreatment	50%	30%	NS		
Follow-up	58%	40%	NS		
<u>Treatment completer</u>					
Posttreatment	46%	9%	P<0.05		
Follow-up	59%	22%	P<0.05		
Total IES <12 <u>ITT</u>					
Follow-up	12%	23%	NS		
<u>Treatment completer</u>					
Follow-up	13%	30%	NS		
	Clinical importance (1-4) [26] 2- some clinically important differences		Relevance (1-5) [27] 1- patient relevant outcomes		
Any other adverse effects [28] No adverse events reported.					
EXTERNAL VALIDITY					
Generalisability [29] The study population is from Australia and relevant to the wider Australian population.					
Applicability [30] Some benefits and no harms were reported in the study.					
Comments [31]					

NC=not calculated due to all continuous data

STUDY DETAILS				
Reference [1] Bryant 1999				
Affiliation/source of funds [2] School of Psychology, University of New South Wales, Sydney, Australia/ supported by the National Health and Medical Research Council				
Study design [3] Randomised controlled trial	Level of evidence [4] II		Location/setting [5] Patients referred to the PTSD Unit at Westmead Hospital, Sydney	
Intervention [6] Prolonged exposure 2 weeks after trauma		Comparator [8] Prolonged exposure + anxiety management 2 weeks after trauma		
Sample size [7] 18 (14 completed treatment)		Sample size [9] 19 (15 completed treatment)		
Population characteristics [10] Survivors of motor vehicle accidents or non-sexual assault referred to the PTSD Unit at Westmead Hospital by hospital staff, local community mental health centres and police. Intervention group – as above Comparator group(s) – as above				
Length of follow-up [11] 6 months		Outcome(s) measured [12] Clinician Administered PTSD scale; Impact of Event Scale (Intrusion and avoidance); Beck Depression Inventory; State-Trait Anxiety Inventory.		
INTERNAL VALIDITY				
Allocation [13] No description of the method of randomisation was given.	Comparison of study groups [14] No significant differences in age, intervals between trauma and assessment, intervals before posttreatment follow-up or pretreatment acute stress disorder severity.	Blinding [15] All posttreatment assessments conducted by a clinical psychologist blind to treatment group status.	Treatment/ measurement bias [16] Apart from treatment assignments, groups appeared to be treated in the same manner.	Follow-up (ITT) [17] 6 months Of the 45 patients who completed treatment, 4 patients were not included in the follow-up assessment as they could not be contacted (n=2) or were instructed by legal counsel not to participate (n=2).
Overall quality assessment (descriptive) [18]. Although the method of randomisation was not given, the treatment groups appeared to be reasonably well matched.				
RESULTS				
Outcome [19]	Intervention group [20] Prolonged exposure	Control group [21] Prolonged exposure + anxiety management	Measure of effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]

IES Intrusion Pretreatment Posttreatment Follow-up	27.62 (SD 8.54) 8.54 (SD 8.64) 11.08 (SD 8.86)	28.46 (SD 5.59) 13.15 (SD15.81) 10.31 (SD10.00)	NR	Harms (NNH) [24] 95% CI [25] NC
IES Avoidance Pretreatment Posttreatment Follow-up	26.46 (SD 9.02) 7.92 (SD 8.20) 8.38 (SD 10.32)	26.46 (SD 6.54) 10.31 (SD10.54) 8.54 (SD 10.20)		
State-Trait Anxiety Inventory score Pretreatment Posttreatment Follow-up BDI score Pretreatment Posttreatment Follow-up CAPS-2 frequency Posttreatment Follow-up CAPS-2 intensity Posttreatment Follow-up	51.69 (SD 12.41) 35.92 (SD 10.12) 36.62 (SD 12.69) 19.69 (SD 11.38) 7.77 (SD 7.70) 7.97 (SD 7.76) 11.31 (SD 10.73) 12.62 (SD 13.63) 9.92 (SD 9.00) 12.23 (SD 11.77)	54.77 (SD10.28) 34.31 (SD16.95) 35.00 (SD12.91) 20.08 (SD12.52) 8.92 (SD 8.98) 8.92 (SD 8.98) 13.69 (SD10.93) 14.62 (SD13.72) 12.00 (SD10.31) 15.00 (SD13.68)	NR	
Patients scoring ≥ 2 SDs below pretreatment mean				
IES intrusion Posttreatment Follow-up IES avoidance Posttreatment Follow-up State-Trait Anxiety inventory Posttreatment Follow-up BDI score Posttreatment Follow-up	10/14 (71%) 8/13 (62%) 10/14 (71%) 9/13 (69%) 6/14 (43%) 6/13 (46%) 3/14 (21%) 3/13 (23%)	12/15 (80%) 10/13 (77%) 10/15 (67%) 8/13 (62%) 8/15 (53%) 5/13 (38%) 3/15 (20%) 2/13 (15%)		
Meet criteria for PTSD				
Posttreatment Follow-up	2/14 (14%) 2/13 (15%)	3/15 (20%) 3/13 (23%)		
Clinical importance (1-4) [26] 3- no clinically important effects			Relevance (1-5) [27] 1- patient relevant outcomes	
Any other adverse effects [28] No adverse events were reported.				
EXTERNAL VALIDITY				

Generalisability [29] The study population was in Australia and generalisable to the wider Australian population.
Applicability [30] No real benefits and no harms were reported in the study.
Comments [31] Patients who dropped out of treatment scored higher severity of acute stress disorder and State-Trait Anxiety Inventory Scores than those who completed treatment.

NC=not calculated because only continuous data reported; NR=not reported

STUDY DETAILS				
Reference [1] Bryant 1999				
Affiliation/source of funds [2] School of Psychology, University of New South Wales, Sydney, Australia/ supported by the National Health and Medical Research Council				
Study design [3] Randomised controlled trial	Level of evidence [4] II		Location/setting [5] Patients referred to the PTSD Unit at Westmead Hospital, Sydney	
Intervention [6] Supportive counselling 2 weeks after trauma		Comparator [8] Prolonged exposure + anxiety management 2 weeks after trauma		
Sample size [7] 19 (16 completed treatment)		Sample size [9] 19 (15 completed treatment)		
Population characteristics [10] Survivors of motor vehicle accidents or non-sexual assault referred to the PTSD Unit at Westmead Hospital by hospital staff, local community mental health centres and police. Intervention group – as above Comparator group(s) – as above				
Length of follow-up [11] 6 months		Outcome(s) measured [12] Clinician Administered PTSD scale; Impact of Event Scale (Intrusion and avoidance); Beck Depression Inventory; State-Trait Anxiety Inventory.		
INTERNAL VALIDITY				
Allocation [13] No description of the method of randomisation was given.	Comparison of study groups [14] No significant differences in age, intervals between trauma and assessment, intervals before posttreatment follow-up or pretreatment acute stress disorder severity.	Blinding [15] All posttreatment assessments conducted by a clinical psychologist blind to treatment group status.	Treatment/ measurement bias [16] Apart from treatment assignments, groups appeared to be treated in the same manner.	Follow-up (ITT) [17] 6 months Of the 45 patients who completed treatment, 4 patients were not included in the follow-up assessment as they could not be contacted (n=2) or were instructed by legal counsel not to participate (n=2).
Overall quality assessment (descriptive) [18]. Although the method of randomisation was not given, the treatment groups appeared to be reasonably well matched.				
RESULTS				
Outcome [19]	Intervention group [20] Supportive counselling	Control group [21] Prolonged exposure + anxiety management	Measure of effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]
IES Intrusion Pretreatment Posttreatment Follow-up	26.47 (SD 4.69) 22.80 (SD 9.17) 15.67 (SD 6.34)	28.46 (SD 5.59) 13.15 (SD15.81) 10.31 (SD10.00)		Harms (NNH) [24] 95% CI [25]

IES Avoidance Pretreatment	22.73 (SD 5.57)	26.46 (SD 6.54)	P<0.01	NC	
Posttreatment	21.33 (SD 6.23)	10.31 (SD10.54)			
Follow-up	20.13 (SD 4.66)	8.54 (SD 10.20)			
State-Trait Anxiety Inventory score Pretreatment	50.47 (SD 7.39)	54.77 (SD10.28)	P<0.02		
Posttreatment	41.47 (SD 12.91)	34.31 (SD16.95)			
Follow-up	44.73 (SD 7.34)	35.00 (SD12.91)			
BDI score Pretreatment	20.47 (SD 7.19)	20.08 (SD12.52)	P<0.01		
Posttreatment	13.73 (SD 7.21)	8.92 (SD 8.98)			
Follow-up	13.73 (SD 7.21)	8.92 (SD 8.98)			
CAPS-2 frequency Posttreatment	22.60 (SD 11.26)	13.69 (SD10.93)	P<0.01		
Follow-up	26.47 (SD 8.40)	14.62 (SD13.72)			
CAPS-2 intensity Posttreatment	20.53 (SD 10.72)	12.00 (SD10.31)	P<0.01		
Follow-up	29.00 (SD 9.91)	15.00 (SD13.68)			
Patients scoring ≥ 2 SDs below pretreatment mean					
IES intrusion Posttreatment	6/16 (38%)	12/15 (80%)			
Follow-up	9/15 (60%)	10/13 (77%)			
IES avoidance Posttreatment	4/16 (25%)	10/15 (67%)			
Follow-up	3/15 (20%)	8/13 (62%)			
State-Trait Anxiety inventory Posttreatment	2/16 (13%)	8/15 (53%)			
Follow-up	2/15 (13%)	5/13 (38%)			
BDI score Posttreatment	3/16 (19%)	3/15 (20%)			
Follow-up	2/15 (13%)	2/13 (15%)			
Meet criteria for PTSD					
Posttreatment	9/16 (56%)	3/15 (20%)	P<0.05		
Follow-up	10/15 (67%)	3/13 (23%)	P<0.05		
	Clinical importance (1-4) [26] 1- clinically important benefits		Relevance (1-5) [27] 1- patient relevant outcomes		
Any other adverse effects [28] No adverse events were reported.					
EXTERNAL VALIDITY					
Generalisability [29] The study population was in Australia and generalisable to the wider Australian population.					
Applicability [30] Benefits and no harms were reported in the study.					

Comments [31] Patients who dropped out of treatment scored higher severity of acute stress disorder and State-Trait Anxiety Inventory Scores than those who completed treatment.

NC=not calculated because only continuous data reported

STUDY DETAILS				
Reference [1] Echeburúa 1996				
Affiliation/source of funds [2] Facultad de Psicología, Universidad del País Vasco, San Sebastián, Spain/ Supported by UPV 006.230-0106/88 from the University of the Basque Country				
Study design [3] Quasi-randomised study	Level of evidence [4] III-1		Location/setting [5] Basque Country, Spain/ Community	
Intervention [6] Progressive muscular relaxation training		Comparator [8] Cognitive restructuring and specific coping-skills training		
Sample size [7] 10		Sample size [9] 10		
Population characteristics [10] Female victims of sexual aggression seeking psychological treatment at the Psychological Counselling Centres for Women of the Basque Country. Intervention group – as above Comparator group(s) – as above				
Length of follow-up [11] 12 months		Outcome(s) measured [12] Scale of Severity of Posttraumatic Stress Disorder Symptoms; Modified Fear Survey (MFS-III); Scale of Adaptation; Beck Depression Inventory (BDI); State-Trait Anxiety Inventory (STAI)		
INTERNAL VALIDITY				
Allocation [13] Assignment was carried out in order of arrival.	Comparison of study groups [14] Given the relatively small group sizes, groups appeared well matched. The MFS-III score of Fears was 141.3 (SD 22.1) in the progressive muscular relaxation training group and 118.4 (SD 33.3) in the CR + specific coping-skills training group (p<0.1).	Blinding [15] No blinding was stated.	Treatment/ measurement bias [16] There was no apparent treatment or measurement bias.	Follow-up (ITT) [17] 12 months with no losses to follow-up reported.
Overall quality assessment (descriptive) [18]. The study has potential bias due to lack of proper randomisation and lack of blinding. However, groups appeared to be well matched.				
RESULTS				

Outcome [19]	Intervention group [20] Progressive muscular relaxation training	Control group [21] Cognitive restructuring and specific coping-skills training	Measure of effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]
Rate of success ⁷			χ^2	
Posttreatment	5 (50%)	8 (80%)	1.97 (NS)	NNT 3 [1-10]
1 month	8 (80%)	10 (100%)	2.22 (NS)	NNT 5 [2-21]
3 months	8 (80%)	10 (100%)	2.22 (NS)	NNT 5 [2-21]
6 months	9 (90%)	10 (100%)	0.05 (NS)	NNT 10 [2-12]
12 months	8 (80%)	10 (100%)	2.22 (NS)	NNT 5 [2-21]
Global PTSD Scale (0-51)			t	
Posttreatment	18.7 (SD 9.2)	12.0 (SD 6.9)	1.84 (p<0.1)	
1 month	14.0 (SD 8.3)	8.0 (SD 4.4)	2.00 (p<0.1)	
6 months	10.3 (SD 6.7)	6.0 (SD 3.6)		
12 months	10.5 (SD 7.2)	5.0 (SD 2.5)		
Subscale of Re-experience (0-12)			t	
Posttreatment	4.7 (SD 2.0)	3.0 (SD 1.2)	2.30 (p<0.05)	
1 month	3.4 (SD 2.3)	2.0 (SD 1.1)	1.77 (p<0.1)	
6 months	2.0 (SD 1.6)	1.3 (SD 0.8)	1.78	
12 months	2.2 (SD 1.3)	0.9 (SD 1.0)	2.49 (p<0.05)	
Subscale of Avoidance (0-21)			t	
Posttreatment	5.6 (SD 4.2)	3.3 (SD 2.7)	1.45	
1 month	3.8 (SD 2.9)	1.5 (SD 1.4)	2.40 (p<0.05)	
6 months	2.7 (SD 2.7)	1.1 (SD 1.3)	1.68	
12 months	2.8 (SD 1.9)	0.8 (SD 1.3)	1.96 (p<0.1)	
Subscale of Arousal (0-18)			t	
Posttreatment	8.4 (SD 3.7)	5.7 (SD 3.4)	1.68	
1 month	6.8 (SD 3.9)	4.5 (SD 2.7)	1.55	
6 months	5.6 (SD 3.0)	3.6 (SD 2.6)	1.60	
12 months	5.5 (SD 3.8)	3.3 (SD 1.8)	1.65	
Fears (MFS-III; 45-225)			t	
Posttreatment	103.1 (SD 26.2)	101.7 (SD 26.9)	0.10	
1 month	100.2 (SD 19.4)	100.0 (SD 29.3)	0.00	
6 months	96.1 (SD 19.9)	98.9 (SD 34.8)	0.22	
12 months	95.8 (SD 22.6)	91.0 (SD 24.1)	0.46	

⁷ Success a Global Score <12 on Severity of Posttraumatic Stress Disorder Symptoms

Anxiety (STAI-E; 0-60)			t	
Posttreatment	20.6 (SD 14.7)	18.5 (SD 9.5)	0.37	
1 month	14.4 (SD 11.3)	19.3 (SD 7.5)	1.14	
6 months	15.0 (SD 10.9)	13.2 (SD 6.7)	0.42	
12 months	13.5 (SD 12.4)	10.4 (SD 4.9)	0.73	
Depression (BDI; 0-63)			t	
Posttreatment	8.0 (SD 9.4)	8.9 (SD 7.9)	0.22	
1 month	7.1 (SD 8.1)	7.0 (SD 6.1)	0.00	
6 months	4.8 (SD 6.2)	3.8 (SD 3.2)	0.46	
12 months	4.1 (SD 4.3)	3.6 (SD 2.7)	0.32	
Inadaptation (1-6)			t	
Posttreatment	2.8 (SD 0.42)	2.4 (SD 0.7)	1.55	
1 month	2.3 (SD 0.8)	2.4 (SD 0.8)	0.26	
6 months	1.9 (SD 0.6)	1.9 (SD 0.6)	0.00	
12 months	1.5 (SD 0.5)	1.8 (SD 0.4)	1.41	
	Clinical importance (1-4) [26] 4 No significant differences in rates of response defined as <12 on Severity of Posttraumatic Stress Disorder Symptoms		Relevance (1-5) [27] 1- patient relevant outcomes	
Any other adverse effects [28] No adverse events were reported.				
EXTERNAL VALIDITY				
Generalisability [29] The results may be generalisable to the Australian female population.				
Applicability [30] Some benefits and no harms were reported.				
Comments [31] The study was not blinded and results may have been limited by the small group sizes.				

STUDY DETAILS				
Reference [1] Eid 2001				
Affiliation/source of funds [2] Royal Norwegian Naval Academy and University of Bergen and Division of Disaster Psychiatry, Institute of Psychiatry, University of Oslo and HQ, Armed Forces Medical Services, Department of Psychiatry, NORWAY/ Source of funds not stated.				
Study design [3] Comparative study with concurrent controls.	Level of evidence [4] III-2	Location/setting [5] Community		
Intervention [6] Operational debriefing and brief stress management counselling	Comparator [8] Operational debriefing and brief stress management counselling + Group Psychological Debriefing			
Sample size [7] 9	Sample size [9] 9			
Population characteristics [10] Participants had assisted at the scene of a severe car accident inside a road tunnel. Intervention group – Military personnel who unexpectedly arrived at the scene (7 conscripts and 2 officers) Comparator group(s) – Firefighters (3 professional and 6 volunteer)				
Length of follow-up [11] 2 weeks	Outcome(s) measured [12] General Health Questionnaire (GHQ-30); Coping Style Questionnaire (CSQ-30); Impact of Event Scale IES); Posttraumatic Symptom Scale-10 (PTSS-10).			
INTERNAL VALIDITY				
Allocation [13] The civilians were given operational debriefing and brief stress management counselling, and the military personnel received additional Group Psychological Debriefing.	Comparison of study groups [14] Demographics of the study groups were not given. Study groups were different, as one group were military personnel whereas the other group were firefighters. In addition, the military personnel were the first at the scene of the accident and the firefighters arrived later.	Blinding [15] No blinding was performed.	Treatment/ measurement bias [16] The groups were treated with operational debriefing and brief stress management counselling at the same time. The surveys were completed at the Naval Base and Fire Station, therefore some differences may have been present in how these were filled out.	Follow-up (ITT) [17] 2 weeks with all participants responding to the survey.
Overall quality assessment (descriptive) [18]. This study is subject to a great deal of bias plus has small group sizes and short follow-up times.				
RESULTS				

Outcome [19]	Intervention group [20] Operational debriefing and brief stress management counselling	Control group [21] Operational debriefing and brief stress management counselling + Group Psychological Debriefing	Measure of effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]
PTSS-10	20.4 (SD 7.1)	13.2 (SD 3.6)	p<0.02	Harms (NNH) [24]
#1 Problems falling asleep	1.4 (SD 0.5)	1.0 (SD 0.0)	p<0.05	95% CI [25]
#4 Jumpiness/startle	2.7 (SD 1.5)	1.3 (SD 0.5)	p<0.05	NC
#7 Mood swings	2.8 (SD 1.3)	1.6 (SD 0.5)	p<0.05	
GHQ-30	22.6 (SD 6.0)	22.0 (SD 6.7)	NS	
IES- Intrusion	8.7 (SD 6.1)	6.7 (SD 3.1)	NS	
IES Avoidance	8.3 (SD 4.8)	4.8 (SD 4.5)	NS	
IES-Sum	17.0 (SD 10.7)	11.4 (SD 6.4)	NS	
	Clinical importance (1-4) [26] 2- some clinically important effects		Relevance (1-5) [27] 1- patient relevant outcomes	
Any other adverse effects [28] No adverse events were reported.				
EXTERNAL VALIDITY				
Generalisability [29] The study may be generalisable to an Australian population of emergency service workers.				
Applicability [30] Some benefits and no harms were reported.				
Comments [31] The study is subject to significant bias, small group sizes, and short follow-up. Therefore it is questionable whether the short term results are significant or not. Furthermore, although it is stated "efforts were made to ensure the anonymity of the participants", some participants may have been reluctant to state that they were having severe problems following the accident.				

NC=not calculated because only continuous data were reported

STUDY DETAILS				
Reference [1] Richards 2001				
Affiliation/source of funds [2] School of Nursing Midwifery and Health Visiting, University of Manchester, UK/ Source of funds not stated				
Study design [3] Comparative study with non-concurrent treatments	Level of evidence [4] III-3	Location/setting [5] Employees working in major financial services branches in the UK.		
Intervention [6] Critical Incident Stress Debriefing (CISD) Sample size [7] 225	Comparator [8] Critical Incident Stress Management (CISM) Sample size [9] 299			
Population characteristics [10] Employees of a major financial services institution who had been victims of armed robberies. Intervention group – as above Comparator group(s) – as above				
Length of follow-up [11] 3-12 months	Outcome(s) measured [12] Impact of events scale (IES); Posttraumatic stress scale (PSS); General Health Questionnaire (GHQ-28)			
INTERNAL VALIDITY				
Allocation [13] Employees received a single intervention CISD for 16 months before a more comprehensive CISM was introduced.	Comparison of study groups [14] There was no difference between the groups on age, gender, or employee grade. However, the groups were not concurrent.	Blinding [15] No blinding was performed.	Treatment/ measurement bias [16] Since the groups were not concurrent, it is possible other treatment or measurement biases were present between the groups.	Follow-up (ITT) [17] A complete dataset was available for 75/225 (33%) of the CISD and 142/299 (47%) of the CISM groups.
Overall quality assessment (descriptive) [18]. It is likely the results are biased since allocation was non-randomised, the groups were non-concurrent and treatment or measurement differences may be present between the two time periods, and the number of patients with complete follow-up was different between the two groups (33% versus 47%).				
RESULTS				
Outcome [19]	Intervention group [20] CISD	Control group [21] CISM	Measure of effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]
Impact of event scale Intrusion <u>Complete sample</u> ⁸ Day 3 post-raid 1 months post-raid Follow-up ⁹ <u>Complete follow-up</u> ¹⁰ Day 3 post-raid 1 months post-raid Follow-up	17.44 (SD 9.17) 4.77 (SD 6.52) 5.02 (SD 6.81) 18.79 (SD 8.29) 4.48 (SD 6.44) 4.04 (SD 6.24)	18.25 (SD 9.05) 6.05 (SD 7.00) 2.50 (4.55) 18.60 (SD 8.89) 5.31 (SD 6.22) 2.40 (SD 4.22)		Harms (NNH) [24] 95% CI [25] NC

⁸ In the CISD group there were n=225 at Day 3, n=114 at 1 month, and n=106 at follow-up. In the CISM group there were n=299 at Day 3, n=249 at 1 month and n=152 at follow-up.

Impact of event scale				
Avoidance				
<u>Complete sample</u>				
Day 3 post-raid	14.17 (SD 9.14)	15.26 (SD 9.66)		
1 months post-raid	3.68 (SD 6.66)	5.08 (SD 7.72)		
Follow-up	3.90 (SD 6.79)	2.67 (SD 5.66)		
<u>Complete follow-up</u>				
Day 3 post-raid	14.16 (SD 8.59)	15.46 (SD 9.58)		
1 months post-raid	3.60 (SD 6.25)	4.17 (SD 6.55)		
Follow-up	3.08 (SD 5.60)	1.77 (SD 4.57)		
Impact of event scale				
Total				
<u>Complete sample</u>				
Day 3 post-raid	31.61 (SD 16.45)	33.52 (SD16.52)		
1 months post-raid	8.46 (SD 12.00)	11.13 (SD13.83)		
Follow-up	8.92 (SD 12.97)	4.31 (SD 8.57)	P<0.01	
<u>Complete follow-up</u>				
Day 3 post-raid	32.95 (SD 15.10)	34.06 (SD16.34)		
1 months post-raid	8.08 (SD 11.43)	9.48 (SD 11.72)		
Follow-up	7.12 (SD 11.17)	4.17 (SD 8.49)		
Posttraumatic stress scale				
<u>Complete sample</u>				
Day 3 post-raid	13.87 (SD 9.57)	15.38 (SD10.71)		
1 months post-raid	4.40 (SD 6.11)	5.42 (SD 7.00)		
Follow-up	4.40 (SD 6.11)	2.75 (SD 5.01)	P<0.05	
<u>Complete follow-up</u>				
Day 3 post-raid	14.39 (SD 8.35)	15.52 (SD10.85)		
1 months post-raid	4.63 (SD 6.17)	4.85 (SD 6.00)		
Follow-up	3.85 (SD 6.40)	2.52 (SD 4.69)		
GHQ-28				
<u>Complete sample</u>				
Day 3 post-raid	7.33 (SD 6.53)	7.92 (SD 6.57)		
1 months post-raid	1.86 (SD 4.00)	2.07 (SD 4.36)		
Follow-up	1.47 (SD 3.77)	1.26 (SD 3.14)	NS	
<u>Complete follow-up</u>				
Day 3 post-raid	8.24 (SD 6.14)	7.71 (SD 6.59)		
1 months post-raid	1.99 (SD 4.19)	1.68 (SD 3.88)		
Follow-up	1.48 (SD 3.93)	1.02 (SD 2.73)		
IES ≥ 26				
Day 3 post-raid	64.5%	67.2%		
1 months post-raid	12.3%	15.7%		
Follow-up	11.3%	5.3%	NS	
	Clinical importance (1-4) [26] 2- some clinically important effects		Relevance (1-5) [27] 1- patient relevant outcomes	
Any other adverse effects [28] No adverse events were reported.				

⁹ The follow-up score was a computed by taking the mean score of the 3, 6 and 12 month points.

¹⁰ CISD n=75 and CISM n=142

EXTERNAL VALIDITY

Generalisability [29] The result is generalisable to the Australian population.

Applicability [30] Benefits and no harms were reported in the study.

Comments [31] The study is weakened by the possibilities for bias due to the non-concurrent design. All employees had been directly confronted, but no firearms were discharged, there were no physical injuries, and no hostages were taken.

NC=not calculated because reported data were continuous

Question 16

STUDY DETAILS		
Reference [1] Bryant 2003		
Affiliation/source of funds [2] The researchers were based in the School of Psychology, University of New South Wales, Sydney, Australia The research was funded by the National Mental Health and Research Council.		
Study design [3] Randomised controlled trial	Level of evidence [4] II	Location/setting [5] Westmead Hospital, Sydney, Australia
Intervention [6] Supportive Counselling (SC) Sample size [7] 18	Comparator [8] Imaginal exposure + cognitive restructuring (IE + CR) Sample size [9] 20	
Population characteristics [10] Civilian trauma survivors consecutively referred to the Westmead Hospital PTSD Unit following nonsexual assault or a motor vehicle accident, who met the criteria for PTSD, as defined by the DSM-IV, of at least 3 months duration. Exclusion criteria included history of psychosis, organic brain syndrome, or substance dependence, current suicidal ideation, history of childhood sexual abuse, or age of less than 17 or more than 60 years. Intervention group – as above Comparator group(s) – as above		
Length of follow-up [11] 6 months	Outcome(s) measured [12] Clinician Administered PTSD Scale – 2 nd Ed. (CAPS-2), Beck Depression Inventory – 2 nd Ed. (BDI-2), Impact of Event Scale (IES), State-Trait Anxiety Inventory – State subscale (STAI-S), Catastrophic Cognitions Questionnaire (CCQ)	
INTERNAL VALIDITY		

Allocation [13] Randomisation was conducted by a process of minimisation stratified on gender, trauma type, and PTSD total score. Participants were randomly assigned according to a random numbers system, and each month Richard A. Bryant amended the allocation to ensure that gender, trauma type, and PTSD severity were balanced across conditions.	Comparison of study groups [14] No significant differences in age, time since trauma, verbal intelligence (as measured by the National Adult Reading Test – NART), years of education or logic or confidence rating were found between groups.	Blinding [15] Blindness was maintained by ensuring that clinicians who conducted assessments did not have access to (a) participant notes, (b) treatment allocation of participants, or (c) supervision discussions of therapy sessions.	Treatment/ measurement bias [16] No differences apart from type of intervention were apparent.	Follow-up (ITT) [17] 3/18 in the SC condition dropped out before completing treatment. 5/20 in the IE+CR condition dropped out before completing treatment. A planned comparison of treatment completers and treatment dropouts indicated that those who dropped out of treatment had higher scores on the BDI-2, IES-Avoidance scale, and CCQ than did those who completed treatment.
Overall quality assessment (descriptive) [18]. 1a., 2c., 3b., 4a.				
RESULTS				
Outcome [19]	Intervention group [20] SC	Control group [21] IE+CR	Measure of effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]
<u>CAPS-2 Intensity</u> <u>ITT</u> Pretreatment Posttreatment 6 month follow-up	32.83 (SD 8.01) 28.00 (SD 15.31) 30.28 (SD 12.89)	32.70 (SD 7.51) 15.90(SD 13.36) 15.70(SD 14.79)	p<.01 (p-h Tukey)	Harms (NNH) [24] 95% CI [25]
<u>Treatment Completer</u> Pretreatment Posttreatment 6 month follow-up	31.87 (SD 7.49) 23.73 (SD 12.94) 26.40 (SD 10.24)	32.73 (SD 7.88) 10.22 (SD 9.75) 8.53 (SD 10.25)	p<.01 (p-h Tukey) p<.01 (p-h Tukey)	

<u>CAPS-2 Frequency</u>				
<u>ITT</u>				
Pretreatment	38.33 (SD 9.64)	36.00 (SD 8.69)		
Posttreatment	30.00 (SD 16.42)	17.20(SD 15.62)		
6 month follow-up	32.44 (SD 13.57)	17.00(SD 15.22)	p<.01 (p-h Tukey)	
<u>Treatment Completer</u>				
Pretreatment	38.33 (SD 9.64)	36.00 (SD 8.69)		
Posttreatment	25.20 (SD 13.14)	10.93(SD 11.97)	p<.01 (p-h Tukey)	
6 month follow-up	28.07 (SD 9.71)	10.00(SD 10.04)	p<.01 (p-h Tukey)	
<u>CAPS-2 PTSD diagnosis</u>				
<u>ITT</u>				
Pretreatment	100%	100%		
Posttreatment	67%	35%	X ² (37, N=38)=3.80, p<.05	NNT 3 [2-7]
6 month follow-up	78%	40%	X ² (37, N=38)=5.55, p<.05	NNT 3 [1-10]
<u>Treatment Completer</u>				
Pretreatment	100%	100%		
Posttreatment	60%	13%	X ² (29, N=30)=7.03, p<.01	NNT 2 [1-5]
6 month follow-up	73%	20%	X ² (29, N=30)=8.57, p<.01	NNT 3 [1-22]
<u>IES-I</u>				
<u>ITT</u>				
Pretreatment	28.44 (SD 6.60)	26.60 (SD 7.02)		
Posttreatment	24.06 (SD 10.82)	17.20(SD 15.62)		
6 month follow-up	25.44 (SD 7.79)	15.95(SD 12.18)	p<.05 (p-h Tukey)	
<u>Treatment Completer</u>				
Pretreatment	27.53 (SD 6.85)	25.27 (SD 7.29)		
Posttreatment	27.53 (SD 6.85)	8.93 (SD 6.25)	p<.01 (p-h Tukey)	
6 month follow-up	22.80 (SD 6.86)	11.07 (SD 9.64)	p<.01 (p-h Tukey)	
<u>IES-A</u>				
<u>ITT</u>				
Pretreatment	26.17 (SD 8.95)	26.40 (SD 6.65)		
Posttreatment	25.50 (SD 9.54)	16.15(SD 13.49)		
6 month follow-up	24.78 (SD 9.55)	14.95(SD 12.32)	p<.01 (p-h Tukey)	
<u>Treatment Completer</u>				
Pretreatment	23.87 (SD 7.80)	24.20 (SD 5.56)		
Posttreatment	25.20 (SD 9.40)	7.80 (SD 7.88)	p<.01 (p-h Tukey)	
6 month follow-up	23.60 (SD 9.16)	9.27 (SD 7.69)	p<.01 (p-h Tukey)	
<u>STAI-S</u>				
<u>ITT</u>				
Pretreatment	56.28 (SD 11.12)	54.60 (SD 8.20)		
Posttreatment	51.50 (SD 12.00)	41.45(SD 14.77)		
6 month follow-up	53.33 (SD 9.70)	43.45(SD 11.85)	p<.05 (p-h Tukey)	
<u>Treatment Completer</u>				
Pretreatment	54.80 (SD 11.65)	53.47 (SD 9.13)		
Posttreatment	49.07 (SD 11.68)	35.93(SD 12.77)	p<.01 (p-h Tukey)	
6 month follow-up	51.13 (SD 9.06)	38.60(SD 11.84)	p<.01 (p-h Tukey)	

<u>BDI-2</u>				
<u>ITT</u>				
Pretreatment	26.56 (SD 11.15)	23.15(SD 10.05)		
Posttreatment	23.78 (SD 12.10)	13.85(SD 14.31)		
6 month follow-up	25.33 (SD 12.05)	14.95(SD 13.99)	p<.05 (p-h Tukey)	
<u>Treatment Completer</u>				
Pretreatment	23.20 (SD 8.39)	19.93 (SD 7.00)		
Posttreatment	19.87 (SD 8.44)	6.93 (SD 6.86)	p<.01 (p-h Tukey)	
6 month follow-up	20.27 (SD 8.22)	8.40 (SD 7.48)	p<.01 (p-h Tukey)	
<u>CCQ</u>				
<u>ITT</u>				
Pretreatment	67.28 (SD 17.21)	66.05(SD 15.00)		
Posttreatment	67.61 (SD 18.58)	55.00(SD 18.61)		
6 month follow-up	70.78 (SD 15.57)	48.65(SD 19.30)	p<.01 (p-h Tukey)	
<u>Treatment Completer</u>				
Pretreatment	64.67 (SD 17.18)	62.20(SD 15.21)		
Posttreatment	65.07 (SD 18.89)	47.47(SD 14.72)	p<.01 (p-h Tukey)	
6 month follow-up	68.87 (SD 15.82)	39.00 (SD 9.80)	p<.01 (p-h Tukey)	
<u>Good end state functioning (defined as CAPS-2 score of <19 and BDI-2 score of <10)</u>				
<u>ITT</u>				
6 month follow-up	0%	40%	X ² (37, N=38)=9.12, p<.01	3 [1-5]
<u>Treatment Completer</u>				
6 month follow-up	0%	60%	X ² (29, N=30)+12.86, p<.01	2 [1-3]
	Clinical importance (1-4) [26] 1 A clinically important benefit for the full range of plausible estimates.		Relevance (1-5) [27] 1 Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.	
Any other adverse effects [28] No adverse effects reported.				
EXTERNAL VALIDITY				
Generalisability [29] The study population were civilian trauma survivors in Westmead, Sydney, NSW, so the study would therefore be generalisable to the Australian population.				
Applicability [30] No harms were reported in this study.				
Comments [31]				

p-h=post hoc

STUDY DETAILS		
Reference [1] Bryant 2003		
Affiliation/source of funds [2] The researchers were based in the School of Psychology, University of New South Wales, Sydney, Australia The research was funded by the National Mental Health and Research Council.		
Study design [3] Randomised controlled trial	Level of evidence [4] II	Location/setting [5] Westmead Hospital, Sydney, Australia
Intervention [6] Imaginal exposure (IE) Sample size [7] 20	Comparator [8] Imaginal exposure + cognitive restructuring (IE + CR) Sample size [9] 20	
Population characteristics [10] Civilian trauma survivors consecutively referred to the Westmead Hospital PTSD Unit following nonsexual assault or a motor vehicle accident, who met the criteria for PTSD, as defined by the DSM-IV, of at least 3 months duration. Exclusion criteria included history of psychosis, organic brain syndrome, or substance dependence, current suicidal ideation, history of childhood sexual abuse, or age of less than 17 or more than 60 years. Intervention group – as above Comparator group(s) – as above		
Length of follow-up [11] 6 months	Outcome(s) measured [12] Clinician Administered PTSD Scale – 2 nd Ed. (CAPS-2), Beck Depression Inventory – 2 nd Ed. (BDI-2), Impact of Event Scale (IES), State-Trait Anxiety Inventory – State subscale (STAI-S), Catastrophic Cognitions Questionnaire (CCQ)	
INTERNAL VALIDITY		

<p>Allocation [13] Randomisation was conducted by a process of minimisation stratified on gender, trauma type, and PTSD total score. Participants were randomly assigned according to a random numbers system, and each month Richard A. Bryant amended the allocation to ensure that gender, trauma type, and PTSD severity were balanced across conditions.</p>	<p>Comparison of study groups [14] No significant differences in age, time since trauma, verbal intelligence (as measured by the National Adult Reading Test – NART), years of education or logic or confidence rating were found between groups.</p>	<p>Blinding [15] Blindness was maintained by ensuring that clinicians who conducted assessments did not have access to (a) participant notes, (b) treatment allocation of participants, or (c) supervision discussions of therapy sessions.</p>	<p>Treatment/ measurement bias [16] No differences apart from type of intervention were apparent.</p>	<p>Follow-up (ITT) [17] 5/20 in the IE condition dropped out before completing treatment. 5/20 in the IE+CR condition dropped out before completing treatment. A planned comparison of treatment completers and treatment dropouts indicated that those who dropped out of treatment had higher scores on the BDI-2, IES-Avoidance scale, and CCQ than did those who completed treatment.</p>
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Overall quality assessment (descriptive) [18].
1a., 2c., 3b., 4a.

RESULTS

Outcome [19]	Intervention group [20] IE	Control group [21] IE+CR	Measure of effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]
<p><u>CAPS-2 Intensity</u> <u>ITT</u> Pretreatment Posttreatment 6 month follow-up <u>Treatment Completer</u> Pretreatment Posttreatment 6 month follow-up</p>	<p>32.50 (SD 8.71) 18.15 (SD 11.12) 20.70 (SD 12.00) 30.67 (SD 7.94) 14.60 (SD 7.96) 16.67 (SD 10.49)</p>	<p>32.70 (SD 7.51) 15.90(SD 13.36) 15.70(SD 14.79) 32.73 (SD 7.88) 10.22 (SD 9.75) 8.53 (SD 10.25)</p>	<p>p<.05 (p-h Tukey)</p>	<p>Harms (NNH) [24] 95% CI [25]</p>

<u>CAPS-2 Frequency</u>				
<u>ITT</u>				
Pretreatment	36.80 (SD 9.82)	36.00 (SD 8.69)		
Posttreatment	20.55 (SD 12.73)	17.20(SD 15.62)		
6 month follow-up	23.25 (SD 12.90)	17.00(SD 15.22)		
<u>Treatment Completer</u>				
Pretreatment	36.80 (SD 9.82)	36.00 (SD 8.69)		
Posttreatment	16.00 (SD 10.14)	10.93(SD 11.97)		
6 month follow-up	19.60 (SD 11.85)	10.00(SD 10.04)	p<.05 (p-h Tukey)	
<u>CAPS-2 PTSD</u>				
<u>diagnosis</u>				
<u>ITT</u>				
Pretreatment	100%	100%		7 [NA*]
Posttreatment	50%	35%		10 [NA*]
6 month follow-up	50%	40%		8 [NA*]
<u>Treatment Completer</u>				7 [NA*]
Pretreatment	100%	100%		
Posttreatment	33%	13%		
6 month follow-up	33%	20%		
<u>IES-I</u>				
<u>ITT</u>				
Pretreatment	23.85 (SD 7.07)	26.60 (SD 7.02)		
Posttreatment	17.65 (SD 7.34)	17.20(SD 15.62)		
6 month follow-up	17.60 (SD 9.88)	15.95(SD 12.18)		
<u>Treatment Completer</u>				
Pretreatment	23.00 (SD 7.40)	25.27 (SD 7.29)		
Posttreatment	15.07 (SD 6.26)	8.93 (SD 6.25)	p<.01 (p-h Tukey)	
6 month follow-up	15.20 (SD 9.86)	11.07 (SD 9.64)	p<.05 (p-h Tukey)	
<u>IES-A</u>				
<u>ITT</u>				
Pretreatment	26.40 (SD 6.65)	26.40 (SD 6.65)		NR
Posttreatment	19.45 (SD 13.48)	16.15(SD 13.49)		
6 month follow-up	20.75 (SD 12.66)	14.95(SD 12.32)		
<u>Treatment Completer</u>				
Pretreatment	25.13 (SD 6.76)	24.20 (SD 5.56)		
Posttreatment	13.87 (SD 10.36)	7.80 (SD 7.88)		NR
6 month follow-up	15.47 (SD 9.93)	9.27 (SD 7.69)		
<u>STAI-S</u>				
<u>ITT</u>				
Pretreatment	56.80 (SD 11.22)	54.60 (SD 8.20)		
Posttreatment	43.10 (SD 13.52)	41.45(SD 14.77)		
6 month follow-up	42.85 (SD 14.90)	43.45(SD 11.85)		
<u>Treatment Completer</u>				
Pretreatment	55.80 (SD 11.85)	53.47 (SD 9.13)		
Posttreatment	37.53 (SD 9.44)	35.93(SD 12.77)		
6 month follow-up	37.20 (SD 11.77)	38.60(SD 11.84)		

<u>BDI-2</u>				
<u>ITT</u>				
Pretreatment	21.65 (SD 11.18)	23.15(SD 10.05)		
Posttreatment	17.45 (SD 12.82)	13.85(SD 14.31)		
6 month follow-up	16.15 (SD 12.19)	14.95(SD 13.99)		
<u>Treatment Completer</u>				
Pretreatment	19.93 (SD 7.00)	19.93 (SD 7.00)		
Posttreatment	14.33 (SD 12.08)	6.93 (SD 6.86)	p<.05 (p-h Tukey)	
6 month follow-up	12.60 (SD 10.69)	8.40 (SD 7.48)		
<u>CCQ</u>				
<u>ITT</u>				
Pretreatment	69.20 (SD 17.87)	66.05(SD 15.00)		
Posttreatment	63.80 (SD 18.15)	55.00(SD 18.61)		
6 month follow-up	60.10 (SD 19.24)	48.65(SD 19.30)		
<u>Treatment Completer</u>				
Pretreatment	65.60 (SD 17.75)	62.20(SD 15.21)		
Posttreatment	58.40 (SD 16.10)	47.47(SD 14.72)	P<.05 (p-h Tukey)	
6 month follow-up	53.47 (SD 15.84)	39.00 (SD 9.80)		
<u>Good end state functioning (defined as CAPS-2 score of <19 and BDI-2 score of <10)</u>				
<u>ITT</u>				
6 month follow-up	15%	40%	X ² (39, N=40)=3.13, p<.07	4 [NA*]
<u>Treatment Completer</u>				
6 month follow-up	20%	60%	X ² (29, N=30)=5.00, p<.05	3 [NA*]
	Clinical importance (1-4) [26] 1 A clinically important benefit for the full range of plausible estimates.		Relevance (1-5) [27] 1 Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.	
Any other adverse effects [28] No adverse effects reported.				
EXTERNAL VALIDITY				
Generalisability [29] The study population were civilian trauma survivors in Westmead, Sydney, NSW, so the study would therefore be generalisable to the Australian population.				
Applicability [30] No harms were reported in this study.				
Comments [31]				

p-h=post hoc, NA*=not applicable because 95 % CI for number needed to treat approached infinity and are thus meaningless

STUDY DETAILS				
Reference [1] Neuner, Schauer, Klaschik, Karunakara & Elbert, 2004				
Affiliation/source of funds [2] The researchers were based at Department of Clinical Psychology, University of Konstanz, Konstanz, Germany and Vivo, Cupramontana, Italy. Also John Hopkins University, School of Public Health and Medecins Sans Frontieres. The research was funded by Deutsche Forschungsgemeinschaft.				
Study design [3] Randomised controlled trial	Level of evidence [4] II		Location/setting [5] Sudanese refugees in a Ugandan refugee settlement	
Intervention [6] Psychoeducation (PE)	Comparator [8] Psychoeducation + narrative exposure (PE + NET)			
Sample size [7] 12	Sample size [9] 17			
Population characteristics [10] Sudanese refugees living in a Ugandan refugee settlement who met the criteria for PTSD Exclusion criteria – mental retardation or psychosis as demonstrated by a clinical examination. Intervention group – as above Comparator group(s) – as above				
Length of follow-up [11] 1 year		Outcome(s) measured [12] Posttraumatic Stress Diagnostic Scale (PDS), Composite International Diagnostic Interview (CIDI) - PTSD part, Self-Reporting Questionnaire (SRQ-20) (anxiety and depression), Medical Outcome Study Self-Report Form (SF-12)		
INTERNAL VALIDITY				
Allocation [13] Participants were assigned to treatment group based on the throw of a dice.	Comparison of study groups [14] No tests of statistical significance were conducted to compare study groups. However, noted sociodemographic differences included: PE + NET treatment condition - 46.7% male, 53.3% female, 25.0% single, 0.0% widowed, 18.8% no occupation. PE treatment condition - 25.0% male, 75%, female, 8.3% single, 25% widowed, 33.3% no occupation.	Blinding [15] The outcome assessors were blind for the participant's treatment condition. The respondents were instructed not to inform the outcome assessors about the type of treatment or the number of sessions they had received.	Treatment/ measurement bias [16] The PE treatment condition consisted of one session, while the PE + NET treatment condition consisted of four sessions.	Follow-up (ITT) [17] 2/17 in the PE + NET treatment group did not complete treatment. 1 year 3/17 in the PE + NET treatment group dropped out 1/12 in the PE treatment group dropped out
Overall quality assessment (descriptive) [18]. 1b. 2b. 3c. 4a.				
RESULTS				

Outcome [19]	Intervention group [20] PE	Control group [21] PE + NET	Measure of effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25] NC
<u>PDS</u> Pretreatment Posttreatment 4 month follow-up 1 year follow-up	19.5 (SD 8.0) 21.2 (SD 9.4) 27.7 (SD 6.6) 23.9 (SD 7.0)	25.2 (SD 7.4) 19.1 (SD 11.7) 24.5 (SD 7.8) 16.0 (SD 5.1)	F(1,106) = 14.00, p<.01	Harms (NNH) [24] 95% CI [25]
<u>CIDI-PTSD</u> Pretreatment 1 year follow-up	14.2 (SD 2.9) 13.4 (SD 3.3)	13.4 (SD 2.1) 8.9 (SD 2.7)	F(1, 34) = 7.03, p=.01	
<u>PTSD diagnosis (CIDI)</u> Pretreatment 1 year follow-up	12 (100%) 8 (80%)	14 (100%) 4 (29%)	X ² (2, N=38)=9.48, p<.01	
<u>SRQ-20</u> Pretreatment Posttreatment 4 month follow-up 1 year follow-up	18.6 (SD 2.0) 15.3 (SD 3.2) 15.1 (SD 2.6) 14.4 (SD 4.1)	15.6 (SD 2.9) 13.1 (SD 5.1) 11.9 (SD 4.9) 11.0 (SD 5.1)	NS NS NS NS	
<u>SRQ-20 (% classified as mental health cases)</u> Pretreatment Posttreatment 4 month follow-up 1 year follow-up	100% 92% 100% 91%	100% 73% 73% 50%	NS	
<u>SF-12</u> Pretreatment Posttreatment 4 month follow-up 1 year follow-up	0.23 (SD 0.15) 0.33 (SD 0.19) 0.37 (SD 0.14) 0.35 (SD 0.17)	0.27 (SD 0.12) 0.36 (SD 0.19) 0.38 (SD 0.12) 0.44 (SD 0.19)	NS NS NS NS	
	Clinical importance (1-4) [26] 1 A clinically important benefit for the full range of plausible estimates.		Relevance (1-5) [27] 1 Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.	
Any other adverse effects [28] No adverse effects reported.				
EXTERNAL VALIDITY				
Generalisability [29] Results could be generalisable to refugee populations within Australia as well as potentially other populations.				

Applicability [30] Some benefits and no harms were reported in the study.

Comments [31]

The incidence of one or more further traumatic events in the 1 year follow-up period was 93%. The mean number of traumatic event types differed significantly between those refugees who stayed ($M=4.00$, $SD=2.40$) and those who left ($M=2.50$, $SD=1.976$) the settlement, $t(39)=2.20$, $p=.03$.

From the PE + NET treatment group, significantly more refugees left the refugee settlement by the time of 1 year follow-up than from the PE treatment group.

NC=not calculated because all reported data were continuous

STUDY DETAILS				
Reference [1] Neuner, Schauer, Klaschik, Karunakara & Elbert, 2004				
Affiliation/source of funds [2] The researchers were based at Department of Clinical Psychology, University of Konstanz, Konstanz, Germany and Vivo, Cupramontana, Italy. Also John Hopkins University, School of Public Health and Medecins Sans Frontieres. The research was funded by Deutsche Forschungsgemeinschaft.				
Study design [3] Randomised control trial	Level of evidence [4] II		Location/setting [5] Sudanese refugees in a Ugandan refugee settlement	
Intervention [6] Psychoeducation (PE) Sample size [7] 12		Comparator [8] Psychoeducation + supportive counselling (PE+SC) Sample size [9] 14		
Population characteristics [10] Sudanese refugees living in a Ugandan refugee settlement who met the criteria for PTSD. Exclusion criteria – mental retardation or psychosis as demonstrated by a clinical examination. Intervention group – as above Comparator group(s) – as above				
Length of follow-up [11] 15 months		Outcome(s) measured [12] Posttraumatic Stress Diagnostic Scale (PDS), Composite International Diagnostic Interview (CIDI) - PTSD part, Self-Reporting Questionnaire (SRQ-20) (anxiety and depression), Medical Outcome Study Self-Report Form (SF-12)		
INTERNAL VALIDITY				
Allocation [13] Participants were assigned to treatment group based on the throw of a dice.	Comparison of study groups [14] No tests of statistical significance were conducted to compare study groups.	Blinding [15] The outcome assessors were blind for the participant's treatment condition. The respondents were instructed not to inform the outcome assessors about the type of treatment or the number of sessions they had received.	Treatment/ measurement bias [16] The PE treatment condition consisted of one session, while the PE + SC treatment condition consisted of four sessions.	Follow-up (ITT) [17] 1/14 failed to complete treatment 1 year 1/12 in the PE treatment group dropped out
Overall quality assessment (descriptive) [18]. 1b. 2b. 3c. 4a.				
RESULTS				

Outcome [19]	Intervention group [20] PE	Control group [21] PE+SC	Measure of effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]
<u>PDS</u> Post 4 month 1 year	21.2 (SD 9.4) 27.7 (SD 6.6) 23.9 (SD 7.0)	19.8 (SD 10.9) 22.8 (SD 10.1) 23.1 (SD 7.7)	NS	Harms (NNH) [24] 95% CI [25]
<u>CIDI-PTSD</u> 1 year	13.4 (SD 3.3)	12.6 (SD 3.2)	NS	NC
<u>PTSD diagnosis (CIDI)</u> 1 year	8 (80%)	11 (79%)	NS	
<u>SRQ-20</u> Post 4 month 1 year	15.3 (SD 3.2) 15.1 (SD 2.6) 14.4 (SD 4.1)	14.3 (SD 5.0) 12.8 (SD 3.9) 12.4 (SD 4.8)	NS	
<u>SRQ-20 (% classified as mental health cases)</u> Pretreatment Posttreatment 4 month follow-up 1 year follow-up	100% 92% 100% 91%	100% 85% 85% 77%	NS	
<u>SF-12</u> Pretreatment Posttreatment 4 month follow-up 1 year follow-up	0.23 (SD 0.15) 0.33 (SD 0.19) 0.37 (SD 0.14) 0.35 (SD 0.17)	0.34 (SD 0.11) 0.33 (SD 0.21) 0.33 (SD 0.14) 0.36 (SD 0.14)	not stated	
	Clinical importance (1-4) [26] 3 No clinically important effects		Relevance (1-5) [27] 1 Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.	
Any other adverse effects [28] No adverse effects reported.				
EXTERNAL VALIDITY				
Generalisability [29] Results could be generalisable to refugee populations within Australia as well as potentially other populations.				
Applicability [30] Some benefits and no harms were reported in the study.				

Comments [31]

The incidence of one or more further traumatic events in the 1 year follow-up period was 93%. The mean number of traumatic event types differed significantly between those refugees who stayed ($M=4.00$, $SD=2.40$) and those who left ($M=2.50$, $SD=1.976$) the settlement, $t(39)=2.20$, $p=.03$.

From the PE + NET treatment group, significantly more refugees left the refugee settlement by the time of 1 year follow-up than from the PE treatment group.

STUDY DETAILS				
Reference [1] Otto et al 2003				
Affiliation/source of funds [2] Pfizer Pharmaceuticals & the van Amerigen Foundation				
Study design [3] Randomised controlled trial	Level of evidence [4] II		Location/setting [5] Outpatient Boston, America	
Intervention [6] Sertraline + CBT (mean dose 100mg/ day) Sample size [7] 5	Comparator(s) [8] Sertraline (mean dose 125mg/ day) Sample size [9] 5			
Population characteristics [10] Intervention group – Cambodian refugees who meet the criteria for PTSD despite ongoing pharmacotherapy as determined by the Structured Clinical Interview for DSM-IV. Women who failed to respond adequately to treatment with clonazepam (0.5-1mg/ day) in combination with an adequate dose of SSRI other than sertraline. Comparator group(s) – Cambodian refugees who meet the criteria for PTSD despite ongoing pharmacotherapy as determined by the Structured Clinical Interview for DSM-IV. Women who failed to respond adequately to treatment with clonazepam (0.5-1mg/ day) in combination with an adequate dose of SSRI other than sertraline.				
Length of follow-up [11] Not stated	Outcome(s) measured [12] Primary - Clinician-Administered PTSD Scale (CAPS) Secondary - depression and anxiety severity as assessed by the Hopkins Symptom Checklist-25; Anxiety Sensitivity Index			
INTERNAL VALIDITY				
Randomisation [13] "Randomly assigned"	Comparison of study groups [14] There were some differences between the baseline scores for CAPS reexperiencing, HSCL-90 somatisation, ASI and ASI-Khmer items	Blinding [15] Open label	Treatment/ measurement bias [16] Sertraline was titrated upward to a maximum dose of 200mg/ day	Follow-up (ITT) [17] 5/5 (100%) sertraline 5/5 (100%) Sertraline + CBT
Overall quality assessment (descriptive) [18] This is a very poor quality study. The sample size is extremely small, the length of follow-up is unknown, the randomisation method is not stated, CI are not provided and the level of statistical significance for each result is not provided. These results cannot be considered reliable given these limitations.				
RESULTS				
Outcome [19]	Intervention group [20] Change in outcome from baseline	Control group [21] Change in outcome from baseline	Measure of effect/effect size [22] Group differences in scores 95% CI [25]	Benefits (NNT) [23] 95% CI [25] Harms (NNH) [24] 95% CI [25] NC
CAPS reexperiencing	4.4 (10.4)	-4.6 (11.5)	0.82	
CAPS avoidance/ numbing	8.0 (7.1)	0.6 (9.9)	0.85	
CAPS hyperarousal	1.6 (3.8)	-0.6 (5.6)	0.45	
HSCL-90 anxiety	8.4 (5.6)	5.2 (5.3)	0.59	

HSCCL-90 depression	8.6 (7.2)	8.6 (6.0)	0.00	
HSCCL-90 somatisation	12.2 (4.4)	8.6 (6.0)	0.62	
ASI	7.8 (10.1)	1.2 (4.8)	0.88	
ASI-Khmer items	12.6 (5.0)	1.8 (7.2)	1.77	
	Clinical importance (1-4) [26] 2		Relevance (1-5) [27] 1- patient relevant outcomes	
Any other adverse effects [28] 40% of patients in each group reported at least one, mild, adverse symptom with treatment. The most common adverse effects were fatigue and nausea. No AE resulted in discontinuation.				
EXTERNAL VALIDITY				
Generalisability [29] The results can be generalised to refugees with PTSD in the Australian population.				
Applicability [30] There is insufficient evidence of potential benefit of sertraline + CBT versus sertraline given the poor study quality. If the benefits were borne out in a better quality trial they would outweigh the potential harms.				
Comments [31]				

NC=not calculated because all continuous data

STUDY DETAILS		
Reference [1] Power, Mc Goldrick, Brown, Buchanan, Sharp, Swanson & Karatzias 2002		
Affiliation/source of funds [2] Department of Psychology, University of Stirling, Scotland, UK		
Study design [3] Randomised controlled trial	Level of evidence [4] II	Location/setting [5] Outpatient referrals were taken from general practitioners and psychiatrists within central Scotland.
Intervention [6] Eye movement desensitization and reprocessing (EMDR)	Comparator [8] Exposure + cognitive restructuring (E + CR)	
Sample size [7] 39	Sample size [9] 37	
Population characteristics [10] Participants with a DSM-IV diagnosis of PTSD aged between 18 and 65. Exclusion criteria – concurrent severe depressive illness, past or present psychotic illness, history of alcoholism or drug abuse within the last 6 months as defined by the DSM-IV, suicidal ideation or intent as assessed at clinical interview, physical illness of clinical significance, psychotherapy commitments outside the study. Intervention group – as above Comparator group(s) – as above		
Length of follow-up [11] 15 months	Outcome(s) measured [12] Clinician-Administered PTSD Scale (CAPS), Montgomery Asberg Depression Rating Scale (MADRS), Hamilton Rating Scale for Anxiety (HAM-A), Impact of Events Scale (IOE), SI-PTSD Symptom Checklist, Hospital Anxiety and Depression Scale (HADS), Sheehan Disability Scale	
INTERNAL VALIDITY		

<p>Allocation [13] Following completion of the entire initial assessment, for those patients who met entry criteria, the blind assessor then opened a sealed envelope that informed as to which group patients were to be allocated.</p>	<p>Comparison of study groups [14] No statistically significant differences were found between treatment groups with regards to age, time since trauma, gender, marital status, previous psychiatric history, type of trauma or psychotropic medication.</p>	<p>Blinding [15] Assessors at pre- and posttreatment were blind to treatment conditions. Assessors at mid-point of treatment and at follow-up were not blind to treatment conditions.</p>	<p>Treatment/ measurement bias [16] No differences in treatment apart from type of intervention were apparent.</p>	<p>Follow-up (ITT) [17] The participants included in the outcome analysis of this study were participants who had completed the treatment programme. Hence, an intention to treat analysis was not conducted. In the EMDR treatment condition 5/39 dropped out after initial assessment and prior to commencement of treatment and 12/39 failed to attend mid-point assessment. At 15 month follow-up 17/39 dropped out. In the E+CR condition, 6/37 dropped out after initial assessment and prior to commencement of treatment and 16/37 failed to attend midpoint assessment. At 15 month follow-up 20/37 dropped out.</p>
<p>Overall quality assessment (descriptive) [18]. 1a, 2c, 3b/c (Assessors at pre- and posttreatment were blinded. However, assessors at mid-point of treatment and at follow-up were not blinded). 4a.</p>				
<p>RESULTS</p>				

Outcome [19]	Intervention group [20] EMDR	Control group [21] E+CR	Measure of effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25]
<u>IOE Total</u>				Harms (NNH) [24]
Pretreatment	35.1 (SD 4.4)	32.7 (SD 5.0)	NS	95% CI [25] NC
Midtreatment	24.0 (SD 8.7)	29.1 (SD 9.2)	NS	
Posttreatment	11.8 (SD 12.0)	19.2 (SD 12.3)	NS	
PT clin sign change	17 (63%)	9 (43%)		
<u>IOE Intrusion</u>				
Pretreatment	17.8 (SD 3.0)	15.8 (SD 3.7)		
Midtreatment	13.7 (SD 5.1)	14.6 (SD 5.3)	NS	
Posttreatment	6.2 (SD 6.6)	8.5 (SD 5.7)	NS	
PT clin sign change	18 (67%)	10 (48%)	NS	
<u>IOE Avoidance</u>				
Pretreatment	17.3 (SD 2.6)	16.9 (SD 3.5)		
Midtreatment	10.3 (SD 4.8)	14.7 (SD 4.6)	NS	
Posttreatment	14.7 (SD 4.6)	10.7 (SD 7.7)	NS	
PT clin sign change	19 (70%)	20 (48%)	NS	
<u>SI-PTSD Total</u>				
Pretreatment	50.6 (SD 8.4)	46.6 (SD 9.9)		
Midtreatment	33.4 (SD 14.0)	41.4 (SD 15.0)	NS	
Posttreatment	16.8 (SD 17.2)	25.9 (SD 17.9)	NS	
PT clin sign change	18 (67%)	11 (52%)	NS	
<u>SI-PTSD Re-exp.</u>				
Pretreatment	12.2 (SD 3.1)	11.2 (SD 3.0)		
Midtreatment	8.6 (SD 4.5)	10.8 (SD 4.3)	NS	
Posttreatment	3.7 (SD 4.8)	5.4 (SD 4.8)	NS	
PT clin sign change	22 (81%)	12 (60%)	NS	
<u>SI-PTSD Avoidance</u>				
Pretreatment	19.6 (SD 4.3)	16.7 (SD 6.5)		
Midtreatment	11.6 (SD 5.6)	16.0 (SD 7.5)	NS	
Posttreatment	5.7 (SD 6.6)	10.2 (SD 8.0)	NS	
PT clin sign change	20 (74%)	12 (60%)	NS	
<u>SI-PTSD Arousal</u>				
Pretreatment	18.6 (SD 3.6)	17.5 (SD 3.6)		
Midtreatment	13.2 (SD 4.7)	15.0 (SD 5.8)	NS	
Posttreatment	7.5 (SD 6.5)	10.3 (SD 6.8)	NS	
PT clin sign change	16 (59%)	7 (35%)	NS	
<u>HADS Anxiety</u>				
Pretreatment	15.3 (SD 3.0)	13.5 (SD 2.9)		
Midtreatment	12.4 (SD 3.9)	12.5 (SD 3.3)	NS	
Posttreatment	7.7 (SD 5.1)	9.6 (SD 5.0)	NS	
PT clin sign change	13 (48%)	7 (33%)	NS	
<u>HADS Depression</u>				
Pretreatment	11.2 (SD 3.4)	11.3 (SD 3.7)		
Midtreatment	8.9 (SD 4.0)	10.0 (SD 5.4)	NS	
Posttreatment	4.0 (SD 5.0)	8.6 (SD 5.8)	NS	
PT clin sign change	22 (81%)	9 (43%)	$\chi^2(df=1)=7.7, p<.05$	

<u>Sheehan Total</u>				
Pretreatment	21.3 (SD 5.4)	22.8 (SD 6.3)		
Midtreatment	20.6 (SD 6.9)	19.2 (SD 7.7)	NS	
Posttreatment	9.2 (SD 10.9)	15.7 (SD 10.5)	NS	
PT clin sign change	19 (70%)	8 (38%)	$\chi^2(df=1)=5.0, p<.05$	
<u>MADRS</u>				
Pretreatment	26.4 (SD 5.5)	24.6 (SD 7.8)		
Midtreatment	20.8 (SD 6.6)	23.5 (SD 8.1)	NS	
Posttreatment	9.3 (SD 10.1)	14.8 (SD 9.2)	NS	
PT clin sign change	21 (78%)	11 (52%)	NS	
<u>HAM-A</u>				
Pretreatment	26.2 (SD 6.4)	24.9 (SD 8.0)		
Midtreatment	19.6 (SD 4.8)	22.9 (SD 8.7)	NS	
Posttreatment	9.1 (SD 8.4)	13.1 (SD 9.0)	NS	
PT clin sign change	22 (82%)	13 (62%)	NS	
<u>CAPS-B (Re-exp)</u>				
<u>Frequency</u>				
Pretreatment	10.2 (SD 2.8)	10.0 (SD 4.0)		
Posttreatment	2.0 (SD 2.8)	3.2 (SD 2.7)	NS	
PT clin sign change	23 (92%)	18 (95%)	NS	
<u>CAPS-B (Re-exp)</u>				
<u>Intensity</u>				
Pretreatment	10.6 (SD 2.9)	10.5 (SD 3.7)		
Posttreatment	2.0 (SD 2.6)	3.8 (SD 3.4)	NS	
PT clin sign change	23 (92%)	14 (74%)	NS	
<u>CAPS-C (Avoid)</u>				
<u>Frequency</u>				
Pretreatment	16.0 (SD 3.7)	15.9 (SD 4.5)		
Posttreatment	3.5 (SD 5.2)	6.8 (SD 5.1)	NS	
PT clin sign change	22 (88%)	12 (63%)	NS	
<u>CAPS-C (Avoid)</u>				
<u>Intensity</u>				
Pretreatment	15.9 (SD 3.9)	15.7 (SD 4.4)		
Posttreatment	3.2 (SD 4.5)	6.3 (SD 5.0)	NS	
PT clin sign change	22 (88%)	15 (79%)	NS	
<u>CAPS-D (Arousal)</u>				
<u>Frequency</u>				
Pretreatment	17.0 (SD 3.3)	16.7 (SD 3.4)		
Posttreatment	5.0 (SD 5.0)	6.8 (SD 4.4)	NS	
PT clin sign change	18 (72%)	11 (58%)	NS	
<u>CAPS-D (Arousal)</u>				
<u>Intensity</u>				
Pretreatment	15.8 (SD 2.8)	15.7 (SD 3.0)		
Posttreatment	4.9 (SD 4.5)	7.1 (SD 4.6)	NS	
PT clin sign change	16 (64%)	8 (42%)	NS	
	Clinical importance (1-4) [26] 3 No apparent clinically significant change.		Relevance (1-5) [27] 1 Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.	

Any other adverse effects [28] No adverse effects reported.
EXTERNAL VALIDITY
Generalisability [29] The study population is from Scotland, and may be generalisable to Australian populations.
Applicability [30] No harms were reported in this study.
Comments [31] The authors state (p.313) that, “A consistent pattern is observable, however, in that for both EMDR and E+CR groups, on measures of PTSD symptomatology, anxiety, depression and social functioning, only about 25-50% of patients maintain treatment gains without additional post-study intervention. It therefore appears that, in this study, regardless of the type of treatment offered, the majority of patients, on most measures, do not achieve clinically significant long-term follow-up gains without additional psychological, psychiatric, or psychotropic treatment.”

NC=not calculated because all continuous data

STUDY DETAILS		
Reference [1] Rothbaum, Cahill, Foa, Davidson, Compton, Connor & Astin (<i>in press</i>)		
Affiliation/source of funds [2] The researchers were based at the Emory University School of Medicine, the University of Pennsylvania and Duke University. The study was funded by an unrestricted educational grant from Pfizer, Inc.		
Study design [3] Randomised controlled trial	Level of evidence [4] II	Location/setting [5] Not stated
Intervention [6] Sertraline	Comparator [8] Sertraline + prolonged exposure	
Sample size [7] 31	Sample size [9] 34	
Population characteristics [10] Male and female adults (age ≥ 18) in general good health with a primary psychiatric diagnosis of chronic PTSD as determined by administration of the SCID. Exclusion criteria – history or a psychotic or bipolar disorder, prior failure of an adequate trial of sertraline for PTSD, current administration of psychiatric medication, and any medical contraindication to taking sertraline. Exclusion criteria at Week 10 (entry into Phase II) – Participants who did not achieve at least 20% reduction in PTSD severity in Phase I (Phase I non-responders) were removed from the study and provided additional treatment or referrals as deemed appropriate. Intervention group – as above Comparator group(s) – as above		
Length of follow-up [11] Assessment ended at end of treatment, i.e. 15 weeks after treatment began.	Outcome(s) measured [12] Structured Interview for PTSD (SIP), Beck Depression Inventory (BDI), State-Trait Anxiety Inventory (STAI)	
INTERNAL VALIDITY		

<p>Allocation [13] Method of randomisation not stated.</p>	<p>Comparison of study groups [14]</p> <p>There was a trend for participants randomly assigned to the SERT + PE condition (M=37.1, SD=10.88) to be younger than those assigned to sertraline alone [(M=41.6, SD=10.13; t (63)=1.72, p=.091)].</p> <p>No differences in gender, years since index trauma, type of index trauma, ethnicity, relationship status, employment status, education or income were found.</p> <p>No differences in medication dose or compliance were found at either Week 10 or Week 15 endpoint.</p>	<p>Blinding [15]</p> <p>The outcome assessors (Week 0, 10 & 15) were not involved in participant's treatment and were kept blind to treatment condition of those participants who entered Phase II.</p>	<p>Treatment/ measurement bias [16]</p> <p>No other differences in treatment aside from type of intervention were apparent.</p>	<p>Follow-up (ITT) [17]</p> <p>Initially 139 individuals were assessed for eligibility. 44/139 were not eligible. 7/139 were eligible but refused to participate.</p> <p>88 participants entered Phase I. During this 10-week stage, 19/88 did not complete treatment, 4/88 completed treatment but did not continue to the next stage, 3/88 did not meet minimal improvement criteria and 1/88 did not continue for clinical reasons.</p> <p>15 weeks 1/31 in the SERT condition dropped out due to a family crisis. 6/34 in the SERT + PE condition dropped out – 2 due to scheduling conflicts, 2 due to the treatment being too difficult, 1 due to family crisis and 1 due to reason unknown. However, 4 of the 6/34 participants who dropped out from the SERT + PE condition returned to</p>
<p>Pre-publication draft – not for circulation</p>				<p>complete the Week 15 ³⁹⁵ assessment.</p>

Overall quality assessment (descriptive) [18]. 1b, 2b, 3b, 4a.				
RESULTS				
Outcome [19]	Intervention group [20]	Control group [21]	Measure of effect size [22]	Benefits (NNT) [23] 95% CI [25]
	SERT	SERT + PE	95% CI [25]	
<u>SIP</u>				Harms (NNH) [24] 95% CI [25]
Week 0	36.0 (SD 8.64)	35.9 (SD 9.41)	NS	
Week 10	14.5 (SD 11.65)	16.1 (SD 10.64)	NS	
Week 15	14.9 (SD 15.27)	10.2 (SD 8.83)	NS	
<u>BDI</u>				NC
Week 0	22.1 (SD 11.69)	21.0 (SD 8.55)	NS	
Week 10	9.5 (SD 7.57)	11.2 (SD 8.94)	NS	
Week 15	9.8 (SD 9.74)	8.0 (SD 8.33)	NS	
<u>STAI-S</u>				
Week 0	54.2 (SD 13.57)	55.2 (SD 11.56)	NS	
Week 10	39.2 (SD 13.90)	43.0 (SD 13.21)	NS	
Week 15	39.20 (SD 17.84)	39.1 (SD 14.48)	NS	
	Clinical importance (1-4) [26] 3 No clinically important effects.		Relevance (1-5) [27] 1 Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival.	
Any other adverse effects [28] No adverse effects reported.				
EXTERNAL VALIDITY				
Generalisability [29] The participants were civilian trauma survivors (37.5% sexual assault, 23.4% non-sexual assault, 9.4% motor vehicle accident, 3.1% witness violence and 26.6% other) in out-patient treatment in the USA. The findings may be relevant to an Australian population.				
Applicability [30] Some benefits and no harms were reported in the study.				
Comments [31]				

NC=not calculated because all continuous data

STUDY DETAILS				
Reference [1] Stein et al 2002				
Affiliation/source of funds [2] Anxiety & Traumatic Stress Disorders Progrmas, VA San Diego Healthcare System, California/ Eli Lilly				
Study design [3] Randomised controlled trial	Level of evidence [4] II		Location/setting [5] Outpatient VA San Diego Healthcare System, California, America	
Intervention [6] Olanzapine (average dose 15mg/ day) +SSRI Sample size [7] 10	Comparator(s) [8] Placebo (average dose 20mg/ day) + SSRI Sample size [9] 9			
Population characteristics [10] Intervention group – Male patients from the VA San Diego Healthcare System; clinically predominant diagnosis of PTSD by DSM-IV who are minimally responsive to 12 weeks or more (4 weeks or more at maximally tolerated doses) of treatment with an SSRI Comparator group(s) – Male patients from the VA San Diego Healthcare System; clinically predominant diagnosis of PTSD by DSM-IV who are minimally responsive to 12 weeks or more (4 weeks or more at maximally tolerated doses) of treatment with an SSRI				
Length of follow-up [11] 8 weeks		Outcome(s) measured [12] PTSD – Clinician-Administered PTSD Scale for DSM-IV; Depressive symptoms – self-rated Center for Epidemiologic Studies Depression Scale (CES-D); sleep – self-reported Pittsburgh Sleep Quality Index ; number of responders defined by the Clinical Global Impression (CGI) scale of change as “much improved” or “very much improved”		
INTERNAL VALIDITY				
Random assignment [13] “random assignment”	Comparison of study groups [14] There does not appear to be any important differences between the study groups	Blinding [15] Not stated	Treatment/ measurement bias [16] Both groups appeared to be measured and treated in the same manner	Follow-up (ITT) [17] 9/9 placebo (100%) 10/10 olanzapine (100%) LOCF
Overall quality assessment (descriptive) [18] The study is very small, it is unclear if patients and investigators are blinded and analyses of patients by type of SSRI is not provided. There are also large SDs around the mean results. It is therefore unlikely that these results can be considered robust.				
RESULTS				
Outcome [19]	Intervention group [20] Mean	Control group [21] Mean	Measure of effect/effect size [22] 95% CI [25]	Benefits (NNT) [23] 95% CI [25] Harms (NNH) [24]
Clinician-Administered PTSD Scale for DSM-IV	-14.8 (14.16)	-2.67 (10.55)	t = -2.21, df = 17, p<0.05	95% CI [25]

Pittsburgh Sleep Quality Index	-3.29 (3.15)	1.57 (2.76)	t = -3.07, df = 12, p = 0.01	NC
CES-D	-5.25 (6.27)	4.88 (9.66)	t = -2.49, df = 14, p<0.05	
	Clinical importance (1-4) [26] 1- clinically important benefits		Relevance (1-5) [27] 1- patient relevant outcomes	
Any other adverse effects [28] Weight gain was significantly greater with olanzapine than placebo (mean 13.2lb [5.9] vs -3.0lb [6.5] respectively, p=0.001)				
EXTERNAL VALIDITY				
Generalisability [29] The results can be generalised to members of the Australian population who suffer from chronic military related PTSD				
Applicability [30] The reduction in PTSD symptoms, depression and sleep disorder over placebo + SSRI may not outweigh the additional weight gain experienced with olanzapine + SSRI				
Comments [31]				

NC=not calculated because all continuous data

Question 17

STUDY DETAILS				
Reference [1] Frommberger, Stieglitz & Nyberg et al. 2004				
Affiliation/source of funds [2] Department of Psychiatry, University of Freiburg, German; GlaxoSmithKline, Neuroscience Clinical Development, Philadelphia, USA and Smith-Kline-Beecham, Munich.				
Study design [3] Randomised controlled trial Parallel-group comparison	Level of evidence [4] II		Location/setting [5] The Department of Psychiatry in the University of Freiburg, Germany.	
Intervention [6] Antidepressant (paroxetine)		Comparator(s) [8] Cognitive behavioural therapy (CBT)		
Sample size [7] 11 patients		Sample size [9] 10 patients		
Population characteristics [10] Patients were recruited from a specialised outpatient PTSD treatment centre, were 18 years and older and fulfilled DSM-III-R criteria for chronic PTSD. Traumas were exclusively civilian traumas including non-sexual violence, sexual violence and serious accidents. Patients were excluded if they were pregnant or suffered from severe illness or injuries, were suicidal, had abused alcohol or drugs in the last 6 months and had a history of schizophrenia or bipolar disorder or had received treatment with SSRIs or MAO inhibitors 6 weeks prior to study entry. Intervention group – as above Comparator group(s) – as above				
Length of follow-up [11] 12 week treatment period Follow-up assessment done at 3 and 6 months.		Outcome(s) measured [12] Changes in depressive and anxiety symptoms via: 1) Clinician-rated instruments - the Montgomery Asberg Depression Rating Scale (MADRS) and the Hamilton Rating Scale for Anxiety (HAMA). 2) Patient-rated instruments – the Posttraumatic Stress Scale (PSS) and the Beck Depression Inventory (BDI)		
INTERNAL VALIDITY				
Intervention [13] Paroxetine dosage began at 10mg/day for 1 week, increased at the discretion of the investigator according to patient response. CBT sessions were conducted weekly.	Comparison of study groups [14] Difference in diagnoses between groups: Major depressive episode(n=6 in paroxetine group; n=5 in CBT group) Depressive symptoms (n=2 in CBT group) Male to female ratios differed	Blinding [15] Open-labelled treatment of paroxetine Person assessing had knowledge of treatment group	Treatment/ measurement bias [16] Appeared to be treated the same apart from the intervention.	Follow-up (ITT) [17] 3 patients in the paroxetine group dropped out within the first 2 weeks of treatment 2 patients in the CBT group dropped out before

Overall quality assessment (descriptive) [18] Study not blinded. The psychopharmacological treatment was conducted by a senior psychiatrist who was also the principle investigator. Small study size. No placebo control group. No independent status of the assessors (the therapists rated the patients).

RESULTS				
Outcome [19]	Intervention group [20]	Control group [21]	Measure of effect/effect size [22]	Benefits (NNT) [23] 95% CI [25] Harms (NNH) [24] 95% CI [25]
	Paroxetine	CBT	95% CI [25]	
CAPS				NC
Pre-test	65.0 (SD 13.4)	70.5 (SD 7.2)	NS	
Post-test	36.1 (SD 12.1)	34.8 (SD 15.0)		
PSS				
Pre-test	34.1 (SD 9.8)	34.5 (SD 4.3)	NS	
Post-test	25.4 (SD 11.6)	15.0 (SD 5.3)		
HAMA				
Pre-test	28.5 (SD 8.8)	27.6 (SD 12.3)	NS	
Post-test	14.1 (SD 7.0)	16.6 (SD 10.7)		
MADRS				
Pre-test	25.0 (SD 9.0)	25.6 (SD 12.7)	NS	
Post-test	9.5 (SD 5.8)	13.4 (SD 12.9)		
BDI				
Pre-test	25.2 (SD 11.8)	19.1 (SD 9.5)	NS	
Post-test	18.5 (SD 15.2)	11.6 (SD 7.2)		
	Clinical importance (1-4) [26] 4			Relevance (1-5) [27] 1
Any other adverse effects [28] Adverse effects were experienced by three patients who dropped out of the paroxetine group within 2 weeks; symptoms included nervousness, agitation, headache, nausea, dizziness and blurred vision. Other patients in the paroxetine group exhibited side effects (agitation, headache, nausea, fatigue, abnormal ejaculation, breast swelling, irregular menstrual period) tolerated these because of the benefits of the drug on symptoms of PTSD. Increased anxiety was experienced by two patients in the CBT group, resulting in their dropping out before the first exposure to treatment.				
EXTERNAL VALIDITY				
Generalisability [29] The study population is relevant to civilian caused trauma victims in Australia.				
Applicability [30] Paroxetine and CBT reduced symptoms equally in PTSD patients. Symptoms of anxiety, depression and PTSD decrease during both treatments. CBT had a slightly greater effect on maintaining improvement in the long-term.				
Comments [31]				

NC=not calculated because all continuous data

Question 18

STUDY DETAILS				
Reference [1] Quimette 2003				
Affiliation/source of funds [2] The Department of Veterans Affairs Mental Health Strategic Health Group and the Health Services Research and Development Service				
Study design [3] Prospective cohort study	Level of evidence [4] III-2		Location/setting [5] Multisite Department of Veterans Affairs program, United States	
Intervention [6] Substance Use Disorder (SUD) treatment plus PTSD treatment Sample size [7] Not stated		Comparator(s) [8] SUD treatment or PTSD treatment Sample size [9] not stated		
Population characteristics [10] Participants of a larger trial assessing the effectiveness of SUD treatments. Comorbid SUD and PTSD. Included participants completed all three follow-ups over 5 years Mean age=44.7 years (SD=4.26) 94% Vietnam-era veterans 86% alcohol dependence 35% drug use dependence 23% drug and alcohol dependence 25% affective disorder 29% personality disorder Intervention group –As above Comparator group(s) –As above				
Length of follow-up [11] 5 years	Outcome(s) measured [12] 5 year substance use remission (abstained from all 13 drugs investigated; no problems related to drug and alcohol abuse; consumed 3 oz or less of alcohol per day on maximum drinking days in the past month)			
INTERNAL VALIDITY				
Allocation [13] Not stated	Comparison of study groups [14] Not stated	Blinding [15] None	Treatment/ measurement bias [16] Unclear	Follow-up (ITT) [17] Follow-up was unrelated to treatment compliance. Those who completed follow-up were more likely to be of white ethnicity
Overall quality assessment (descriptive) [18] Poor quality study to compare between combined treatment or sequential treatment, as does not explicitly state how many people received the different treatments. There is no indication how different treatments were selected.				
RESULTS				
Outcome [19] 5 year SUD remission	Intervention group [20] NR	Control group [21] NR	Measure of effect/effect size [22] 95% CI [25] NR	Benefits (NNT) [23] 95% CI [25]
				Harms (NNH) [24] 95% CI [25]

	Clinical importance (1-4) [26] 1 Clinically important benefit in receiving PTSD treatment	Relevance (1-5) [27] 1 Patient relevant outcomes
Any other adverse effects [28] Not stated		
EXTERNAL VALIDITY		
Generalisability [29] High- many patients with PTSD will also have comorbidities, and this study assesses the effectiveness of treatments within this population		
Applicability [30] Potential benefits likely to outweigh potential harms		
Comments [31] The only outcome measure was 5 year remission rate for SUD, no PTSD symptoms were measured.		

Appendix G Excluded studies

Questions 1 and 2

Incorrect population

Bachar, E., L. Canetti, et al. (2004). "Group versus individual supportive - Expressive psychotherapy for chronic, symptomatically stabilised outpatients." Psychotherapy Research **14**(2): 244-251.

Ehlers, A., D. M. Clark, et al. (2003). "A randomised controlled trial of cognitive therapy, a self-help booklet, and repeated assessments as early interventions for posttraumatic stress disorder." Arch Gen Psychiatry **60**(10): 1024-32.

Glick, I. D. (2004). "Adding psychotherapy to pharmacotherapy: Data, benefits, and guidelines for integration." American Journal of Psychotherapy **58**(2): 186-208.

Kamiyama, K., N. Yamami, et al. (2004). "Effects of a structured stress management program on psychological and physiological indicators among marine hazard rescues." Journal of Occupational Health **46**(6): 497-499.

Incorrect intervention

Van Honk, J., D. J. L. G. Schutter, et al. (2004). "Transcranial Magnetic Stimulation and Processing of Facial Threats [8]." American Journal of Psychiatry **161**(5): 928-929.

Incorrect study design

Gardner, B., J. Rose, et al. (2005). "Cognitive therapy and behavioural coping in the management of work-related stress: An intervention study." Work and Stress **19**(2): 137-152.

Shore, J. H. and S. M. Manson (2004). "The American Indian veteran and posttraumatic stress disorder: A telehealth assessment and formulation." Culture, Medicine and Psychiatry **28**(2): 231-243.

Duplicates

Rose-S, J. Bisson, et al. (2005). "Psychological debriefing for preventing post traumatic stress disorder (PTSD)."

Summerfield, D. A., B. P. R. Gersons, et al. (2005). "Coping with the aftermath of trauma [5] (multiple letters)." British Medical Journal **331**: 50%N 7507.

Intervention given too late

Basoglu, M., E. Salcioglu, et al. (2005). "Single-session behavioral treatment of earthquake-related posttraumatic stress disorder: a randomised waiting list controlled trial." Journal of Traumatic Stress **18**(1): 1-11.

Bisson, J. I., J. P. Shepherd, et al. (2004). "Early cognitive behavioural therapy for posttraumatic stress symptoms after physical injury. Randomised controlled trial." Br J Psychiatry **184**: 63-9.

Ryding, E. L., E. Wirn, et al. (2004). "Group counseling for mothers after emergency cesarean section: a randomised controlled trial of intervention." Birth **31**(4): 247-253.

Turpin, G., M. Downs, et al. (2005). "Effectiveness of providing self-help information following acute traumatic injury: Randomised controlled trial." British Journal of Psychiatry **187**(JULY): 76-82.

Zatzick, D., P. Roy-Byrne, et al. (2004). "A randomised effectiveness trial of stepped collaborative care for acutely injured trauma survivors." Arch Gen Psychiatry **61**(5): 498-506.

No intervention

Guthrie, R. M. and R. A. Bryant (2005). "Auditory startle response in firefighters before and after trauma exposure." Am J Psychiatry **162**(2): 283-90.

Jackson, C., C. Knott, et al. (2004). "The trauma of first episode psychosis: The role of cognitive mediation." Australian and New Zealand Journal of Psychiatry **38**(5): 327-333.

Not a study (editorial/letter/commentary/review)

Blanchard, E. B., E. J. Hickling, et al. (2004). Early intervention for psychological consequences of personal injury motor vehicle accidents. Early intervention for trauma and traumatic loss. New York, Guilford Press: 284-300.

Bryant, R. A. (2005). "Psychosocial approaches of acute stress reactions." CNS Spectr **10**(2): 116-22.

Cline, J. R. (2004). "Posttraumatic stress disorder: Early recognition and intervention in the emergency department." Wisconsin Medical Journal **103**(6): 43-44.

Davidson, J. R. (2004). "Long-term treatment and prevention of posttraumatic stress disorder." J Clin Psychiatry **65 Suppl 1**: 44-8.

Fagan, N. and K. Freme (2004). "Confronting posttraumatic stress disorder." Nursing **34**(2): 52-53.

Messer-DW and B. Bledsoe (2004). "Things science can't measure. May 2003 EMS. (EMS myth #3 critical incident stress management is effective in managing EMS-related stress)." (Emergency-Medical-Services (EMERG-MED-SERV) 2004 Feb; 33(2): 12, 14).

- Oldham, J. (2004). "Psychotherapy and Pharmacotherapy: Tried and True." Journal of Psychiatric Practice **10**: 77%N 2.
- Oldham, J. (2004). "Psychotherapy, Revisited." Journal of Psychiatric Practice **10**: 1%N 1.
- Pomerantz, J. M. (2005). 'Preventing posttraumatic stress disorder', *Drug Benefit Trends*, 17 (2), 81-82.
- Riddell, K. and M. Clouse (2004). "Comprehensive psychosocial emergency management promotes recovery." Int J Emerg Ment Health **6**(3): 135-45.
- Stahl, S. M. (2005). "Is psychopharmacologic "inoculation" effective in preventing posttraumatic stress disorder?" The Journal of clinical psychiatry **66**(1): 5-6.
- Taneja, N., A. Dheer, et al. (2005). "Emotional first aid - Critical incident stress management (multiple letters) [5]." Medical Journal Armed Forces India **61**(1): 99-100.
- Wagner, S. L. (2005). "Emergency response service personnel and the critical incident stress debriefing debate." Int J Emerg Ment Health **7**(1): 33-41.
- Watson-PJ (2004). "Cognitive behavioural therapy modestly reduces posttraumatic stress symptoms resulting from physical injury." (Evidence-Based-Mental-Health (EVID-BASED-MENT-HEALTH) 2004 Aug; 7(3): 74 (2 ref)).
- Not effectiveness of intervention**
- Onyut, L. P., F. Neuner, et al. (2004). "The Nakivale Camp Mental Health Project: building local competency for psychological assistance to traumatised refugees." Intervention **2**(2): 90-107.
- Not peer reviewed**
- Reed, G. L. (2004). A forgiveness intervention with post-relationship psychologically abused women [dissertation], University of Wisconsin - Madison: 164 p.
- Swiney, U. M. (2004). The efficacy of EMDR for survivors of a natural disaster: intervention after Hurricane Floyd [dissertation], University of North Carolina at Chapel Hill: 119 p.
- Miscellaneous**
- Blanchard, E. B., E. J. Hickling, et al. (2004). "One- and two-year prospective follow-up of cognitive behavior therapy or supportive psychotherapy." Behav Res Ther **42**(7): 745-59.

Watkins, K. E., S. B. Hunter, et al. (2005). "Review of treatment recommendations for persons with a co-occurring affective or anxiety and substance use disorder." Psychiatric Services **56**(8): 913-926.

Questions 3 and 4

Incorrect question

Back, S. E., J. L. Jackson, et al. (2005). "Alcohol dependence and posttraumatic stress disorder: Differences in clinical presentation and response to cognitive-behavioral therapy by order of onset." Journal of Substance Abuse Treatment **29**(1): 29-37.

Incorrect population

Wegener-ST and E. L. Shertzer (2004). "Psychological interventions in the management of SCI-related pain." (SCI-Psychosocial-Process (SCI-PSYCHOSOC-PROCESS) 2004 Winter; 17(4): 238-46 (54 ref)).

Zatzick, D., P. Roy-Byrne, et al. (2004). "A randomised effectiveness trial of stepped collaborative care for acutely injured trauma survivors." Arch Gen Psychiatry **61**(5): 498-506.

Incorrect intervention

Neuner, F., M. Schauer, et al. (2004). "A comparison of narrative exposure therapy, supportive counseling, and psychoeducation for treating posttraumatic stress disorder in an African refugee settlement." Journal of Consulting and Clinical Psychology **72**(4): 579-587.

Stein-DJ, N. Zungu Dirwayi, et al. (2004). "Pharmacotherapy for post traumatic stress disorder (PTSD)."

Van Honk, J., D. J. L. G. Schutter, et al. (2004). "Transcranial Magnetic Stimulation and Processing of Facial Threats [8]." American Journal of Psychiatry **161**(5): 928-929.

Cohen, H., Z. Kaplan, et al. (2004). "Repetitive Transcranial Magnetic Stimulation of the Right Dorsolateral Prefrontal Cortex in Posttraumatic Stress Disorder: A Double-Blind, Placebo-Controlled Study." American Journal of Psychiatry **161**(3): 515-524.

Incorrect study design

Igreja, V., W. C. Kleijn, et al. (2004). "Testimony method to ameliorate posttraumatic stress symptoms. Community-based intervention study with Mozambican civil war survivors." Br J Psychiatry **184**: 251-7.

Jackson, C., C. Knott, et al. (2004). "The trauma of first episode psychosis: The role of cognitive mediation." Australian and New Zealand Journal of Psychiatry **38**(5): 327-333.

Onyut, L. P., Neuner, F. et al (2004). 'The Nakivale Camp Mental Health Project: building local competency for psychological assistance to traumatised refugees', Intervention, 2 (2), 90-107.

Otter, L. and J. Currie (2004). "A long time getting home: Vietnam Veterans' experiences in a community exercise rehabilitation programme." Disabil Rehabil **26**(1): 27-34.

Shore, J. H. and S. M. Manson (2004). "The American Indian veteran and posttraumatic stress disorder: A telehealth assessment and formulation." Culture, Medicine and Psychiatry **28**(2): 231-243.

Stalker, C. A., S. E. Palmer, et al. (2005). "Specialised inpatient trauma treatment for adults abused as children: a follow-up study." Am J Psychiatry **162**(3): 552-9.

Wells, A. and S. Sembi (2004). "Metacognitive therapy for PTSD: a preliminary investigation of a new brief treatment." J Behav Ther Exp Psychiatry **35**(4): 307-18.

No intervention

Lamprecht, F., C. Kohnke, et al. (2004). "Event-related potentials and EMDR treatment of posttraumatic stress disorder." Neuroscience Research **49**(2): 267-272.

No comparator

Bleiberg, K. L. and J. C. Markowitz (2005). "A pilot study of interpersonal psychotherapy for posttraumatic stress disorder." Am J Psychiatry **162**(1): 181-3.

Collinge, W., R. Wentworth, et al. (2005). "Integrating complementary therapies into community mental health practice: An exploration." Journal of Alternative and Complementary Medicine **11**(3): 569-574.

Hinton, D., T. Pham, et al. (2004). "CBT for Vietnamese refugees with treatment-resistant PTSD and panic attacks: a pilot study." Journal of Traumatic Stress **17**(5): 429-433.

Monson, C. M., P. P. Schnurr, et al. (2004). "Cognitive-Behavioral Couple's Treatment for posttraumatic stress disorder: initial findings." J Trauma Stress **17**(4): 341-4.

Morland, L. A., K. S. Pierce, et al. (2004). "Telemedicine and coping skills groups for Pacific Island veterans with posttraumatic stress disorder: a pilot study." Journal of Telemedicine and Telecare **10**(5): 286-289.

Shore, J. H. and S. M. Manson (2004). "Telepsychiatric care of American Indian Veterans with posttraumatic stress disorder: Bridging gaps in geography, organisations, and culture." Telemedicine Journal and e-Health **10**(SUPPL. 2): S-64-S-69.

Prior to search period

Bisson, J. (2004). "Posttraumatic stress disorder." Clin Evid(11): 1343-61.

Bradley-R, J. Greene, et al. (2005). "A multidimensional meta-analysis of psychotherapy for PTSD." (*American-Journal-of-Psychiatry (AM-J-PSYCHIATRY)* 2005 Feb; 162(2): 214-27 (65 ref)).

Bradley, R., J. Greene, et al. (2005). "A multidimensional meta-analysis of psychotherapy for PTSD." *Am J Psychiatry* **162**(2): 214-27.

Ehlers, A., D. M. Clark, et al. (2003). "A randomised controlled trial of cognitive therapy, a self-help booklet, and repeated assessments as early interventions for posttraumatic stress disorder." *Arch Gen Psychiatry* **60**(10): 1024-32.

Hertlein, K. M. and R. J. Ricci (2004). "A systematic research synthesis of EMDR studies: implementation of the platinum standard." *Trauma Violence Abuse* **5**(3): 285-300.

Not peer reviewed

Bornstein, H. A. (2004). "A meta-analysis of group treatments for posttraumatic stress disorder: How treatment modality affects symptoms." *Dissertation Abstracts International: Section B: The Sciences and Engineering* **64**(10-B): 5207.

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Incorrect comparator

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No comparator

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Not a study

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Question 13

Incorrect population

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Incorrect intervention

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Question 14

Incorrect study design

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Incorrect intervention

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Incorrect comparator

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Not a study

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Question 15-pharmacological interventions

Incorrect population

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Incorrect comparator

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No comparator

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Iruela, L. M., I. Gilaberte, et al. (1991). "Clonidine-imipramine therapy [1]." Journal of Nervous and Mental Disease **179**: 304-305.

Prigerson, H. G., M. K. Shear, et al. (1997). "Traumatic grief: A case of loss-induced trauma." American Journal of Psychiatry **154**(7): 1003-1009.

Not a study

Dieperink, M., C. Erbes, et al. (2005). "Comparison of treatment for posttraumatic stress disorder among three department of Veterans Affairs medical centers." Military Medicine **170**(4): 305-308.

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Pomerantz, J. M. (2005). 'Preventing posttraumatic stress disorder', *Drug Benefit Trends*, 17 (2), 81-82.

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Cannot extract data

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Not a study

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Irrelevant

Ramos-Gomez F J, Huang G, Masouredis C M, Braham R L. (1996) Prevalence and treatment costs of infant caries in northern California. ASDC Journal of Dentistry for Children; **63**(2): 108-12.

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Hughes M L, Maskell G, Goh T H, Wilkinson J L. (2002) Prospective comparison of costs and short term health outcomes of surgical versus device closure of atrial septal defect in children. Heart; **88**(1): 67-70.

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Liu C-F, Hedrick S C, Chaney E F, Heagerty P, Felker B, Hasenberg N, Fihn S, Katon W. (2003) Cost-effectiveness of collaborative care for depression in a primary care veteran population. Psychiatric Services; **54**(5): 698-704.

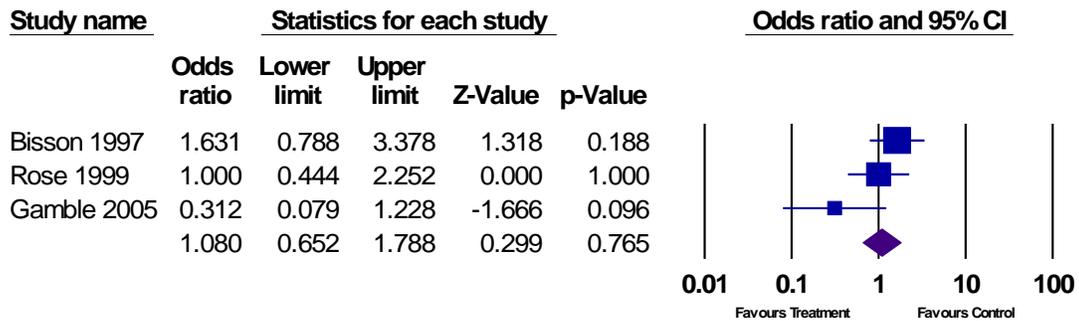
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Appendix H Updated meta-analyses

Question 1

Debriefing vs control – PTSD diagnosis - Fixed

Test for heterogeneity, $p=0.110$
 Fixed model effects



Meta Analysis

Publication bias could not be tested for due to the small number of studies.

Question 2

There were no meta-analyses performed for research question 2.

Question 3

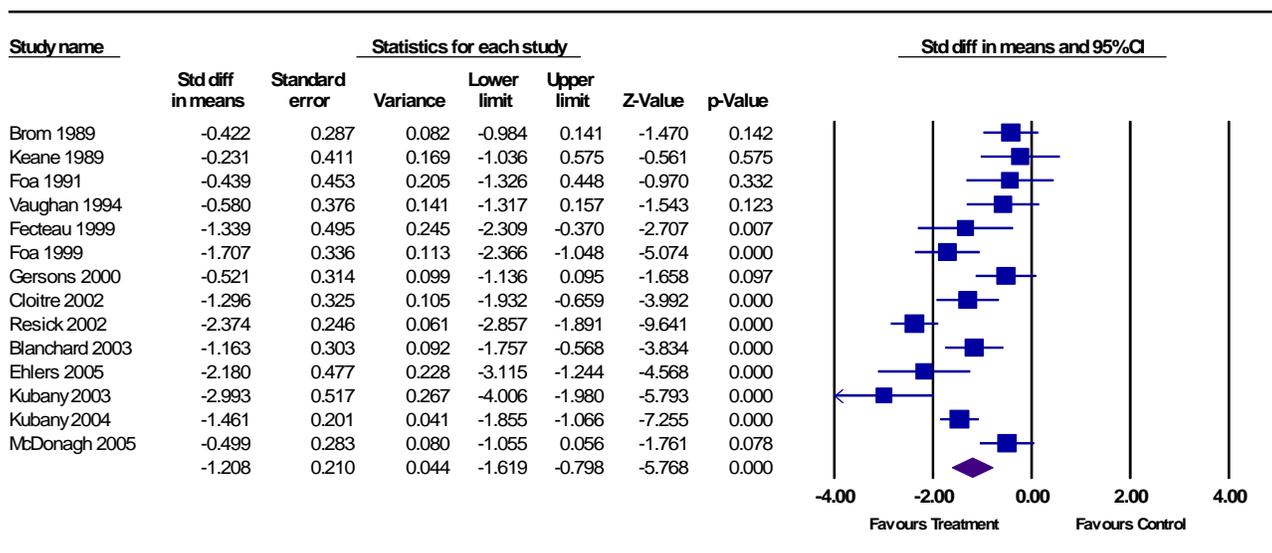
CBT vs waitlist or usual care - Severity of PTSD - random

Number of studies = 14

Standard difference in means -1.208, 95% CI [-1.619, -0.798]

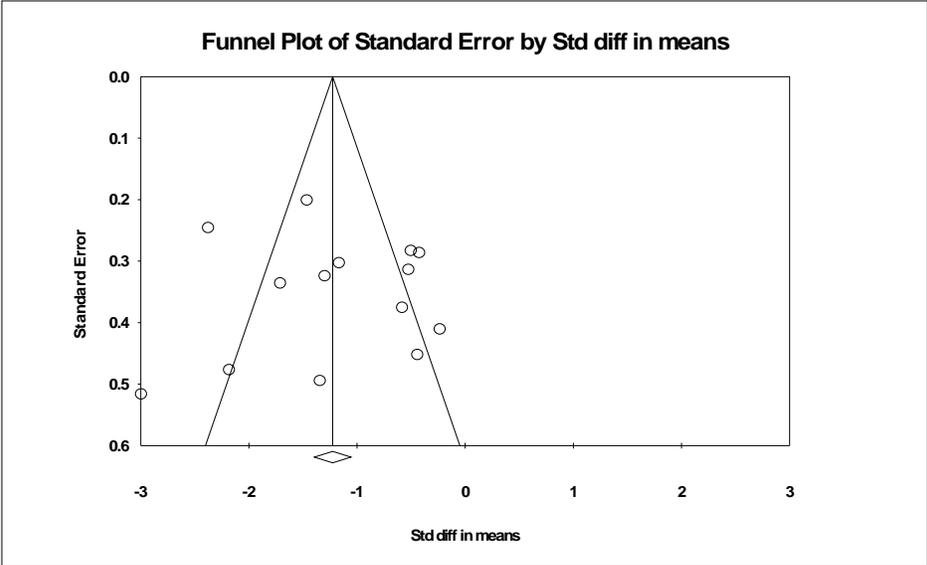
Test for heterogeneity, $p=0.00$

Random effects model



Meta Analysis

Publication Bias



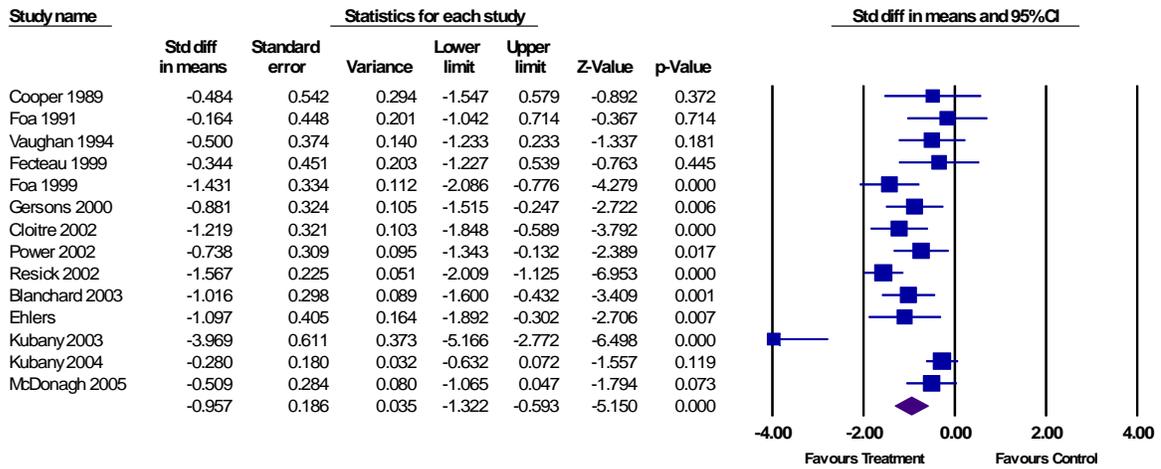
CBT vs waitlist or usual care- Depression - Random

Number of studies = 14

Standard difference in means -0.957, 95% CI [-1.322, -0.593]

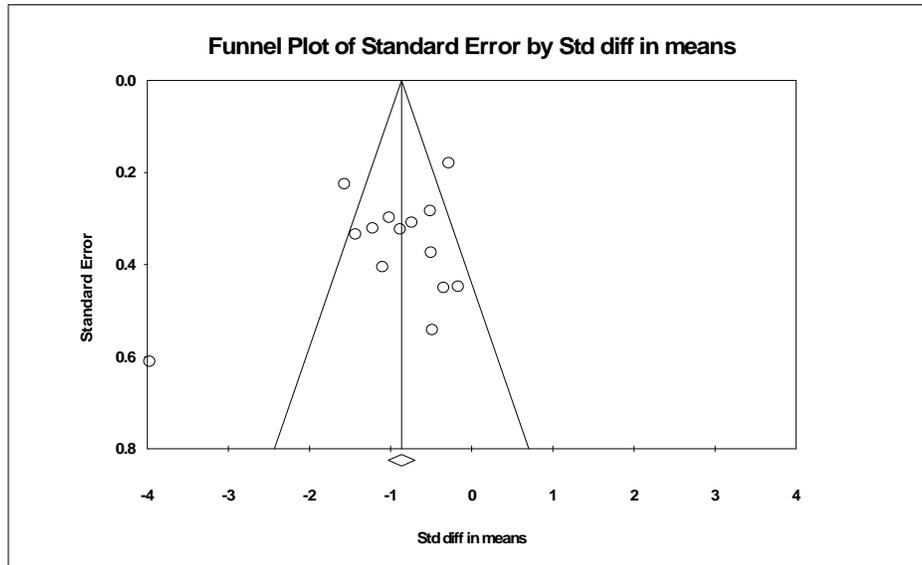
Test for heterogeneity, $p=0.00$

Random effects model



Meta Analysis

Publication Bias



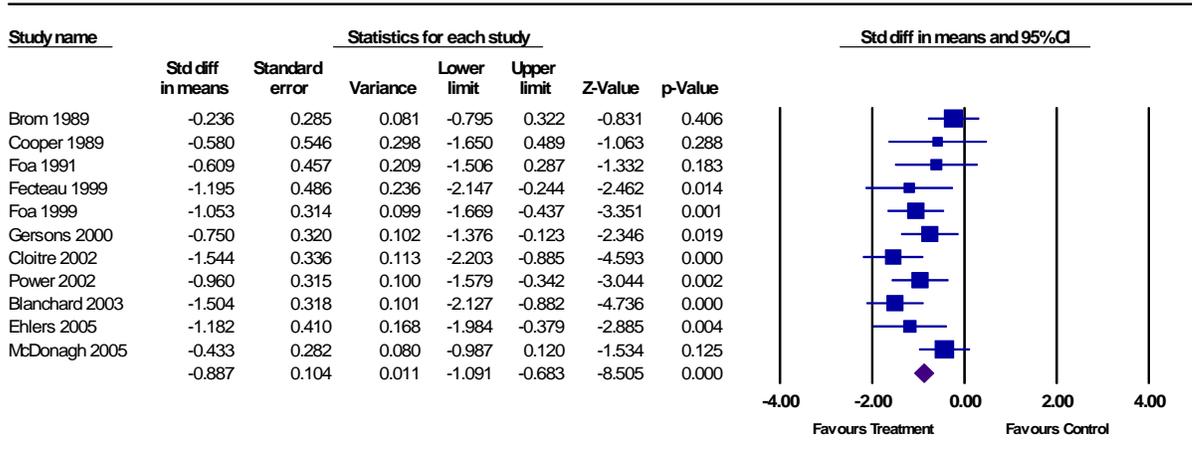
CBT vs waitlist or usual care - Anxiety - Fixed

Number of studies = 11

Standard difference in means -0.887, 95% CI [-1.091, -0.683]

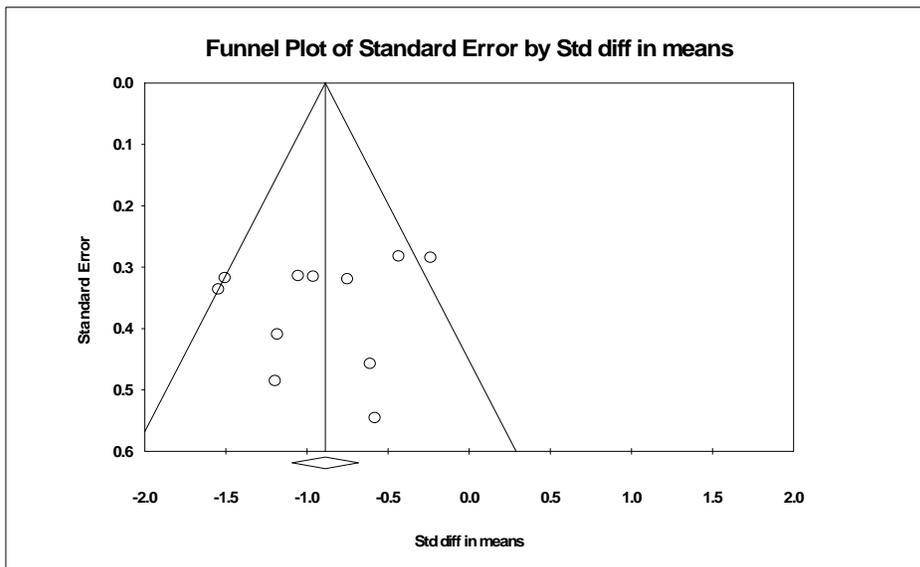
Test for heterogeneity, $p=0.093$

Fixed effects model



Meta Analysis

Publication Bias



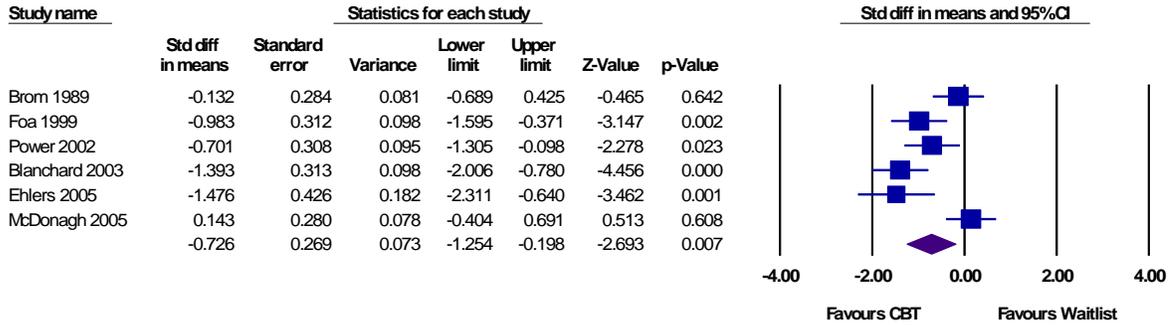
CBT vs waitlist or usual care - QOL - Random

Number of studies = 6

Standard difference in means -0.762, 95% CI [-1.254, -0.198]

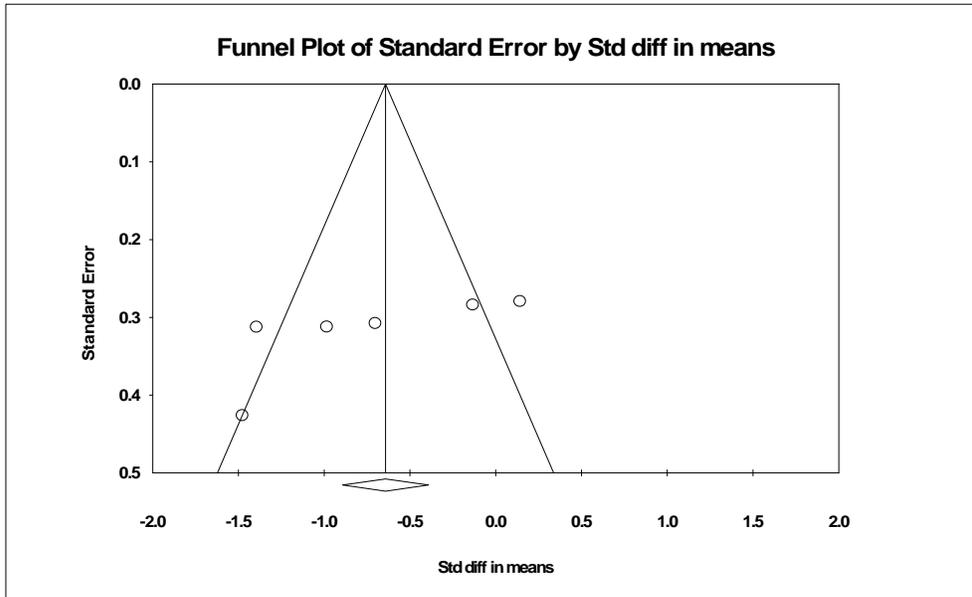
Test for heterogeneity, $p=0.001$

Random effects model



Meta Analysis

Publication Bias



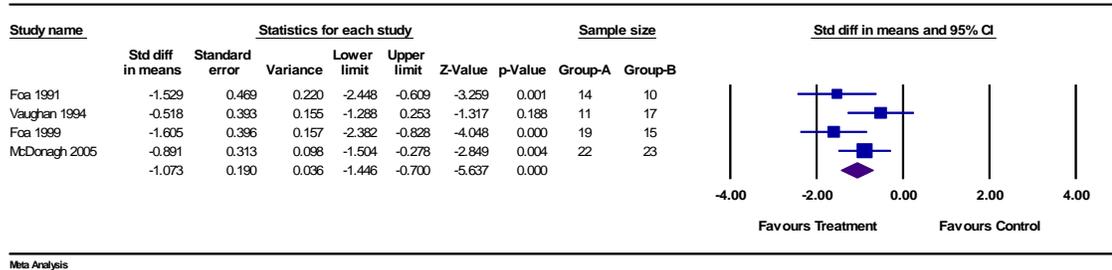
Stress Management vs waitlist or usual care - Severity of PTSD (Clinician) - Random

Number of studies = 4

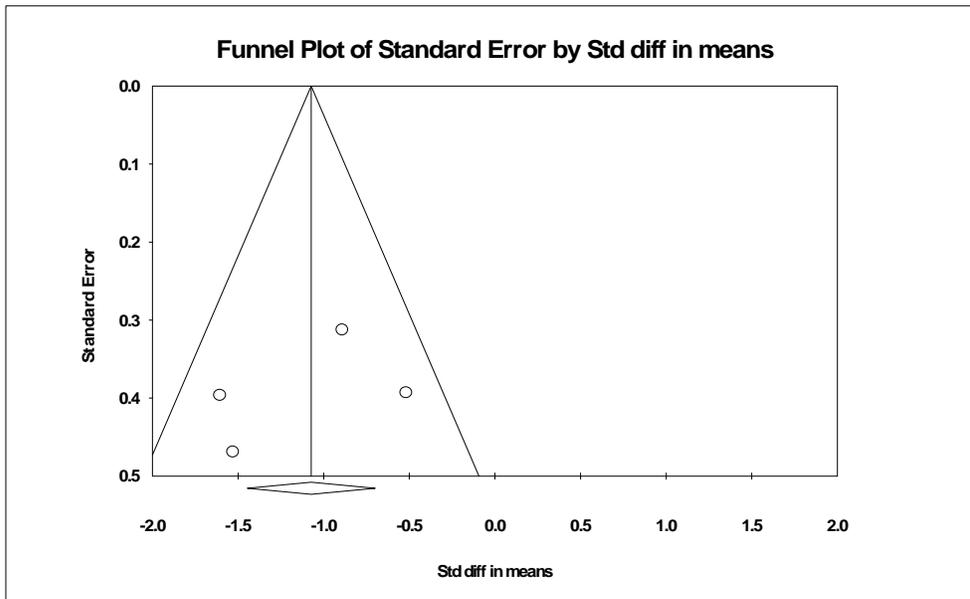
Standard difference in means -1.073, 95% CI [-1.446, -0.7]

Test for heterogeneity, $p=0.004$

Random effects model



Publication Bias



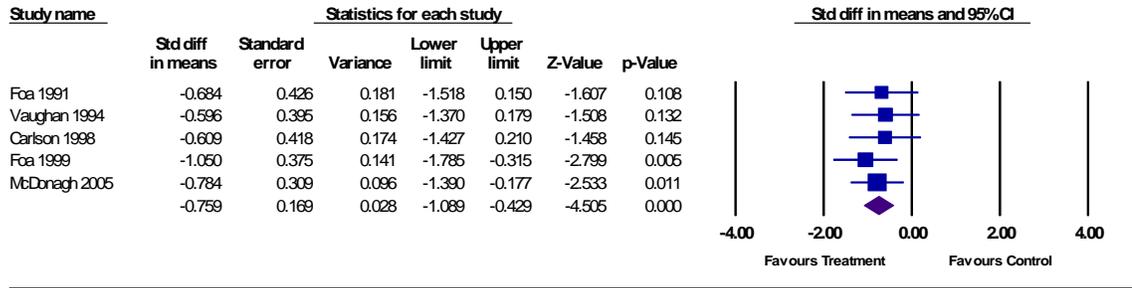
Stress Management vs waitlist or usual care - Depression - Fixed

Number of studies = 5

Standard difference in means -0.759, 95% CI [-1.089, -0.429]

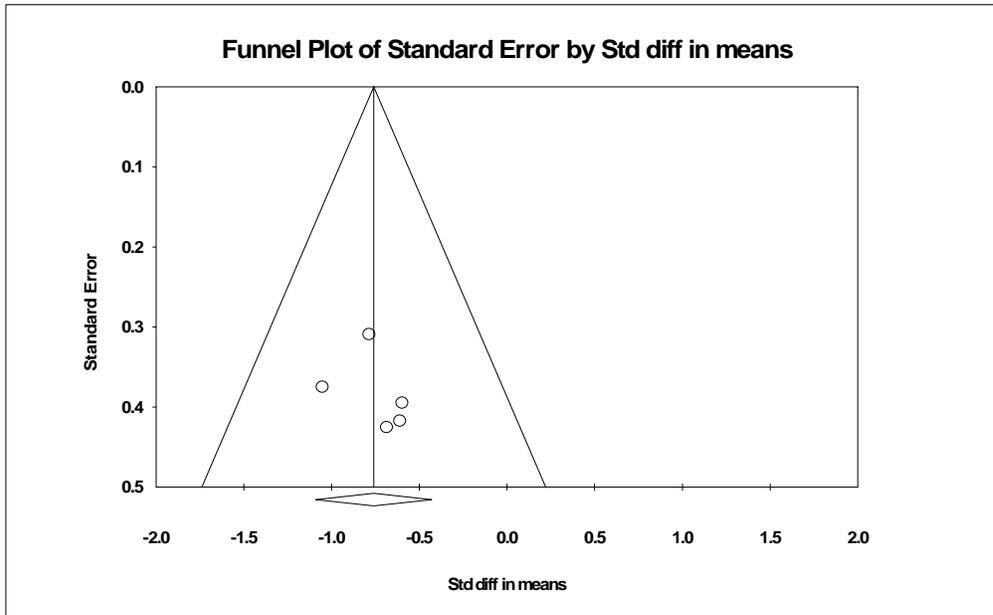
Test for heterogeneity, $p=0.166$

Fixed effects model



Meta Analysis

Publication Bias



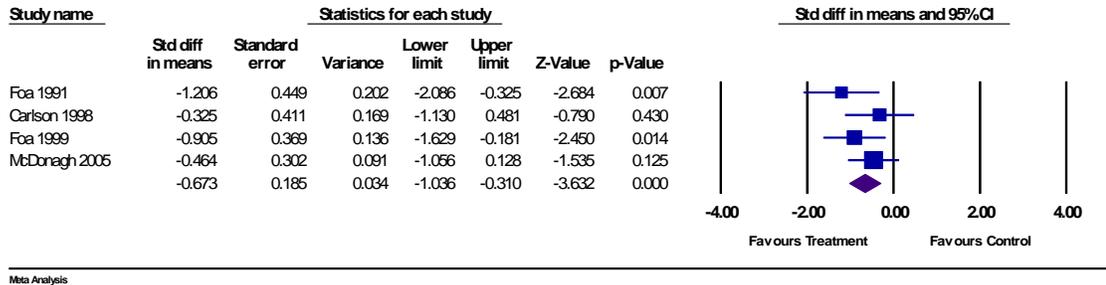
Stress Management vs waitlist or usual care - Anxiety -Fixed

Number of studies = 4

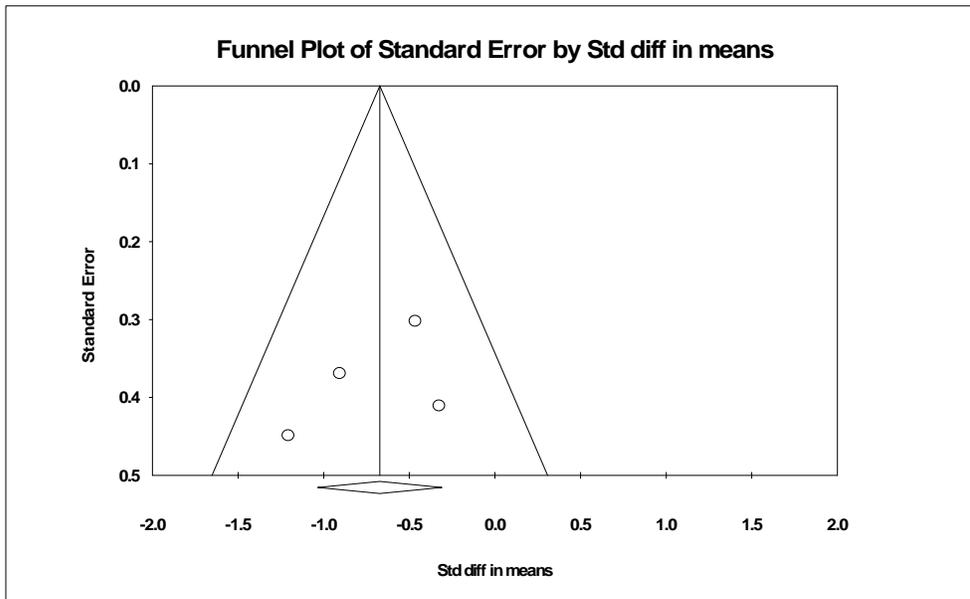
Standard difference in means -0.673, 95% CI [-1.036, -0.310]

Test for heterogeneity, $p=0.392$

Fixed effects model



Publication Bias



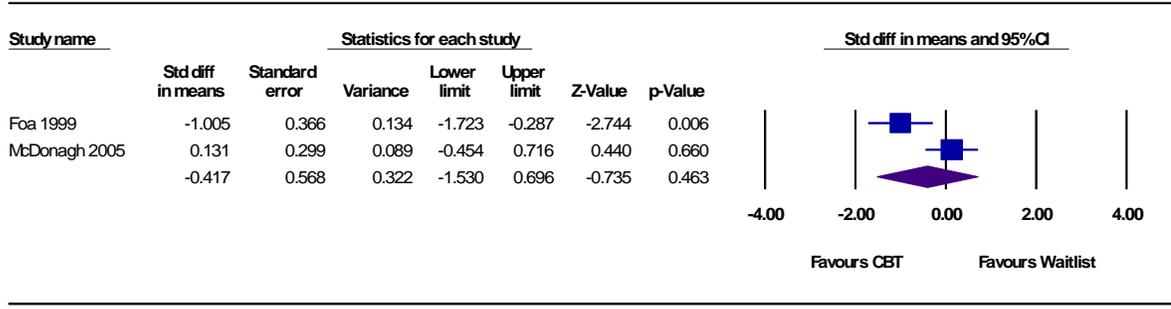
Stress Management vs waitlist or usual care- QOL –Random model

Number of studies = 2

Standard difference in means -0.417, 95% CI [-1.530, 0.696]

Test for heterogeneity, $p=0.016$

Random effects model



Meta Analysis

Publication bias could not be tested for due to the small number of studies.

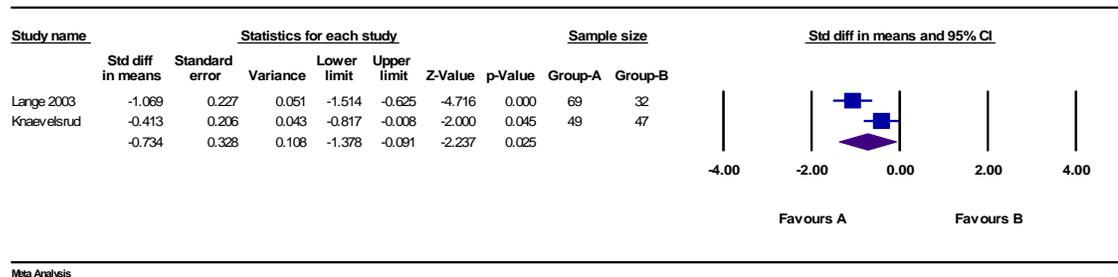
Interapy vs waitlist – Depression - Random model

Number of studies = 2

Standard difference in means -0.734, 95% CI [-1.378, -0.091]

Test for heterogeneity, $p=0.032$

Random effects model



Meta Analysis

Publication bias could not be tested for due to the small number of studies.

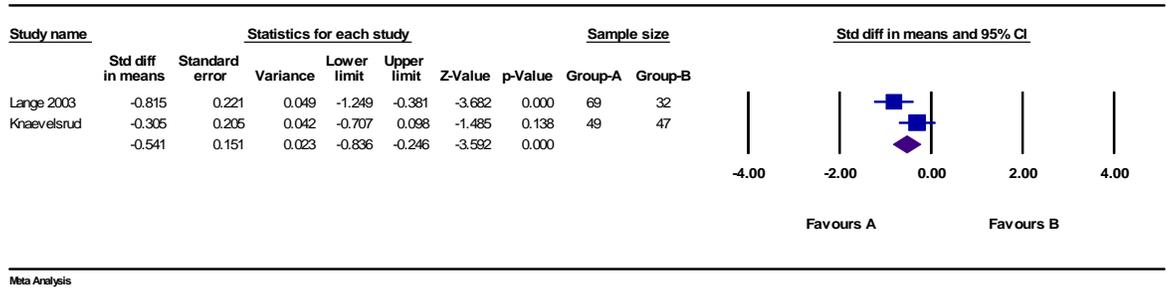
Interapy vs waitlist –Anxiety - Fixed model

Number of studies = 2

Standard difference in means -0.541, 95% CI [-0.836, -0.246]

Test for heterogeneity, $p=0.091$

Fixed effects model



Publication bias could not be tested for due to the small number of studies.

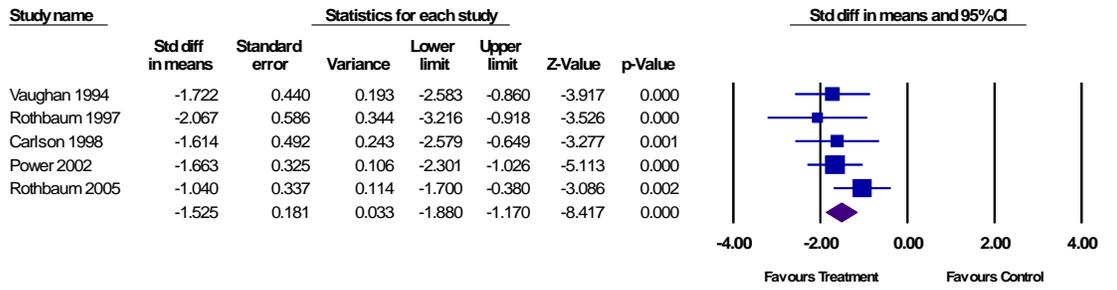
EMDR vs waitlist or usual care- Depression –Fixed model

Number of studies = 5

Standard difference in means -1.525, 95% CI [-1.880, -1.170]

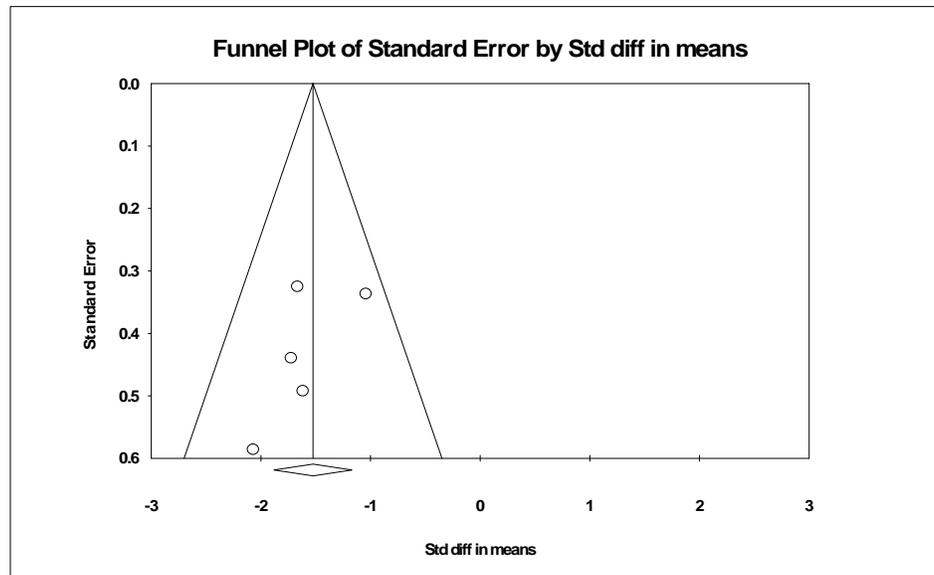
Test for heterogeneity, $p=0.502$

Fixed effects model



Meta Analysis

Publication Bias



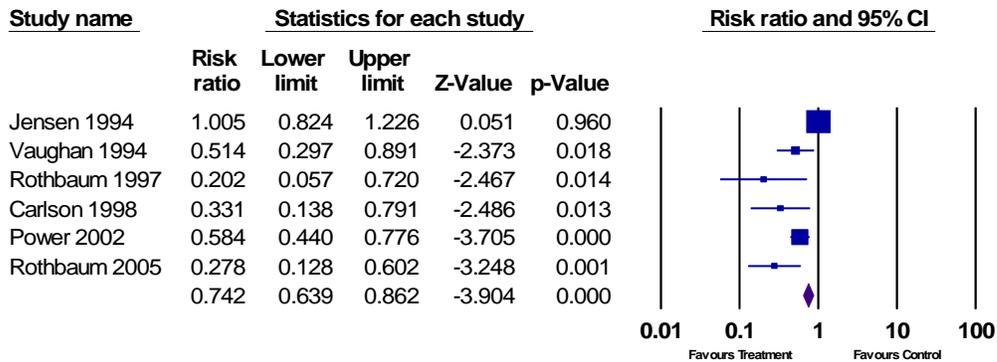
EMDR vs waitlist or usual care- PTSD diagnosis –Fixed model

Number of studies = 6

Standard difference in means 0.742, 95% CI [0.639, 0.862]

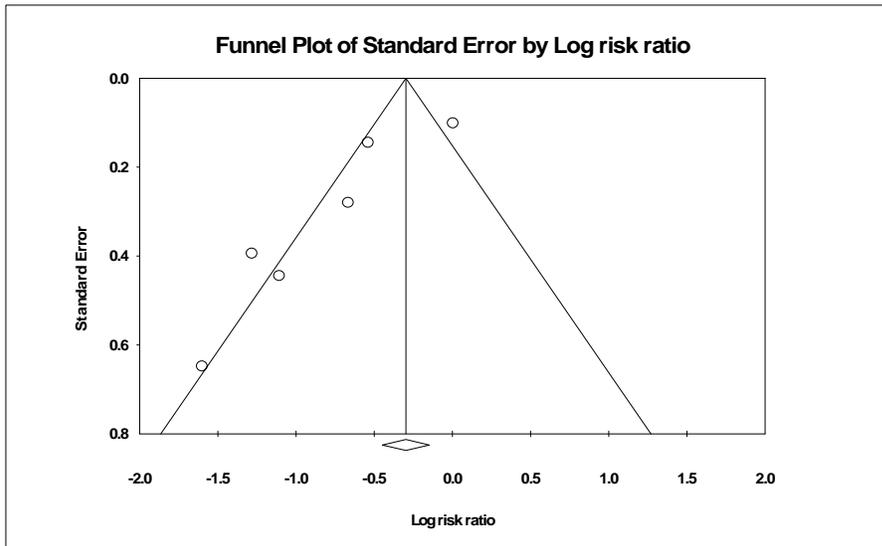
Test for heterogeneity, $p=0.502$

Fixed effects model



Meta Analysis

Publication Bias



Question 4

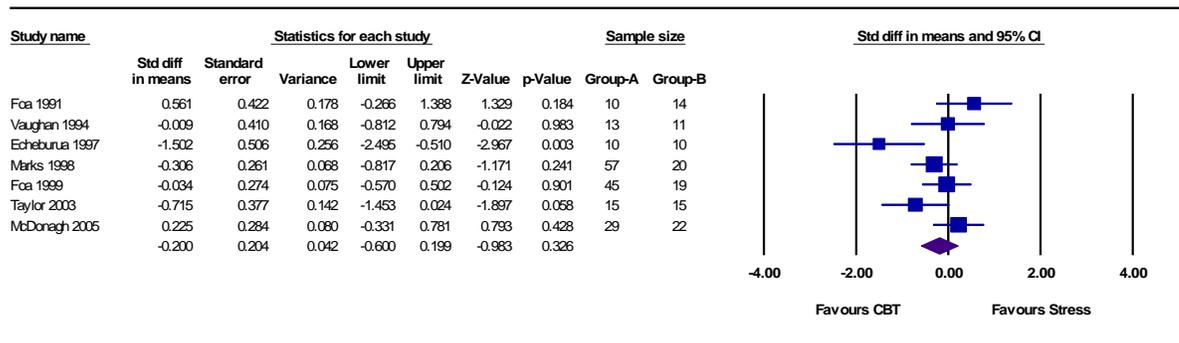
Trauma-focused CBT vs stress management therapy- Severity of PTSD – Random model

Number of studies = 7

Standard difference in means -0.200, 95% CI [-0.600, 0.199]

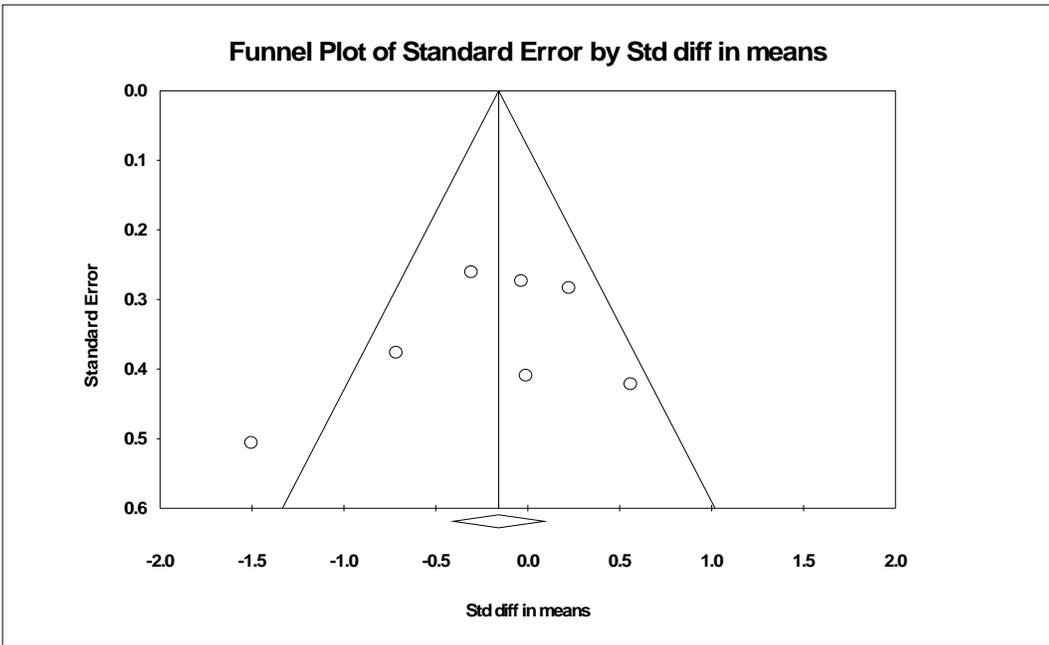
Test for heterogeneity, $p=0.023$

Random effects model



Meta Analysis

Publication Bias



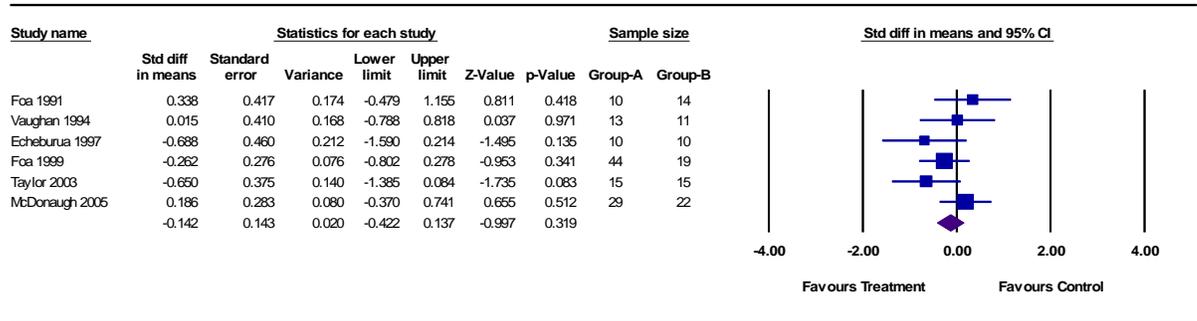
Trauma-focused CBT vs stress management therapy- Depression –Fixed model

Number of studies = 6

Standard difference in means -0.142, 95% CI [-0.422, 0.137]

Test for heterogeneity, $p=0.283$

Fixed effects model



Meta Analysis

Publication bias



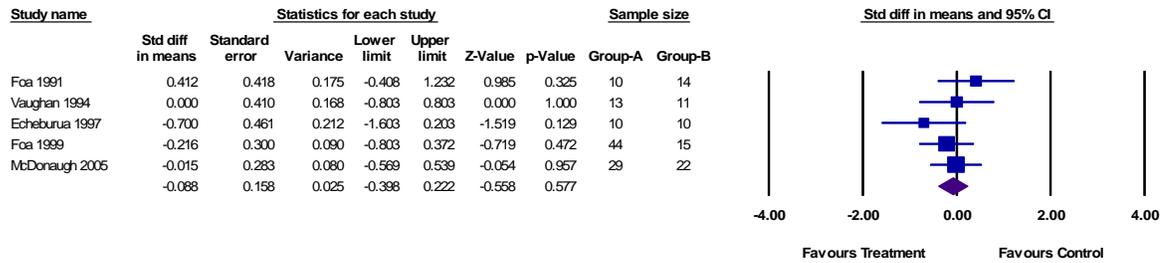
Trauma-focused CBT vs stress management therapy- Anxiety –Fixed model

Number of studies = 5

Standard difference in means -0.088, 95% CI [-0.398, 0.222]

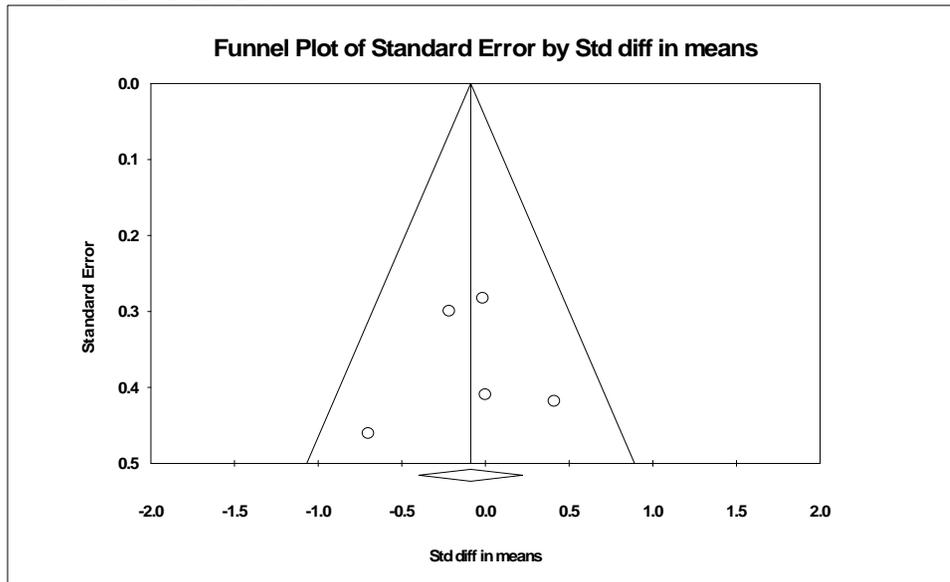
Test for heterogeneity, $p=0.480$

Fixed effects model



Meta Analysis

Publication bias



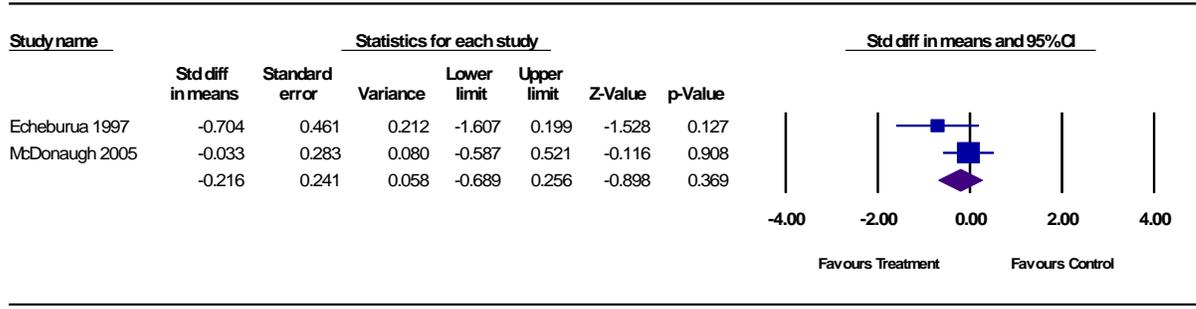
Trauma-focused CBT vs stress management therapy- Quality of Life –Fixed model

Number of studies = 2

Standard difference in means -0.216, 95% CI [-0.689, 0.256]

Test for heterogeneity, $p=0.214$

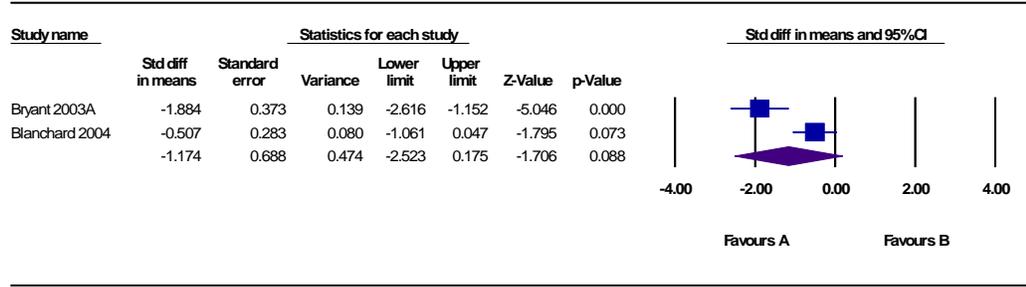
Fixed effects model



Publication bias could not be tested for due to the small number of studies.

CBT vs supportive psychotherapy – PTSD symptom severity (clinician assessed) Random model

Number of studies = 2
 Standard difference in means -1.174, 95% CI [-2.523, 0.175]
 Test for heterogeneity, p=0.003
 Random effects model

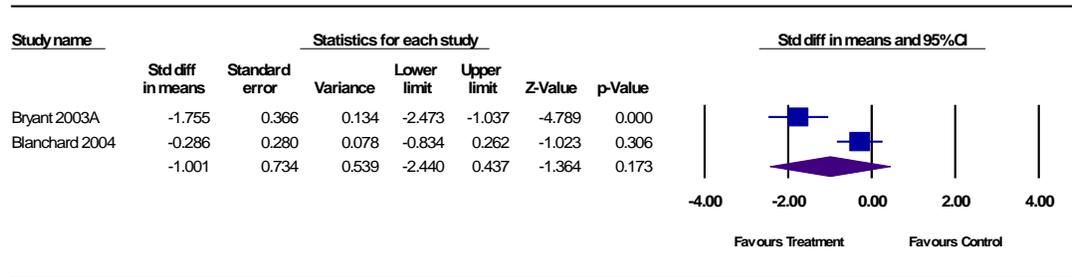


Meta Analysis

Publication bias could not be tested for due to the small number of studies.

CBT vs supportive psychotherapy – PTSD symptom severity (self-report) Random model

Number of studies = 2
 Standard difference in means -1.001, 95% CI [-2.440, 0.437]
 Test for heterogeneity, p=0.001
 Random effects model



Meta Analysis

Publication bias could not be tested for due to the small number of studies.

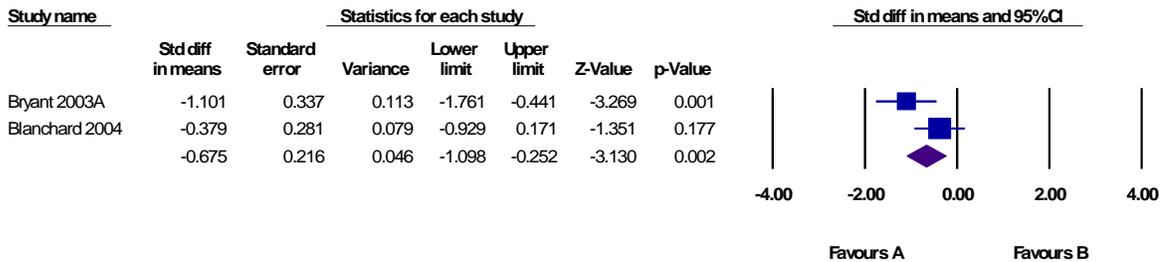
CBT vs supportive psychotherapy – Depression – Fixed model

Number of studies = 2

Standard difference in means -0.675, 95% CI [-1.098, -0.252]

Test for heterogeneity, $p=0.1$

Fixed effects model



Meta Analysis

Publication bias could not be tested for due to the small number of studies.

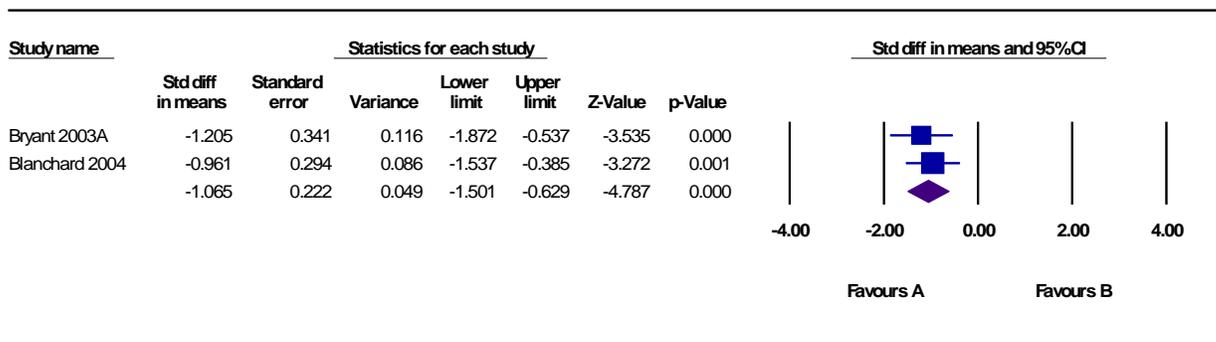
CBT vs supportive psychotherapy – Anxiety – Fixed model

Number of studies = 2

Standard difference in means -1.065, 95% CI [-1.501, -0.629]

Test for heterogeneity, $p=0.588$

Fixed effects model



Meta Analysis

Publication bias could not be tested for due to the small number of studies.

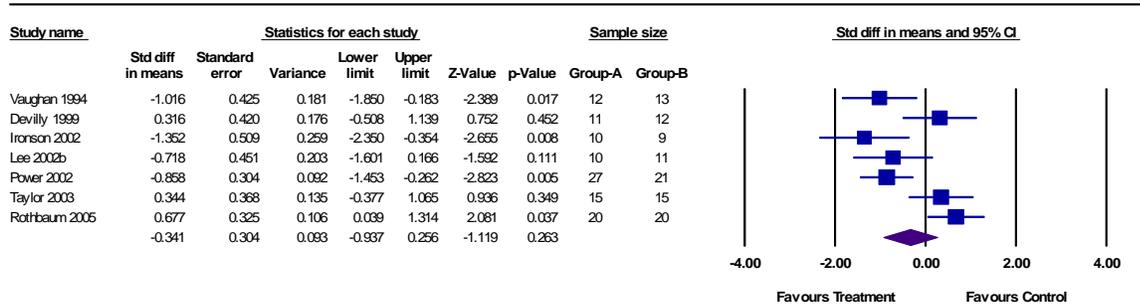
EMDR vs CBT – Depression – Random model

Number of studies = 7

Standard difference in means -0.341, 95% CI [-0.937, 0.256]

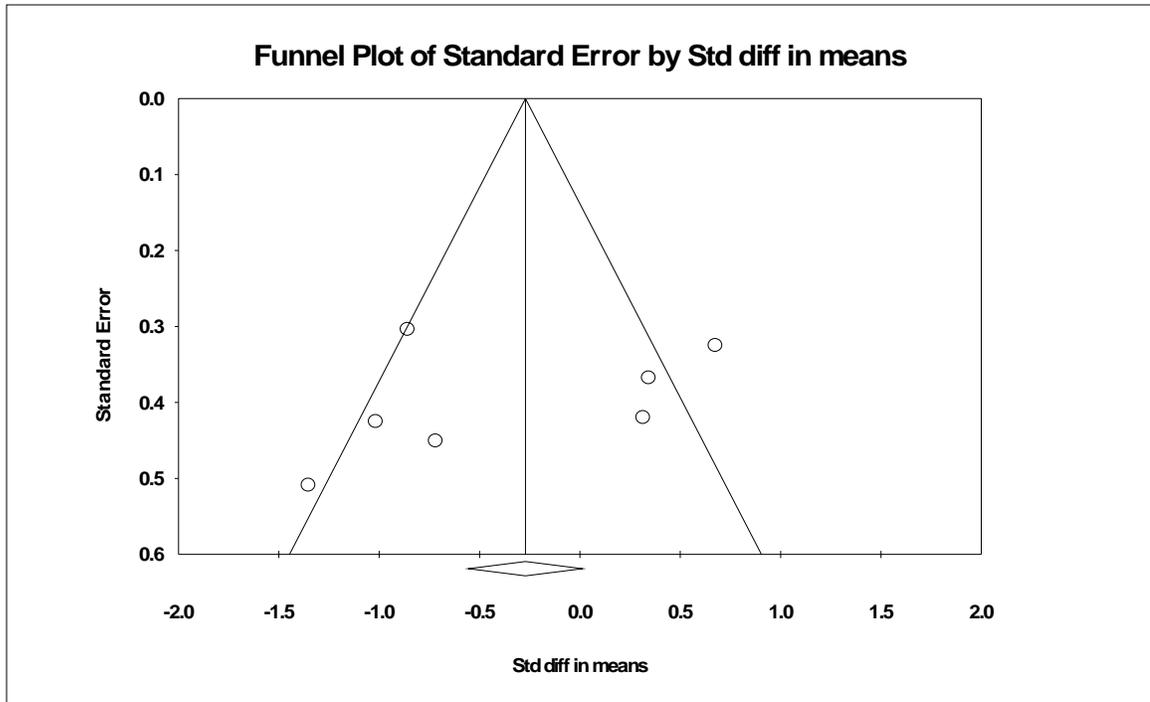
Test for heterogeneity, $p=0.000$

Random effects model



Meta Analysis

Publication bias



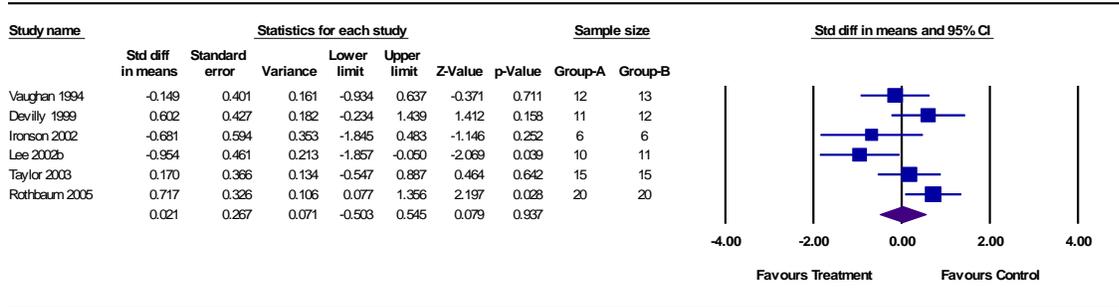
EMDR vs CBT – Depression (2-6 months)– Random model

Number of studies = 6

Standard difference in means 0.021, 95% CI [-0.503, 0.545]

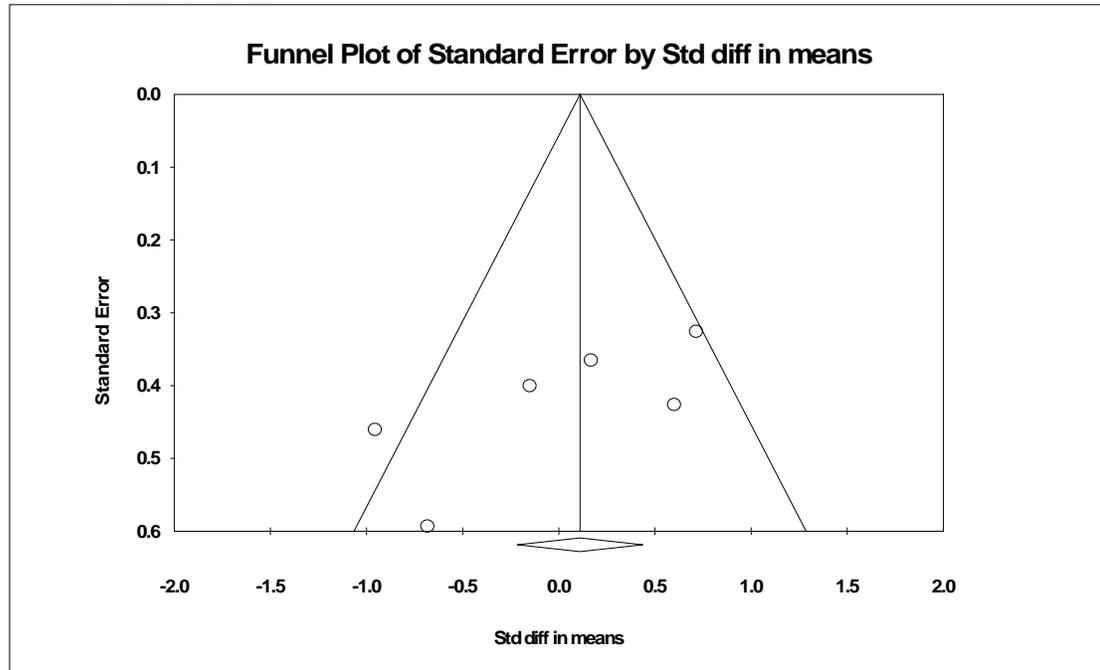
Test for heterogeneity, $p=0.031$

Random effects model



Meta Analysis

Publication bias



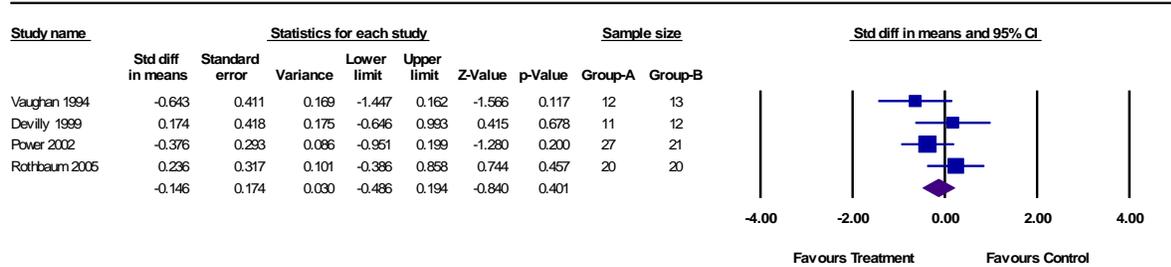
EMDR vs CBT – Anxiety– Fixed model

Number of studies = 4

Standard difference in means -0.146, 95% CI [-0.486, 0.194]

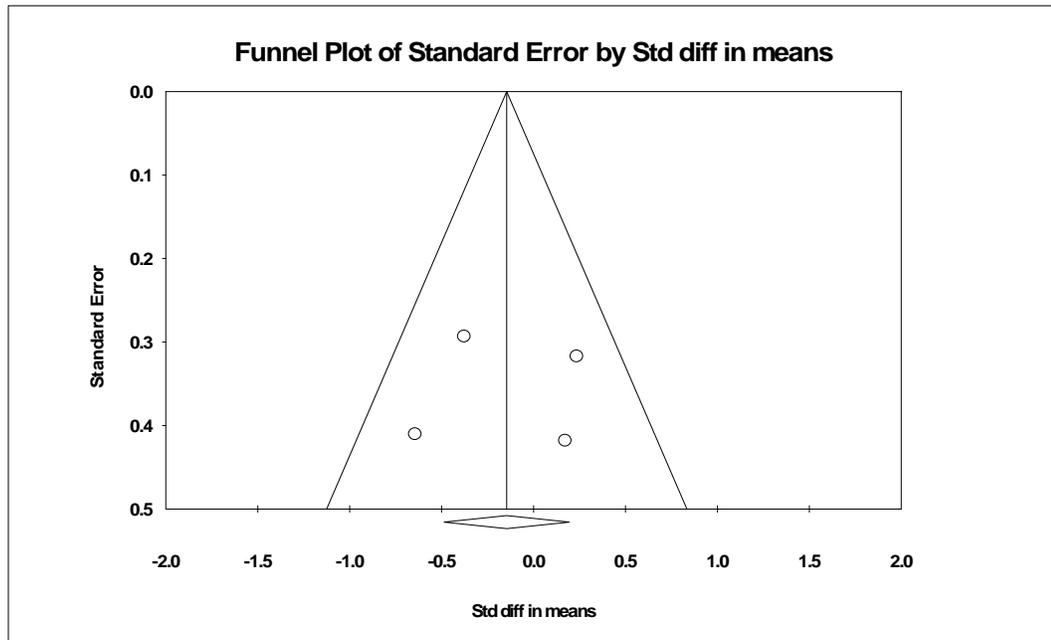
Test for heterogeneity, $p=0.250$

Fixed effects model



Meta Analysis

Publication bias



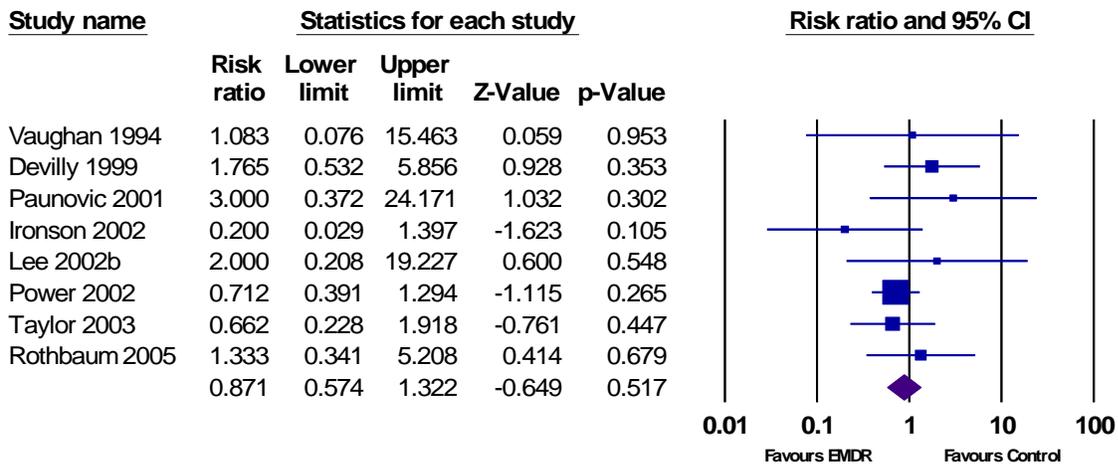
EMDR vs CBT – Dropouts– Fixed model

Number of studies = 8

Risk ratio = 0.871, 95% CI [0.574, 1.322]

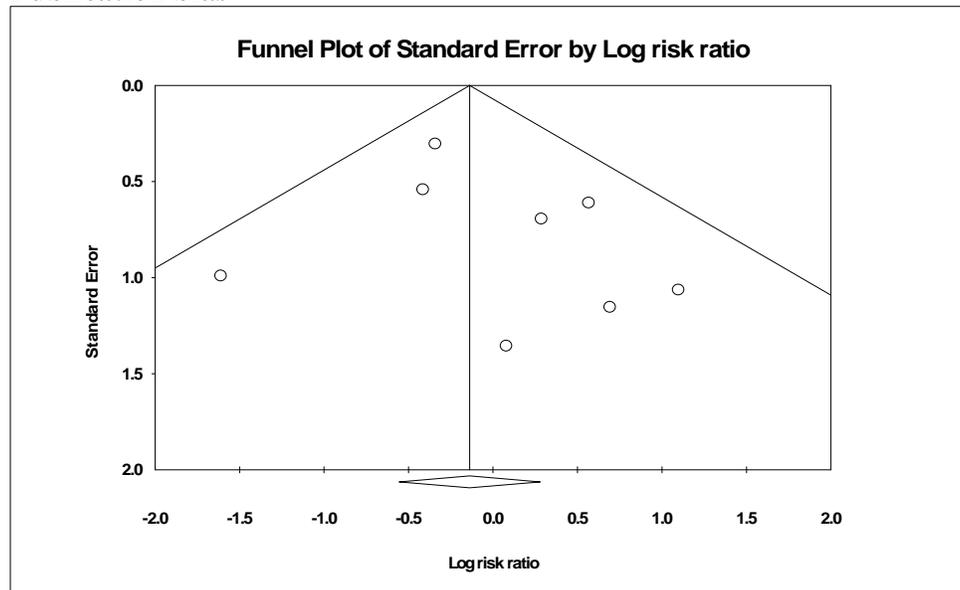
Test for heterogeneity, $p=0.381$

Fixed effects model



Meta Analysis

Publication bias



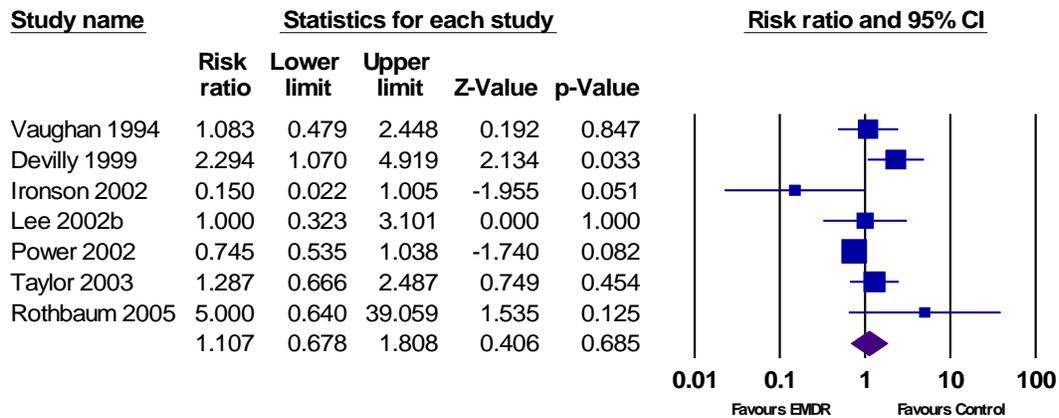
EMDR vs CBT – PTSD diagnosis– Random model

Number of studies = 7

Risk ratio= 1.107, 95% CI [0.678, 1.808]

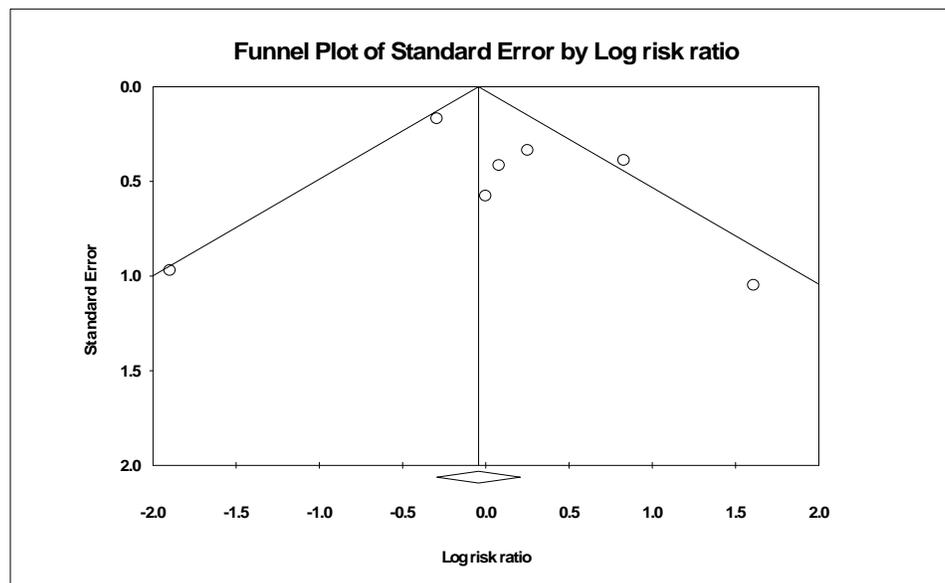
Test for heterogeneity, $p=0.008$

Random effects model



Meta Analysis

Publication bias



Question 5

There were no meta-analyses performed for research question 5.

Question 6

There were no meta-analyses performed for research question 6.

Question 7

There were no meta-analyses performed for research question 7.

Question 8

There were no meta-analyses performed for research question 8.

Question 9

There were no meta-analyses performed for research question 9.

7.9.1 Question 10

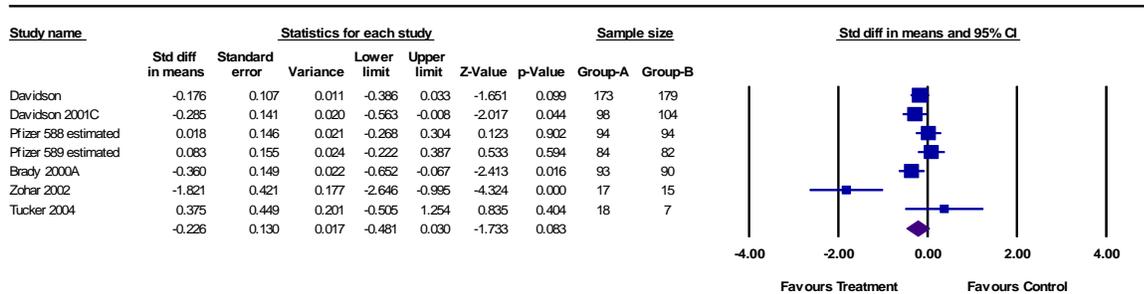
Sertraline vs placebo – Severity of PTSD– Random model

Number of studies = 7

Standard difference in means -0.226, 95% CI [-0.481, 0.030]

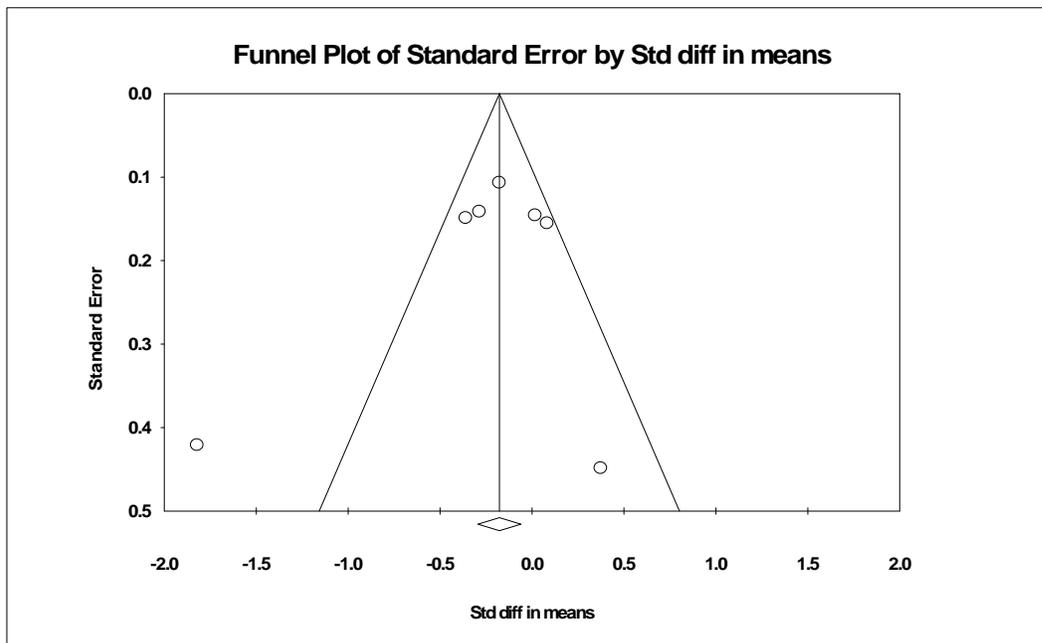
Test for heterogeneity, $p=0.001$

Random effects model



Meta Analysis

Publication bias



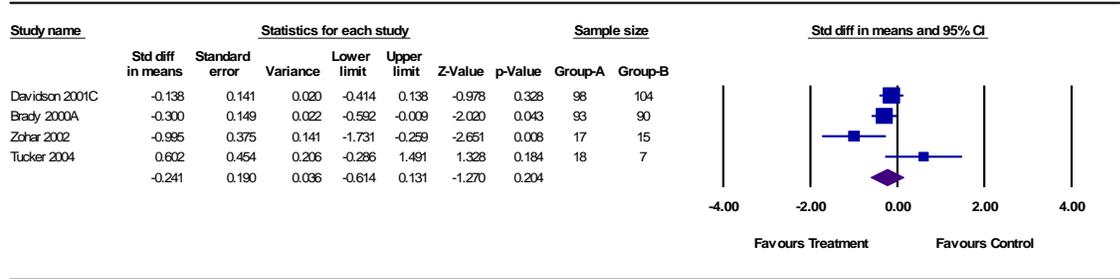
Sertraline vs placebo – Depression– Random model

Number of studies = 4

Standard difference in means -0.241, 95% CI [-0.614, 0.131]

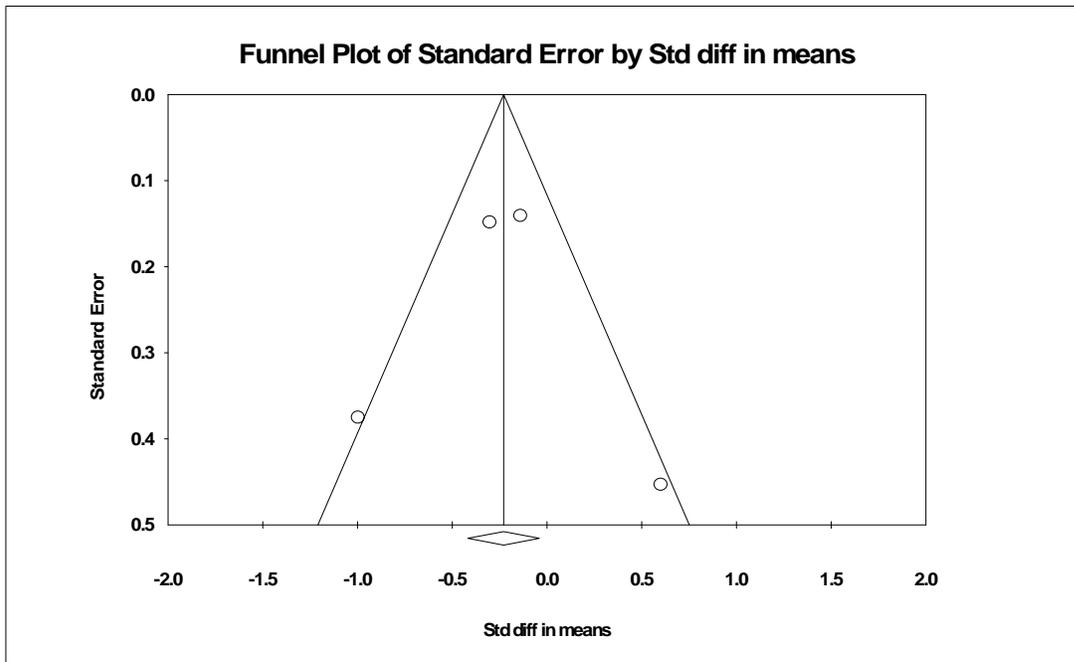
Test for heterogeneity, $p=0.043$

Random effects model



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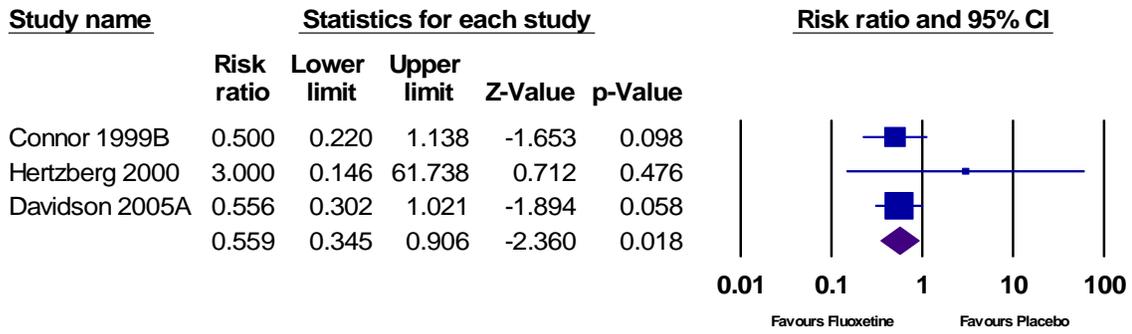
Fluoxetine vs placebo – Dropouts– Fixed model

Number of studies = 3

Risk ratio = 0.559, 95% CI [0.345, 0.906]

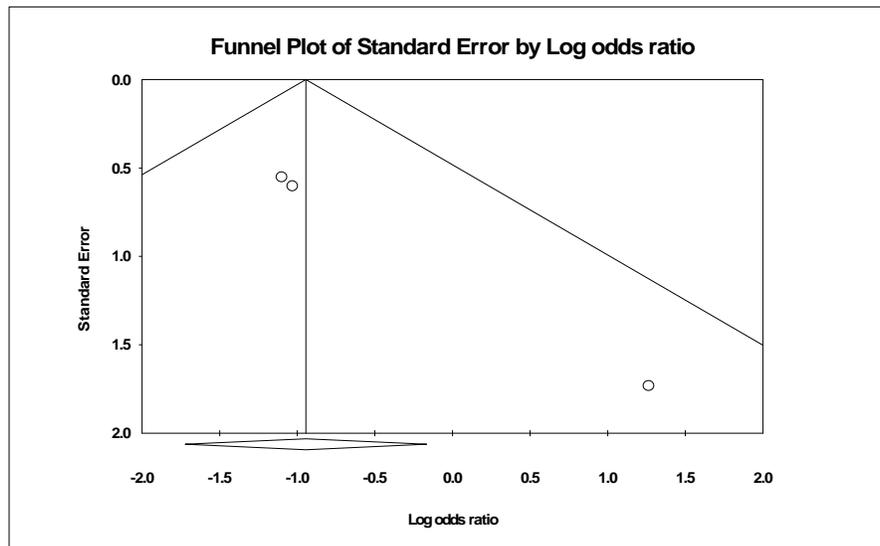
Test for heterogeneity, $p=0.422$

Fixed effects model



Meta Analysis

Publication bias



Question 11

There were no meta-analyses performed for research question 11.

Question 12

There were no meta-analyses performed for research question 12.

Question 13

There were no meta-analyses performed for research question 13.

Question 14

There were no meta-analyses performed for research question 14.

Question 15

There were no meta-analyses performed for research question 15.

Question 16

There were no meta-analyses performed for research question 16.

Question 17

There were no meta-analyses performed for research question 17.

Question 18

There were no meta-analyses performed for research question 18.

Appendix I NICE Grading scheme

The following guidance is evidence-based. All evidence was classified according to an accepted hierarchy of evidence that was originally adapted from the US Agency for Healthcare Policy and Research Classification (see Box 1). Recommendations were then graded A to C based on the level of associated evidence. This grading scheme is based on a scheme formulated by the Clinical Outcomes Group of the NHS Executive (1996).

Box 1: Hierarchy of evidence and recommendations grading scheme

Level	Type of evidence	Grade	Evidence
I	Evidence obtained from a single randomised controlled trial or a meta-analysis of randomised controlled trials	A	At least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence level I) without extrapolation
IIa	Evidence obtained from at least one well-designed controlled study without randomisation	B	Well-conducted clinical studies but no randomised clinical trials on the topic of recommendation (evidence levels II or III); or extrapolated from level-I evidence
IIb	Evidence obtained from at least one other well-designed quasi-experimental study		
III	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies	C	Expert committee reports or opinions and/or clinical experiences of respected authorities (evidence level IV) or extrapolated from level I- or II-evidence. This grading indicates that directly applicable clinical studies of good quality are absent or not readily available
IV	Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities		
		GPP	Recommended good practice based on the clinical experience of the GDG
Adapted from Eccles, M. & Mason, J (2001). How to develop cost-conscious guidelines. <i>Health Technology Assessment</i> 5: 16; Mann, T. (1996) <i>Clinical Guidelines: Using Clinical Guidelines to Improve Patient Care Within the NHS</i> . London: Department of Health.			

Appendix J List of Abbreviations

A, B, C, GPP	Grades of evidence forming the basis for a guideline statement for NICE guidelines
ACPMH	Australian Centre for Posttraumatic Mental Health
ASD	Acute Stress Disorder
CAPS	Clinician-Administered PTSD Scale for DSM–IV
CBT	Cognitive Behavioural Therapy
CI	Confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
DARE	Database of Abstracts of Reviews of Effects
DESNOS	Disorders of Extreme Stress Not Otherwise Specified
DSM	Diagnostic and Statistical Manual of Mental Disorders
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders - Fourth edition
DSM-IV-TR	Diagnostic and Statistical Manual of Mental Disorders - Fourth edition - Text revision
DTS	Davidson Trauma Scale
EMBASE	Excerpta Medica Database
EMDR	Eye movement desensitization and Reprocessing
GP	General Practitioner
GPP	Good practice point
HAM-A	Hamilton rating scale for anxiety
HAM-D	Hamilton rating scale for depression
HTA	Health Technology Appraisal

ICD-10	International Classification of Diseases - Version 10
IES (-R)	Impact of Event Scale (-Revised)
K	Number of studies, the evidence from which has been used to compile an evidence statement
MADRS	Montgomery-Asberg Depression Rating Scale
MAOI	monoamine oxidase inhibitors
N	Number of participants
NHMRC	National Health and Medical Research Centre
NICE	National Institute for Clinical Excellence
NNH	Number needed to harm
NNT	Number needed to treat
PCL	PTSD Checklist
PDS	Posttraumatic Diagnostic Scale
PICO	Specifies the studies to be included in the systematic review by: Population, Intervention, Comparator, Outcome
PSS	Posttraumatic Stress Scale
PTSD	Posttraumatic Stress Disorder
QOL	Quality of life
RCT	Randomised controlled trial
RR	Relative risk/risk ratio
SD	Standard deviation
SMD	Standard mean difference
SSRI	Selective serotonin reuptake inhibitors
VA/DoD	Veterans Affairs/ Department of Defense

Carer– A person not employed as a health practitioner who provides care for another individual with a long-term medical condition

Comorbidity- The occurrence of more than one mental health disorder at the same time

Consumer- A person who has experienced mental health problems following a traumatic event and has used or required health services

Case-controlled study – A study conducted in a naturalistic setting, which compares people who show improvement on the outcome/s of interest with those who do not.

Clinician/health professional or provider – A professional such a doctor, nurse, psychologist or psychiatrist employed in clinical practice

Cohort study –A study in which subjects who have a certain condition and/or receive a particular treatment are followed over time and have measures taken at two or more points in time.

Comparator – The comparison treatment or condition (e.g. waitlist) used to measure the effectiveness of the treatment under investigation

Completer data - Outcome data that is based only on those who completed treatment, rather than also including those who dropped out of treatment

Confidence interval – The probability that a population parameter will lie within an estimated range of values.

Cost-effectiveness – the relative costs and benefits of a range of intervention options

Differential Diagnosis- An alternative diagnosis that could be made on the basis of observed signs and reported symptoms

Early intervention – interventions within the first month of the traumatic event including those that target all adults exposed to the event, and those that target only those with symptoms of ASD or early PTSD

Efficacy – The degree to which a particular intervention produces beneficial outcomes under ideal research conditions.

Effectiveness – The degree to which a particular intervention produces beneficial outcomes in everyday settings.

Epidemiological study – A study that investigates the incidence and prevalence of a particular disorder across the population

Expert consensus – The agreed position of experts in the field – relied upon only in the absence of research evidence on the issue

Fixed-effects model – A fixed-effects model of meta-analysis is based on a mathematical assumption that every study is evaluating a common treatment effect. That means the effect of treatment, allowing for chance, was the same in all studies. Another way of explaining this is to imagine that if all the studies were infinitely large they would give identical results.

Functional improvement – Outcomes that indicate a higher degree of social, occupational and/or psychological functioning.

Grading scheme – A set of criteria used to rate the strength of research evidence.

Heterogeneity in studies – Different outcomes for the same interventions across studies

Historically controlled study – A study in which a group receiving an intervention is compared to another group who has received the same intervention in the past.

Intent-to-treat – Outcome data includes all subjects randomised to receive a treatment in a randomised controlled trial, regardless of whether they complete treatment.

Internal validity – The extent to which the outcomes of the study are due to the effects of the variable under investigation and not other, extraneous variables.

Interpersonal Trauma- Traumatic experience that involves intentional threat or injury caused by another person such as physical or sexual assault.

Interrupted time series – A study in which participants are assessed before and after an intervention on multiple occasions. The trend found in multiple pre-tests are then compared to trends in multiple post-tests. The study may or may not contain a control group.

Meta-analyses – A statistical analysis that combines the results of a number of studies that have investigated the same research question

Observational study – Studies in which investigators observe patients in natural settings

Outcomes of interest – The specific aspects of functioning, including psychological, social and occupational, changes within which are used to evaluate the effects of an intervention

Peer review – A process by which research is reviewed by experts in the same field to determine whether it meets specific criteria for approval.

Posttraumatic growth – Positive psychological change experienced as a result of the struggle with traumatic experiences

Pseudorandomised controlled trial – A study that includes both an intervention and control condition to which participants are allocated on the basis of preexisting characteristics.

Publication bias – The greater likelihood for studies with positive findings to be submitted and/or published compared to those with negative or null findings.

Qualitative synthesis – a summary of research evidence that is based on a subjective analysis of the data rather than statistical analysis.

Quality of life (health-related quality of life) – A multidimensional concept that encompasses the social, occupational, psychological and physical aspects of a person's functioning and enjoyment of life.

Random effects model – A random effects model of meta-analysis assumes that the true treatment effects in the individual studies may be different from each other. That means there is no single number to estimate in the meta-analysis, but a distribution of numbers. The most common random effects model also assumes that these different true effects are normally distributed. The meta-analysis therefore estimates the mean and standard deviation of the different effects.

Randomised control trial – A clinical trial in which participants have the same likelihood of being allocated to a treatment or control condition. Both control and intervention groups are reassessed posttreatment to investigate differences in outcomes.

Recovery- includes reduction in PTSD symptoms and achieving optimal psychosocial functioning across social, occupational and/or personal settings.

Recovery can be an outcome of treatment or occur as a result of a person's existing internal and external resources.

Relative risk - The probability of an event occurring (or disorder developing) in one group (exposed) compared to another (non-exposed) group.

Research question – Specific and clearly defined questions concerning key areas of interest which are addressed in the systematic review of the literature

Secondary prevention- early intervention for individuals who have developed mental health problems following trauma, designed to prevent more severe or protracted mental health problems

Screening- assessment process that aims to identify individuals who are experiencing mental health problems and/or are not showing the normal recovery trajectory following the experience of a traumatic event

Single arm study – A study designed to investigate participants receiving one type of treatment at a particular time, often in order to compare outcomes with those of another treatment at a later date.

Stakeholders – Parties with a specific interest in the area under investigation.

Standardised mean difference – A statistical method used to combine the outcomes of studies, including those utilising different measures, in order to examine the effect of an intervention.

Systematic review – A process by which specific, well-defined research questions are investigated according to a predetermined protocol that outlines explicit methods for searching literature, evaluating studies and collating findings.

Therapeutic alliance- working relationship between health practitioner and person receiving treatment

Appendix L References

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