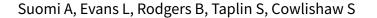


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Couple and family therapies for post-traumatic stress disorder (PTSD) (Review)



Suomi A, Evans L, Rodgers B, Taplin S, Cowlishaw S. Couple and family therapies for post-traumatic stress disorder (PTSD). *Cochrane Database of Systematic Reviews* 2019, Issue 12. Art. No.: CD011257. DOI: 10.1002/14651858.CD011257.pub2.

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[Intervention Review]

Couple and family therapies for post-traumatic stress disorder (PTSD)

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ABSTRACT

Background

Post-traumatic stress disorder (PTSD) refers to an anxiety or trauma- and stressor-related disorder that is linked to personal or vicarious exposure to traumatic events. PTSD is associated with a range of adverse individual outcomes (e.g. poor health, suicidality) and significant interpersonal problems which include difficulties in intimate and family relationships. A range of couple- and family-based treatments have been suggested as appropriate interventions for families impacted by PTSD.

Objectives

The objectives of this review were to: (1) assess the effects of couple and family therapies for adult PTSD, relative to 'no treatment' conditions, 'standard care', and structured or non-specific individual or group psychological therapies; (2) examine the clinical characteristics of studies that influence the relative effects of these therapies; and (3) critically evaluate methodological characteristics of studies that may bias the research findings.

Search methods

We searched MEDLINE (1950-), Embase (1980-) and PsycINFO (1967-) via the Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR) to 2014, then directly via Ovid after this date. We also searched the Cochrane Central Register of Controlled Trials (CENTRAL) via the Cochrane Library. We conducted supplementary searches of PTSDPubs (all available years) (this database is formerly known as PILOTS (Published International Literature on Traumatic Stress)). We manually searched the early editions of key journals and screened the reference lists and bibliographies of included studies to identify other relevant research. We also contacted the authors of included trials for unpublished information. Studies have been incorporated from searches to 3 March 2018.

Selection criteria

Eligible studies were randomised controlled trials (RCTs) of couple or family therapies for PTSD in adult samples. The review considered any type of therapy that was intended to treat intact couples or families where at least one adult family member met criteria for PTSD. It was required that participants were diagnosed with PTSD according to recognised classification systems.

Data collection and analysis

We used the standard methodological procedures prescribed by Cochrane. Three review authors screened all titles and abstracts and two authors independently extracted data from each study deemed eligible and assessed the risk of bias for each study. We used odds ratios



(OR) to summarise the effects of interventions for dichotomous outcomes, and standardised mean differences (SMD) to summarise post-treatment between-group differences on continuous measures.

Main results

We included four trials in the review. Two studies examined the effects of cognitive behavioural conjoint/couple's therapy (CBCT) relative to a wait list control condition, although one of these studies only reported outcomes in relation to relationship satisfaction. One study examined the effects of structural approach therapy (SAT) relative to a PTSD family education (PFE) programme; and one examined the effects of adjunct behavioural family therapy (BFT) but failed to report any outcome variables in sufficient detail — we did not include it in the meta-analysis.

One trial with 40 couples (80 participants) showed that CBCT was more effective than wait list control in reducing PTSD severity (SMD -1.12, 95% CI -1.79 to -0.45; low-quality evidence), anxiety (SMD -0.93, 95% CI -1.58 to -0.27; very low-quality evidence) and depression (SMD -0.66, 95% CI -1.30 to -0.02; very low-quality evidence) at post-treatment for the primary patient with PTSD. Data from two studies indicated that treatment and control groups did not differ significantly according to relationship satisfaction (SMD 1.07, 95% CI -0.17 to 2.31; very low-quality evidence); and one study showed no significant differences regarding depression (SMD 0.28, 95% CI -0.35 to 0.90; very low-quality evidence) or anxiety symptoms (SMD 0.15, 95% CI -0.47 to 0.77; very low-quality evidence) for the partner of the patient with PTSD.

One trial with 57 couples (114 participants) showed that SAT was more effective than PFE in reducing PTSD severity for the primary patient (SMD -1.32, 95% CI -1.90 to -0.74; low-quality evidence) at post-treatment. There was no evidence of differences on the other outcomes, including relationship satisfaction (SMD 0.01, 95% CI -0.51 to 0.53; very low-quality evidence), depression (SMD 0.21, 95% CI -0.31 to 0.73; very low-quality evidence) and anxiety (SMD -0.16, 95% CI -0.68 to 0.36; very low-quality evidence) for intimate partners; and depression (SMD -0.28, 95% CI -0.81 to 0.24; very low-quality evidence) or anxiety (SMD -0.34, 95% CI -0.87 to 0.18; very low-quality evidence) for the primary patient.

Two studies reported on adverse events and dropout rates, and no significant differences between groups were observed. Two studies were classified as having a 'low' or 'unclear' risk of bias in most domains, except for performance bias that was rated 'high'. Two studies had significant amounts of missing information resulting in 'unclear' risk of bias. There were too few studies available to conduct subgroup analyses.

Authors' conclusions

There are few trials of couple-based therapies for PTSD and evidence is insufficient to determine whether these offer substantive benefits when delivered alone or in addition to psychological interventions. Preliminary RCTs suggest, however, that couple-based therapies for PTSD may be potentially beneficial for reducing PTSD symptoms, and there is a need for additional trials of both adjunctive and standalone interventions with couples or families which target reduced PTSD symptoms, mental health problems of family members and dyadic measures of relationship quality.

PLAIN LANGUAGE SUMMARY

Couple and family therapies for post-traumatic stress disorder (PTSD)

Why is this review important?

PTSD is a severe condition that is linked to both individual and relationship problems. Therapies targeting couples and families have been recommended for the treatment of PTSD, but it is not clear if these are helpful in reducing trauma symptoms, and other mental health or relationship problems. The current review is the first attempt to summarise the findings from studies on couple and family therapies for adults with PTSD.

Who will be interested in this review?

People who suffer from trauma, as well as their families; researchers; and mental health professionals.

What questions does this review aim to answer?

Are couple or family therapies helpful in treating PTSD symptoms and other mental health and relationship problems in comparison to 'no treatment' or other types of therapy?

Is there any type of couple and family therapy that is more beneficial than others?

Which studies were included in the review?

We included all published studies of couple and family therapies for PTSD. We found four studies of relevant therapies for adults where one adult person in the couple/family was diagnosed with PTSD.



What does the evidence from the review tell us?

There were few relevant studies and more research is needed to be sure about the benefits of couple and family therapies for PTSD. The four studies included in this review provided early suggestion that couple-based treatments may be helpful in reducing trauma symptoms for the person with PTSD. However, the benefits were not as clear for improving relationship quality or the mental health of family members.

What should happen next?

More studies, including different types of trauma and different types of couple and family therapies for PTSD, are required.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Stand-alone couple or family therapy compared to no treatment for post-traumatic stress disorder (PTSD)

Stand-alone couple or family therapy compared to no treatment for post-traumatic stress disorder (PTSD)

Patient or population: post-traumatic stress disorder (PTSD)

Intervention: stand-alone couple or family therapy

Comparison: no treatment

| Outcomes | Anticipated absolute effects* (95% CI) | | Relative ef- fect | № of partici- pants | Certainty of the evi- dence | Comments | |
|---|--|--|-----------------------------|------------------------|---------------------------------|--|--|
| | Risk with no treatment | Risk with stand-alone couple or family therapy | (95% CI) | (studies) | (GRADE) | | |
| Severity of PTSD symptoms | - | SMD 1.12 lower (1.79 lower to 0.45 lower) | - | 40 (1 RCT) | ⊕⊕⊙⊝ LOW ¹² | | |
| Dyadic adjustment | - | SMD 1.07 higher (0.17 lower to 2.31 higher) | - | 100 (2 RCTs) | ⊕⊝⊝⊝ VERY LOW ²³⁴ | Despite the large effect size, CI in- cludes zero as a possible val- ue | |
| Family functioning | - | - | - | 0 studies | - | | |
| Family member severity of depression | - | SMD 0.28 higher (0.35 lower to 0.90 higher) | - | 40 (1 RCT) | ⊕⊝⊝⊝ VERY LOW 123 | | |
| Family member severity of anxiety - | | SMD 0.15 higher (0.47 lower to 0.77 higher) | - | 40 (1 RCT) | ⊕⊝⊝⊝ VERY LOW 123 | | |
| Primary PTSD patient severity of depression | | SMD 0.66 lower (1.30 lower to 0.02 lower) | - | 40 (1 RCT) | ⊕⊝⊝⊝ VERY LOW ¹²³ | | |
| Primary PTSD patient severity of anxiety | - | SMD 0.93 lower (1.58 lower to 0.27 lower) | - | 40 (1 RCT) | ⊕⊝⊝⊝ VERY LOW 123 | | |
| Treatment dropout (treatment acceptability) | Study population | on | OR 0.41 - (0.09 to 1.95) | 40 (1 RCT) | ⊕⊕⊝⊝ LOW ¹² | | |
| ارو٠٠ | 850 per 1000 | 699 per 1000 | (3.03 to 1.33) | (21101) | LOVV | | |

| | (338 to 917) | | | |
|--------------------------------|------------------------------------|---|---|---|
| Instances of severe aggression | Data omitted from outcome analyses | - | - | - |

*The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

- ¹ Downgraded 1 level due to only one study being available
- ² Downgraded 1 level due to small sample: high level of imprecision with large confidence interval
- ³ Downgraded 1 level due to bias related to self-report measure
- 4 Downgraded 1 level due to inconsistency between 2 studies

Summary of findings 2. Stand-alone couple or family therapy compared to other structured or non-specific intervention for post-traumatic stress disorder (PTSD)

Stand-alone couple or family therapy compared to other structured or non-specific intervention for post-traumatic stress disorder (PTSD)

Patient or population: post-traumatic stress disorder (PTSD)

Intervention: stand-alone couple or family therapy **Comparison:** other structured or non-specific intervention

| Outcomes Anticipated absolute effects* (95% CI) | | Relative ef- | № of partici- | Certainty of the evi- dence | Comments | |
|---|--|--|---------------|--------------------------------|---------------------------------|--|
| | Risk with oth- er structured or non-specific intervention | Risk with stand-alone couple or family therapy | (95% CI) | (studies) | (GRADE) | |
| Severity of PTSD symptoms | - | SMD 1.32 lower (1.90 lower to 0.74 lower) | - | 57 (1 RCT) | ⊕⊕⊙⊝ LOW ¹³ | |
| Dyadic adjustment | - | SMD 0.01 higher (0.51 lower to 0.53 higher) | - | 57 (1 RCT) | ⊕⊝⊝⊝ VERY LOW ¹²³ | |

| Family functioning | - | | - | 0 Studies | - |
|---|---|--|---------------------------|---------------|---------------------------------|
| Family member severity of depression | - | SMD 0.21 higher (0.31 lower to 0.73 higher) | - | 57 (1 RCT) | ⊕⊝⊝⊝ VERY LOW ¹²³ |
| Family member severity of anxiety | - SMD 0.16 lower (0.68 lower to 0.36 higher) | | - | 57 (1 RCT) | ⊕⊝⊝⊝ VERY LOW 123 |
| Severity of depression | - SMD 0.28 lower (0.81 lower to 0.24 higher) | | - | 57 (1 RCT) | ⊕⊝⊝⊝ VERY LOW 123 |
| Severity of anxiety | - SMD 0.34 lower (0.87 lower to 0.18 higher) | | - | 57 (1 RCT) | ⊕⊝⊝⊝ VERY LOW ¹²³ |
| Treatment dropout (treatment acceptability) | Study population | | OR 0.95 (0.29 to 3.19) | 57 (1 RCT) | ⊕⊕⊝⊝ LOW13 |
| ability) | 250 per 1000 | 241 per 1000 (88 to 515) | - (0.29 to 3.19) | (I NCI) | LOW |
| Instances of severe aggression | Data omitted from outcome analyses | | - | - | - |

^{*}The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

Summary of findings 3. Adjunctive couple or family therapy compared to structured or non-specific individual therapy alone for post-traumatic stress disorder (PTSD)

Adjunctive couple or family therapy compared to structured or non-specific individual therapy alone for post-traumatic stress disorder (PTSD)

Patient or population: post-traumatic stress disorder (PTSD)

¹ Downgraded 1 level due to only 1 study being available

² Downgraded 1 level due to bias related to self-report measure

³ Downgraded 1 level due to small sample: high level of imprecision with large confidence interval

Intervention: adjunctive couple or family therapy

Comparison: structured or non-specific individual therapy alone

| Outcomes | Anticipated absolute effects* (95% CI) | | Relative ef- | № of participants (studies) | Certainty of Comments the evidence |
|--|---|---|---------------------|--------------------------------|------------------------------------|
| | Risk with structured or non-specific individual therapy alone | Risk with Adjunctive couple or family ther- apy | (95% CI) | (studies) | (GRADE) |
| Severity of PTSD symptoms | - | - | - | (0 studies) | - |
| Dyadic adjustment | - | - | - | (0 studies) | - |
| Family member severity of depression | - | - | - | (0 studies) | - |
| Family member severity of anxiety | - | - | - | (0 studies) | - |
| Severity of depression | - | - | - | (0 studies) | - |
| Severity of anxiety | - | - | - | (0 studies) | - |
| Family functioning | - | - | - | (0 studies) | - |
| Treatment dropout (treatment ac- | Study population | lation | | 29 | ⊕⊕⊝⊝ Low12 |
| ceptability) | 0 per 1000 | 0 per 1000 (0 to 0) | (0.71 to 279.83) | (1 study) | LOW 12 |
| Instances of severe aggression or violence | Study population | | - | (0 studies) | - |
| violence | - | - | | | |

^{*}The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; OR: Odds ratio

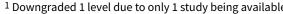
GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect



 1 Downgraded 1 level due to only 1 study being available 2 Downgraded 1 level due to small sample: high level of imprecision with large confidence interval



BACKGROUND

Description of the condition

Post-traumatic stress disorder (PTSD) refers to an anxiety or trauma- and stressor-related disorder where symptom onset is linked to personal or vicarious exposure to traumatic events. These include events characterised by sexual violence, or death or threatened death, as well as actual or threatened serious injury (American Psychiatric Association 2013). The previous edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV TR) provides the most commonly used definition in available research, and defines three categories of symptoms that may indicate a diagnosis of PTSD (American Psychiatric Association 2000). These include:

- intrusive re-experiencing of the event (e.g. through flashbacks and dreams);
- 2. avoidance of reminders and emotional numbing; and
- 3. persistent high levels of arousal and reactivity (e.g. hypervigilance to threat).

These symptom clusters have been re-organised in the recent fifth edition of the DSM (DSM-5) (American Psychiatric Association 2013), which now identifies the following four categories of PTSD symptoms.

- 1. Intrusion
- 2. Avoidance
- 3. Negative alterations in cognitions and mood
- 4. Alterations in arousal and reactivity

The revised symptoms thus re-position emotional numbing in a category that includes negative cognitions (e.g. self-blame) and emotions, while arousal symptoms are repositioned in a category including irritable and reckless or self-destructive behaviour (the latter are new symptoms). Notwithstanding these revisions, the fundamental construct reflected in the updated criteria is unchanged (Friedman 2011), whereby close comparability between DSM-IV and DSM-5 diagnoses is expected (Regier 2013). Most recent data suggest a lifetime prevalence of PTSD of between 2% to 9% in the general population (Atwoli 2015), and indicates a disorder that often follows a chronic course (Orcutt 2004; Solomon 2006). PTSD is associated with a range of adverse individual outcomes (e.g. poor health, suicidality) (Sareen 2007), and significant interpersonal problems, including difficulties in intimate and family relationships (Taft 2011).

Most evidence linking PTSD to family problems is derived from studies of military veterans, from Europe and the USA, which document associations among post-traumatic symptoms and various adverse relationship outcomes (Galovski 2004). These include low relationship satisfaction (Goff 2007), family violence (Glenn 2002), and family members' own mental health problems (Jordan 1992). Comparative investigations of other trauma-exposed populations are relatively few, but they also suggest links between PTSD and problems in intimate relationships. For example, studies following natural disasters indicate associations between post-traumatic stress symptoms and poor relationship adjustment (Taft 2009), while PTSD following interpersonal victimisation predicts family violence (Krause 2006). Studies of survivors of childhood sexual abuse also suggest problems with intimate relationships in adulthood (Cloitre 1997; Lamoureux 2012), including specific difficulties

with intimacy and sexual dysfunction (Davis 2000). However, the unique influences of PTSD in the development of these long-term problems remain poorly understood.

The relationships between PTSD and family problems are likely to be complex, reflecting both the impact of post-traumatic stress symptoms on family members, and the effects of the family environment on PTSD. On the one hand, avoidance symptoms may reduce involvement in family activities, while emotional numbing can inhibit self-disclosure and intimacy (Erbes 2008). Hyperarousal symptoms are linked to irritability and anger and can also precipitate aggression and family conflict (Taft 2007a; Taft 2007b). On the other hand, prospective studies of veterans show that family relationships can predict change in PTSD (Evans 2009; Evans 2010), whereby an adaptive family environment can reduce the severity of symptoms, or exacerbate problems if interpersonal patterns are dysfunctional. These relationships are likely to be particularly complex when PTSD is linked to certain types of trauma. These may include interpersonal trauma (e.g. sexual assault), where couple relationships may trigger traumatic events, as well as other events (e.g. natural disasters, motor vehicle accidents) which can impact directly on multiple family members simultaneously (Riggs 2009).

Description of the intervention

Evidence of associations between post-traumatic symptoms and family difficulties has provided impetus for the consideration of couple and family therapies for PTSD. General reviews of the literature on couple therapies, such as Baucom 1998 and Snyder 2006, distinguish two main classes of couple-based interventions (and by extension, therapies working with broader family systems). These include (1) generic therapies, developed to treat distressed relationships and address common interpersonal problems that can exacerbate individual symptoms, and (2) disorder-specific interventions, targeting interactions between interpersonal processes and specific symptoms of the disorder or its treatment.

Snyder 2006 describes several classes of generic therapies for distressed relationships that are considered in clinical trials. First among these are the behavioural therapies (e.g. traditional behavioural couple therapy) (Christensen 2004), which comprise techniques for enhancing family members' relationship skills in problem-solving and communication, and increasing the frequency of positive interactions. Second are therapies based on psychodynamic and attachment theory perspectives (e.g. insight-oriented marital therapy) (Snyder 1989) that are characterised by a broad focus on developing awareness and expression of unknown feelings, thoughts and needs that may underlie interpersonal patterns (Baucom 1998). Other generic therapies are also available (although considered less often in clinical trials) (Snyder 2006), and can include cognitive strategies for changing ways of thinking about behaviours and relationships, as well as techniques for enhancing emotional acceptance. Another general class of interventions may include 'systemic' therapies (Coulter 2013), potentially including structural and strategic family therapies that focus on changing patterns of family interaction and organisation (Madanes 1981; Minuchin 1974). Integrative therapies draw from multiple conceptual models (Lebow 1997).

A number of disorder-specific couple and family therapies for PTSD have also been proposed and are reviewed by Riggs 2009. They include therapies based on behavioural principles and others grounded in cognitive-behavioural models or attachment the-



ory (Figley 1988; Johnson 1998; Monson 2004; Mueser 1995). These targeted therapies are commonly oriented towards reducing partners' distress or dysfunction in the couple relationship, as well as promoting improvements in individual PTSD. Monson 2004, for example, proposed a stand-alone cognitive-behavioural treatment for post-traumatic stress symptoms and relationship functioning that consists of several stages. These initially deliver psycho-education about PTSD and relationship functioning, and include behavioural interventions (e.g. communication skills training) to address avoidance and numbing in the context of relationships. Subsequent stages comprise scheduled activities to reduce experiential avoidance and increase positive couple experiences, as well as dyadic cognitive interventions that target cognitions maintaining PTSD and relationship problems (Brown-Bowers 2012). Alternative PTSD-specific interventions comprise adjunctive therapies that are delivered alongside other primary psychological and pharmacological treatments (Sautter 2009). Most of these interventions have been developed in the context of combat-related PTSD (Monson 2009), with a small number (such as emotionally focused therapy) proposed originally for use with victims of sexual or physical abuse (Johnson 1998), or with traumatised populations more generally (Figley 1988).

How the intervention might work

Given the complex interrelations between post-traumatic stress symptoms and family adjustment, multiple mechanisms of change may underlie effects of couple and family therapies for PTSD. For example, interventions that enhance relationship skills, including problem-solving and communication, can equip families to better manage interpersonal difficulties such as avoidance of social situations, and potentially minimise relationship conflicts linked to PTSD. Therapies which promote family members' mutual understanding of post-traumatic stress symptoms and its impacts on relationship dynamics might assist in correcting erroneous beliefs about interpersonal behaviour and further reduce family conflict. Interventions that enhance communication, or shared thoughts and feelings, may facilitate self-disclosure and related experiences of intimacy (Laurenceau 1998). These therapies will also operate through common factors shared across interventions (Sprenkle 2004), and other processes that are relatively unique to specific clinical models; for example, emotionally focused therapy which, it is argued, works in part by accessing and reprocessing negative affect that underlies problematic patterns (Johnson 1998).

Improvements in individual functioning during therapy, including reductions in post-traumatic stress symptoms, are expected to involve various mechanisms. The individual benefits may result from the reduction of significant negative exchanges within family relationships (e.g. reflecting high levels of criticism, hostility and emotional over-involvement) that can act as psychosocial stressors and exacerbate PTSD (Tarrier 1999). Conversely, couple and family therapies may promote symptom change by enabling family members to provide both comfort and social support, the latter predicting positive adjustment to both physical health problems and psychological disorders like PTSD (Dirkzwager 2003; Frasure-Smith 2000; Glass 1992; Kaniasty 2008). With reference to trauma in particular, Johnson 1998 suggests that comforting and supportive relationships provide a safe and secure recovery environment where individuals can reprocess and integrate traumatic memories, safely experience post-traumatic symptoms (e.g. flashbacks), and learn to regulate associated negative affective states.

Why it is important to do this review

Despite a growing research literature on links involving PTSD and qualities of intimate and family relationships, there remains limited understanding of the effects of couple and family therapies for PTSD in adults. As far as can be ascertained, there is only one Cochrane Review that has considered family-based therapies (among others) for PTSD, and this review did not consider adult samples but focused on children and adolescents (Gillies 2012). Other Cochrane Reviews of interventions for PTSD in adults have considered psychological therapies (Bisson 2007; Bisson 2013), pharmacological treatments (Amos 2014; Stein 2006), as well as combined pharmacological and psychological interventions (Hetrick 2010). A recent review has addressed psychological interventions for PTSD in people with severe mental illness (Sin 2017). Other relevant Cochrane Reviews have focused on prevention of PTSD and treatment of distress immediately following trauma exposure (Roberts 2009; Rose 2002). None of these have considered couple or family therapies. This review will thus provide the first focused examination of best quality clinical trials of couple and family therapies for PTSD in adults.

OBJECTIVES

The objectives of this review were to: (1) assess the effects of couple and family therapies for adult PTSD, relative to 'no treatment' conditions, 'standard care', and structured or non-specific individual or group psychological therapies; (2) examine the clinical characteristics of studies that influence the relative effects of these therapies; and (3) critically evaluate methodological characteristics of studies that may bias the research findings.

For purposes of this review, the effects of interventions were defined by primary outcomes including PTSD symptoms for the primary presenting patient, and dyadic adjustment as reported by the primary presenting patient, family members or clinicians. See Types of outcome measures for further details on the primary and secondary outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

Eligible studies were randomised controlled trials (RCTs) of couple or family therapies for PTSD in adult samples. We did not expect cross-over trials in this context, but were prepared to include them if couples or families were randomly allocated to treatment sequence. Cluster-randomised trials were also eligible. We did not use sample size and the language of the report to determine inclusion, and there were no restrictions on the study settings that were eligible for this review. We did not consider quasi-randomised trials which used non-random methods of allocation to groups (such as sequential allocation).

Types of participants

Participants were intact couples comprising family members of any ethnicity or sexual orientation in which at least one adult family member (over the age of 18 years) met criteria for PTSD. Consistent with Lebow 2012, we defined couples as "long-term committed unions of romantic partners whether or not these unions are recognised by the state", thus including gay, lesbian and other long-



standing relationships, irrespective of their formal recognition as 'married'. Although we considered studies of diverse family structures, we expected that most participants would be adult couples who are intimate partners in marital or common law relationships. We did not consider studies where intimate partners were divorced or separated. Studies of treatments for child or adolescent PTSD or therapies that focus mainly on family violence were out of scope.

We required that participants were diagnosed with PTSD according to recognised classification systems, including the International Classification of Diseases (ICD-10; WHO 2010), DSM-IV or DSM-5 (American Psychiatric Association 2000; American Psychiatric Association 2013). Assessment strategies considered appropriate for ascertainment of PTSD criteria included general clinical interviews (e.g. based on DSM criteria) and structured clinical interviews (e.g. Clinician Administered PTSD Scale) (Blake 1995). We also considered self-report assessment tools (e.g. PTSD Checklist; Weathers 1993) with validated clinical cut-offs. If studies were based on samples in which a subset of participants were eligible, then these were included if more than 80% of participants met the inclusion criteria, and were excluded otherwise or if the proportion of eligible participants was not reported.

Types of interventions

Experimental interventions

The review considered any type of therapy that was intended to treat intact couples or families where at least one adult family member met criteria for PTSD. The focus of the review was on several categories of therapies as described below. We will consider additional categories of interventions in future updates to this review as studies become available.

- Cognitive-behavioural therapies, including interventions based predominantly on behavioural and cognitive-behavioural approaches to treatment (Figley 1988; Monson 2004). Therapies based on pure cognitive approaches were also classified under this category.
- Psychodynamic therapies, including interventions based predominantly on psychodynamic approaches to treatment. This could include emotion-focused and insight-oriented therapies (Johnson 1998; Snyder 1989).
- 3. Systemic therapies, including interventions derived from general systems theory (von Bertalanffy 1969) such as structural therapies as well as strategic therapies, among others (Coulter 2013; Madanes 1981; Minuchin 1974), and interventions that draw from multiple systemic frameworks.
- 4. Integrative therapies, including interventions where components of treatment were drawn from multiple conceptual models (Lebow 1997), including those listed above. Where potential integrative therapies were apparent, initial efforts were made to classify the therapy as predominantly one type of treatment (where around 80% of sessions are dedicated to one component of treatment). Where it was not possible for us to classify one predominant type of treatment, we would classify the intervention as an integrative therapy.

Eligible therapies could be delivered as 'stand-alone' treatments, as well as 'adjunctive' therapies delivered in conjunction with other primary treatments (e.g. individual psychological therapy). These included disorder-specific interventions developed for treatment of PTSD or associated family difficulties (Riggs 2009), as well as

generic therapies for relationship discord delivered in the context of family members with PTSD (Snyder 2006).

For the purpose of this review, we required that interventions were delivered by psychiatrists, psychologists, counsellors, nurses or other health professionals with specialist training in family therapy (including students under supervision). We did not consider group therapy formats including more than one family 'unit' or studies where patients mainly attended therapy sessions alone. We did not place any restrictions based on duration or intensity of the intervention.

Control conditions

A range of control comparators were potentially eligible, including 'no treatment' controls, 'standard care', and structured or non-specific individual psychological therapies. For the purpose of this review, 'no treatment' controls refer mainly to wait-list and assessment-only controls. Standard care refers to a heterogeneous category of treatments or clinical practices that may be non-specific and described variously as 'existing practice', 'treatment as usual' or 'usual care' (Freedland 2011). These may involve relatively rigorous conditions (e.g. standard of care) or other eclectic interventions including naturalistic prescribing of medications, or minor systemic components (e.g. family member psycho-education).

Structured or non-specific interventions include any manualised programmes including individual therapies such as those based on general approaches described in Types of interventions (e.g. cognitive-behavioural), and other therapies for PTSD (e.g. eye movement desensitisation and reprocessing) (Bisson 2007; Bisson 2013) or group-based interventions. Non-specific structured interventions provide generic features of therapy, including clinical contact and human interaction (e.g. clinician warmth, empathy, social support), and a treatment rationale (Mohr 2009). As such, they may reflect practices that approximate supportive or humanistic therapy to varying degrees.

We excluded potential studies that compared a couple or family therapy with an experimental pharmacological treatment (although comparisons with individual therapies that involve naturalistic prescribing of medications were eligible).

Types of outcome measures

The review considered outcomes addressing multiple domains of individual, couple and family adjustment. Additional outcomes, such as marital stability, observational measures of marital interaction, parental functioning measures or other outcomes related to how trauma interacts with the family system, as well as potential adverse events (e.g. substance abuse, self-harm/suicidality/suicide) may be considered in updates to this review as further studies become available.

Primary outcomes

- Severity of PTSD symptoms for the primary presenting patient, ascertained using self-reports or clinician reports on measurement scales such as the PTSD Checklist (Weathers 1993), the PTSD symptom scale (Foa 1993), as well as the Clinician Administered PTSD Scale (Blake 1995). The last is considered a 'gold standard' measure in many contexts (Weathers 2001).
- 2. Dyadic adjustment, ascertained using self-report, family member reports or clinician reports on measures of relationship sat-



isfaction or distress, like the Dyadic Adjustment Scale or the Marital Adjustment Test (Locke 1959; Spanier 1976).

Secondary outcomes

- Severity of anxiety or depression (or both) of family members, ascertained using self-reports or clinician reports on measurement scales such as the Beck Depression Inventory or the Beck Anxiety Inventory (Beck 1961; Beck 1988); or of psychological distress (measured by, for example, the five-item Mental Health Index of the 36-item Short Form health survey (SF-36); Ware 2000). We intended to consider data from adult intimate partners and children separately where sufficient data were available.
- Severity of co-occurring depression or anxiety (or both), as demonstrated by the primary presenting patient and ascertained using self-reports or clinician reports on measurement scales such as the Beck Depression Inventory or the Beck Anxiety Inventory (Beck 1961; Beck 1988).
- Overall family functioning, ascertained using self-report, family member reports or clinician reports of overall family functioning, or specific characteristics of family interaction (e.g. communication), as measured through scales like the McMaster Family Assessment Device or the Family Environment Scale (Epstein 1983; Moos 1986).
- 4. We used treatment dropout as a proxy measure of treatment acceptability, and defined it as the proportion of participants in treatment and control conditions that provided data at the most immediate post-treatment assessment.
- 5. Instances of severe aggression or violence were considered as a type of adverse event (see <u>Christensen 2005</u>). Other types of adverse events (e.g. substance abuse, self-harm) may be considered in updates of this review as data becomes available.

Multiple informants

When data on dyadic adjustment or family functioning were available from multiple family members (e.g. when both partners in a couple reported on relationship satisfaction), we combined data from multiple informants and used the simple arithmetic mean of scores (assuming that all family members provided reports on the same scale) and pooled variance. We considered exceptional cases to be where different family members showed widely divergent perspectives on relationships, as demonstrated by limited shared variance (i.e. < 50% or r = 0.70). In such instances, we considered reports from different family members in separate analyses. We intended to examine the implications of decisions to average across multiple informants through sensitivity analyses, where appropriate.

Timing of outcome assessment

We examined data from outcomes at immediate post-treatment assessments, conducted from 0 to 3 months following completion of therapy. We will consider follow-up assessments — conducted more than 3 months but less than 12 months following completion of therapy, and longer periods of follow-up — in future updates when data becomes available.

Search methods for identification of studies

We conducted a systematic search to identify all available relevant studies. The search comprised two main strategies: (1) electronic

searches of databases and clinical trials registries; and (2) manual searches of other resources.

Electronic searches

We performed electronic searches of the following bibliographic databases to 3 March 2018:

- Ovid MEDLINE (1950 onwards);
- Ovid Embase (1974 onwards);
- Ovid PsycINFO (1967 onwards);
- Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR) (all years to June 2016 (only));
- Cochrane Central Register of Controlled Trials (CENTRAL) (via the Cochrane Library;
- Proquest PTSDPubs (formerly known as PILOTS (Published International Literature on Traumatic Stress)) (all available years).

Searches of MEDLINE, Embase and PsycINFO were initially conducted via the Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR) to June 2016. However after the CCMDCR fell out of date (June 2016 onwards) searches were conducted directly on these databases via the Ovid platform, with an overlap from 2014 to date.

The CCMDCTR was searched (all years to June 2016) using the following free-text terms:

(PTSD or post-trauma* or *trauma* or "stress disorder*" or (combat and disorder*) or (war and neuro*)) AND (couple* or partner* or marriage or marital or husband* or wife or wives* or spous* or family or families or multi-family or conjoint or interpersonal or relations* or "significant other*" or (child* and parent*)) AND (*therap* or counsel* or treat* or intervention*)

For a full description of the CCMDCTR, please see Appendix 1.

Consistent with the CCMDCTR search strategy, we applied RCT filters on searches across the other databases to limit the results to controlled trials (as appropriate). We adapted the search terms to conduct analogous searches of PILOTS/PTSDPubs.

The database searches conducted in March 2018 (Appendix 2) were part of a much larger search (based on population alone) for a suite of PTSD reviews within CCMD.

We also searched the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) search portal (apps.who.int/trialsearch) and ClinicalTrials.gov (ClinicalTrials.gov) to identify unpublished and/or ongoing studies (to February 2019).

We applied no restrictions based on date, language, or publication status to the searches (other than those described above).

We conducted an update search (22 February 2019) (Appendix 3) with terms tailored to couple and family therapies for PTSD. The results will be incorporated into the next version of this review (as appropriate).



Searching other resources

Handsearching

We manually searched the early editions of key journals to identify potentially relevant studies that were not indexed in the databases. These journals included:

- 1. Journal of Traumatic Stress (1988 to 2000);
- 2. Journal of Family Psychology (1987 to 2000); and
- 3. Journal of Marital and Family Therapy (1980 to 2000).

Reference lists

We manually screened the reference lists and bibliographies of all included studies to identify other relevant references. We also contacted all authors of included studies for any unpublished or ongoing studies, or studies not otherwise identified in the search.

Data collection and analysis

Selection of studies

We reviewed and selected studies in several stages. First, we screened the titles and abstracts (where available) of all records retrieved to determine potentially eligible studies. Three review authors (AS, SC, ST) screened all titles and abstracts; two reviewers screened each record. Where there were disagreements, the third author also reviewed the record. The alpha for interrater reliability between two authors for the first screening stage was above 0.95. We obtained full-text articles of any studies that seemed to meet inclusion criteria, as well as those that could not be excluded based on title and abstract. Two review authors (AS, SC) then independently examined each full-text article in order to confirm eligibility and resolved any disagreements through discussion. We identified any duplicate (secondary) publications and listed them alongside the primary publication. We recorded and presented decisions made during the study selection process, as well as the names and numbers of studies and reasons for exclusion at each stage, in a PRISMA flow diagram.

Data extraction and management

We extracted data on the characteristics of eligible studies from reports using a piloted, structured data extraction template. This addressed information (where available) relating to publication details (e.g. country of origin, year of publication), sample characteristics (e.g. age and ethnicity of participants, predominant type of trauma), clinical characteristics (e.g. type of therapy, duration of treatment), methodology (e.g. inclusion/exclusion criteria, timing of follow-up assessments), statistical analyses and results (e.g. strategies for managing non-independent data from family members, group means and standard deviations for primary and secondary outcomes). Two review authors (AS, SC) independently extracted data from each study.

Main comparisons

We planned multiple comparisons to evaluate the effects of standalone couple or family therapies for PTSD, compared to relevant control comparators. These included:

- 1. stand-alone couple or family therapy versus no treatment;
- 2. stand-alone couple or family therapy versus standard care; and

3. stand-alone couple or family therapy versus other structured or non-specific intervention.

Additional comparisons were planned to evaluate the effects of adjunctive couple or family therapies, additional to primary treatment, relative to controls. These included:

- 1. adjunctive couple or family therapy versus standard care; and
- 2. adjunctive couple or family therapy versus structured or nonspecific individual therapy alone.

Additional types of comparisons may be considered as studies become available.

Comparisons involving adjunctive therapies were limited to control conditions that involved substantively similar primary treatments. We therefore did not consider comparisons between couple or family therapies adjunctive to primary treatment and (a) 'no treatment' controls, and (b) substantively different primary treatments (e.g. cognitive-behavioural therapy versus psychodynamic individual therapy). Where multiple couple or family therapy conditions were compared with control conditions, it was intended that couple or family therapy conditions would be combined (Unit of analysis issues).

Assessment of risk of bias in included studies

Two review authors (AS, SC) independently assessed the risk of bias associated with each study. Both authors allocated a judgement of 'High', 'Low' or 'Unclear' risk of bias with regard to several design characteristics that are among the main sources of bias in clinical trials (Higgins 2017). We resolved disagreements with regard to classification of bias through discussion. In line with available recommendations (Juni 1999), we assessed each source of bias independently.

Random allocation to groups (sequence generation)

One of the eligibility requirements included random allocation of studies to groups. Notwithstanding this, we envisaged that the level of detail published about randomisation procedures would vary. We classified studies which provide limited or no detail about randomisation as having unclear risk of bias.

Allocation concealment

Adequate concealment of allocation requires that participants and researchers are kept unaware, and are unable to foresee the groups to which participants are allocated (Schulz 2002). We classified studies that lack allocation concealment as having high risk of bias.

Blinding

Blinding can refer to hiding the nature of the intervention delivered from multiple potential groups (e.g. participants, treatment providers, outcome assessors) (Montori 2002). We considered the following blinding aspects.

- Participants and treatment providers: blinding of participants and treatment providers can be accomplished in studies of pharmacological treatments, but it is rarely feasible for psychosocial therapies. Accordingly, we expected that most studies would be classified as having a high risk of bias
- 2. Outcome assessors: this refers to masking of group allocation from outcome assessors, such as researchers administering



symptom scales. Studies that failed to blind outcome assessors (including studies relying on self-report measures completed by participants) were classified as having a high risk of bias. Given that blinding of outcomes assessors may vary within studies and across outcomes (e.g. some may be self-reported with other outcomes evaluated using blinded outcome assessors), we assessed this characteristic separately for each outcome considered in Types of outcome measures.

Incomplete outcome data

According to Higgins 2017, missing data can be caused by both study exclusions and attrition. Justifiable reasons for exclusions may include identifying (after randomisation) that participants were ineligible for the study. In contrast, participants may be excluded because they did not receive the intended intervention in accordance with the protocol (or for other reasons), which may lead to bias (Higgins 2017). In case of missing data from attrition, primary studies may report analyses conducted using data from participants providing complete information (i.e. 'completers only'), or by including data from all participants through use of various missing data strategies. These include recommended strategies based on principles of maximum likelihood or multiple imputation, as well as older (and potentially biased) forms of imputation, including mean imputation and last observation carried forward (LOCF) (Graham 2009).

For the purpose of this review, we classified studies as having a high risk of bias if they violated any of three principles of intention-to-treat (ITT) analyses described by Higgins 2017. These are:

- "keep participants in the intervention groups to which they were randomised, regardless of the intervention they received";
- 2. "measure outcome data on all participants"; and
- 3. "include all randomised participants in the analyses".

Given that approaches to managing incomplete outcome data (from attrition in particular) may vary within studies and across outcomes, we assessed these approaches separately for each outcome considered in Types of outcome measures.

Selective outcome reporting

Selective outcome reporting refers to the presentation of a limited subset of data or analyses based on the nature (e.g. statistical significance) of results (Hutton 2000). Although there are various issues suggestive of selective outcome reporting (Higgins 2011b), we classified studies in this review as having high risk of bias if they had protocols or entries in trial registries that list primary or secondary outcomes that differ from those reported in the published results (lacking credible explanation). We classified studies that were not associated with published protocols or adequately detailed entries in trial registries as having an unclear risk of bias.

Other sources of bias

We assessed each study for any other problems that could put it at a high risk of bias including bias relating to the study design or claims of fraudulence, or other sources of bias that are not covered in the other sources of bias above.

Measures of treatment effect

Dichotomous data

For evaluation of treatment effects based on dichotomous outcomes (e.g. scores in the clinically significant range on relationship adjustment), we used risk ratios (RRs) and associated 95% confidence intervals (CIs).

Continuous data

For evaluation of treatment effects based on continuous outcomes we used mean differences (MDs) where outcomes were reported on the same scale, or the standardised mean difference (SMDs) where outcomes were reported on different scales. We obtained SMDs by calculating the difference between raw means and dividing by the pooled variance of treatment and control conditions. We used 95% CIs around the MDs or SMDs.

Unit of analysis issues

Cluster-randomised trials

If a cluster-randomised trial had been identified, we would have extracted the methods used to analyse data, and use the inflated standard error approach to adjust standard errors for non-independence of observations (Higgins 2011b). To facilitate this, we would have extracted the degree of non-independence, as reflected in the intra-class correlation (ICC). Where the ICC is not reported, we would intend that a value of 0.05 would be assumed.

Cross-over trials

Where a cross-over trial was identified, we intended that data from the between-group comparison from the first treatment stage only would be considered.

Studies with multiple treatment groups

Where multiple couple or family therapy conditions were compared with a 'no treatment' or individual intervention control, we planned to combine the couple or family therapy conditions using the formulae reported by Higgins 2011a. Exceptions would be where a stand-alone couple or family therapy and adjunctive therapy (alongside another primary treatment) were both compared with an individual therapy condition, and where the adjunctive condition provided a significant additional dosage of therapy in terms of number of sessions. Rather, we evaluated stand-alone and adjunctive therapy conditions in separate comparisons (Data extraction and management). Where different groups were involved in the same treatment, but have results reported separately, it was intended that we would combine these data.

Dealing with missing data

Missing information about study design and results/statistics

We initially gathered Information about research design that was not reported in a primary publication through examination of duplicate publications. Where informative duplicate publications were unavailable, and where missing data related to the inclusion criteria or risk of bias (as defined in this review), we contacted the study authors for additional information. We also sought clarification from the study authors where statistics necessary for the estimation of treatment effects (e.g. standard deviations) were missing.



Missing observations from primary studies due to attrition

Our decision to consider 'completers only' data or data from all participants was initially determined by the type of information reported; for example, where the study only reported analyses of the 'completers only' sample. However, we gave preference to data from all randomised participants (where available). Given certain 'old' missing data strategies (such as mean or single imputation or LOCF) that may still introduce bias into the study (Graham 2009), we examined these through sensitivity analyses.

Assessment of heterogeneity

Clinical heterogeneity

For studies that were clinically heterogeneous or presented insufficient information to facilitate quantitative synthesis, we presented a narrative summary of results.

Statistical heterogeneity

Given a sufficient number of studies, we planned to assess statistical heterogeneity using the I^2 statistic, which indicates the percentage of total variability across studies that is due to between-study differences (Huedo-Medina 2006). Although thresholds for I^2 are arbitrary, there are overlapping bands that suggest minor (0% to 40%), moderate (30% to 60%), substantial (50% to 90%), and considerable (75% to 100%) levels of heterogeneity (Deeks 2011). Interpretation of the I^2 statistic is qualified through evaluation of the pattern of variability, and whether all studies indicate beneficial effects of treatment. Where strong evidence of true heterogeneity was present, we considered the pooled effect as a limited, although 'best available' estimate of the expected magnitude of the treatment effect.

Assessment of reporting biases

We examined multiple databases to identify published research, and searched trial registers to identify unpublished studies. We intended that funnel plots and linear regression tests would be used to evaluate publication bias if there were more than 10 studies available (Egger 1997; Sterne 2011). We also screened relevant databases and trial registers to identify reports published in a non-English language.

Data synthesis

Two authors (AS, SC) entered data into the Cochrane statistical software, Review Manager 2014, and employed the random-effects model to provide weighted estimates of the effects of each intervention relative to control. This random-effects model assumes true variability in effect sizes across studies, and estimates both the average effect and degree of variability across studies (Normand 1999). Where there is evidence of true heterogeneity, it may be inappropriate to place inordinate emphasis on a weighted mean effect size (especially if some studies indicate harmful effects), and we thus qualified the pooled estimates through discussion of statistical diversity of studies.

Subgroup analysis and investigation of heterogeneity

In the case of observed statistical heterogeneity, we planned to pursue subgroup analyses to examine factors explaining between-study variability, which included the following.

- Disorder-specific versus generic couple or family therapies: disorder-specific and generic therapies share a focus on improved relationship outcomes. However, disorder-specific therapies may include components of treatment targeting individual psychopathology, and may thus have greater impacts on individual post-traumatic stress symptoms. The more singular focus of generic therapies on relationship problems may lead to larger improvements in couple and family adjustment.
- 2. Nature of trauma linked to disorder onset: patients exposed to interpersonal trauma (e.g. sexual assault) may demonstrate greater severity of problems in couple and family functioning, relative to traumas that do not have equivalent interpersonal components (e.g. combat exposure, natural disasters). Accordingly, disorders associated with interpersonal trauma may benefit more from couple and family therapies.
- Recent onset versus chronic PTSD: disorders with recent onset (e.g. within one year of trauma exposure) may be more amenable to change following couple and family therapies for PTSD, relative to longer-standing conditions where symptoms and interpersonal patterns have become established over time.

We intended to carry out subgroup analyses where at least 10 studies were available, and planned to use the approach described by Deeks 2011, applying the test for subgroup differences available in Review Manager 2014. We may consider other potential clinical characteristics (e.g. couple versus family-based therapies for PTSD) in updates as studies and literature becomes available.

Sensitivity analysis

We conducted sensitivity analyses to examine whether findings were robust to approaches adopted in this review (Deeks 2011). The following characteristics of assumptions were considered sequentially for the purposes of these analyses.

- Where outcome data from multiple informants are available, we excluded data from family members.
- 2. We excluded cluster randomised trials.
- 3. We varied the ICC used during analyses of cluster randomised trials.
- 4. We excluded cross-over trials.
- 5. We excluded results based on 'completers only'.

We may include additional sensitivity analyses based on methodological quality of studies as more evidence becomes available. For the current review, there were too few trials to undertake sensitivity analyses on the basis of risk of bias.

'Summary of findings' table

We developed the 'Summary of findings' table to summarise the key findings of the review, for all relevant populations, in line with Schünemann 2011. We used the GRADE approach to interpret findings and used GRADEpro to import data from Review Manager 5 to create the 'Summary of findings' table. Summary of findings for the main comparison presents findings relating to each type of intervention in terms of primary and secondary outcomes (Types of outcome measures) for our main comparison, Comparison 1. Summary of findings 2 presents the outcomes for the other comparison we had data available, Comparison 3. The tables present standardised effect size estimates (and 95% CIs) to illustrate comparative risk, the number of studies and participants, and the quality of evidence based on standards of the GRADE working group (Balshem 2011).



Given the general absence of evidence due to a low number of included studies, the certainty of evidence ranges from low to very low across the outcomes.

RESULTS

Description of studies

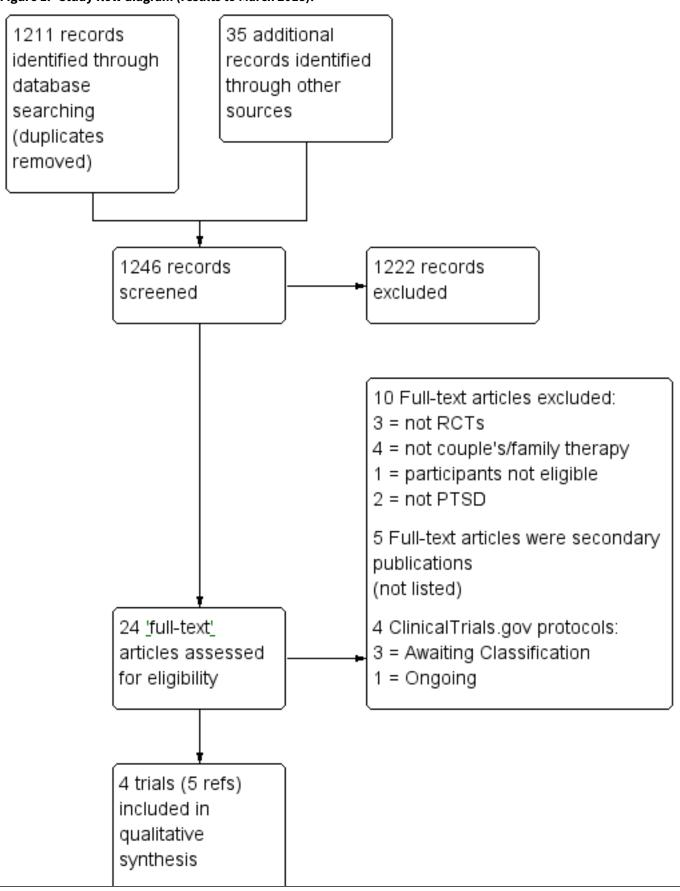
Results of the search

Searches of the CCMDCTR and other databases to 3 March 2018 yielded 1246 records to screen (after the removal of duplicates).

Three authors (AS, SC and ST) reviewed titles and abstracts and obtained full-text versions of 24 articles (including four ClinicalTrials.gov protocols). Four studies (five references) met the inclusion criteria and we included them in the analysis. Figure 1 presents the PRISMA diagram for the study review process. We contacted all the authors (4) for additional information and one responded to queries.



Figure 1. Study flow diagram (results to March 2018).



Couple and family therapies for post-traumatic stress disorder (PTSD) (Review)Copyright © 2019 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

4 trials included in quantitative



In February 2019 a further update search identified 327 references. Among these references, we found new updated results (as of November 2018) of a study we had previously classified as 'ongoing' (NCT01035788), we subsequently moved this study to Characteristics of studies awaiting classification, and will incorporate it at a later date, as appropriate. Personal communication (March 2019) with the main author of this trial (NCT01035788) indicated that the main outcome publication will be available in late 2019.

Included studies

We included four studies in the review, although one study reported data on relationship satisfaction only (and no other outcomes) (Ahmady 2009), while one study reported baseline information on pre-specified outcomes only, and no post-treatment data (Glynn 1999). Two studies provided data on a range of primary and secondary outcome measures at post-treatment (Monson 2012; Sautter 2015). We describe the characteristics of these studies below (see also Characteristics of included studies).

Design

All included studies were described as randomised controlled/clinical trials. Sautter 2015 used a 'simple' type of randomisation to SAT and PFE conditions while Monson 2012 used a computer random number generator to allocate participants to wait list and treatment. Glynn 1999 adopted a three-group design (one adjunctive therapy group, one individual therapy group only and one control group) and reported using a sequential random balancing strategy with a modification of randomisation odds to permit 50% likelihood of being assigned to the adjunctive therapy group, and 25% chance of being assigned to the two other groups. In three studies participants and personnel were not blinded and were thus aware of the intervention conditions (Glynn 1999; Monson 2012; Sautter 2015). Ahmady 2009 did not report about randomisation method or blinding of the participants.

One trial comprised 9 weeks of individual therapy followed by adjunct family therapy (16 to 18 sessions) with post-treatment assessments scheduled immediately after treatment and at 6 months (Glynn 1999). Two trials were conducted over a 12-week period, and included pre-treatment, post-treatment (immediately after 12-week treatment) and 12-week follow-up assessments (Monson 2012; Sautter 2015). Monson 2012 included one mid-treatment assessment at four weeks; and Sautter 2015 included two mid-treatment assessments at three and six weeks into the programme. Ahmady 2009 was conducted over 6 months (16 to 18 sessions) and reported post-treatment assessment immediately after the intervention (with no other indication of the timing of assessments).

Setting

Three studies were two-site trials run out of outpatient veterans' mental health services, including two different outpatient veterans' mental health services (Ahmady 2009; Sautter 2015), and one outpatient veterans' mental health service and a university-based mental health clinic (Monson 2012). One study did not specify the number of sites but they reported that the treatment was embedded in Veterans' Affairs customary care in Los Angeles (Glynn 1999). The sites were situated in the USA (Glynn 1999), Iran (Ahmady 2009), Canada (Sautter 2015), and the USA and Canada (Monson 2012).

Participants

The four studies included a total of 186 couples/family units (372 individuals). Glynn 1999 included 29 male veterans who were in military service during the Vietnam conflict and met criteria for PTSD, and their family members. Sautter 2015 included 57 veterans with PTSD and their intimate partners, while Monson 2012 sampled 40 couples in which one partner met criteria for PTSD (including veterans and members of the general community). Glynn 1999, Monson 2012 and Sautter 2015 used the Clinician Administered PTSD scale (CAPS: Blake 1995; Weathers 2001) and Ahmady 2009 used PTSD Checklist (PCL; Weathers 1993) to screen for PTSD at baseline. Glynn 1999, Monson 2012 and Sautter 2015 asked participants to refrain from other psychological therapy (couples or individual) and to maintain a stabilised regimen of psychotropic medications. Monson 2012 and Sautter 2015 reported outcomes for both primary patients with PTSD and their intimate partners; Glynn 1999 and Ahmady 2009 only reported outcomes in relation to the primary patient.

The mean age for primary patients with PTSD was 38.9 years (SD = 7.2) and mean age for partners was 35.6 years (SD = 7.5); Glynn 1999 did not report the age of the family members. Only Sautter 2015 and Monson 2012 reported the gender of participants; the primary patients with PTSD were predominantly male (68.1%) and partners were predominantly female (69.1%). Family members in Glynn 1999 were predominantly female partners, with two siblings and two parents. Sautter 2015 included opposite-sex partners but only those who had been either married for at least three years or in an intimate partnership for six or more consecutive months. Monson 2012 included both same and opposite sex partners and no minimum time requirement for the length of the relationship. Ahmady 2009's couples had been married for a minimum of 3 years at the beginning of the trial.

Interventions

Description of each manualised intervention

Both Glynn 1999 and Ahmady 2009 followed the Behavioural Family Therapy (BFT) protocol detailed in Mueser & Glynn 1999, which consisted of 16 to 18 sessions across five phases: (1) orientation and general evaluation of the primary patient and spouse (three sessions); (2) education about PTSD and complications related to the course of the disorder (two sessions); (3) communication training on how to express feelings and ideas (three sessions); (4) anger control (two sessions); and (5) problem solving abilities, strategies, techniques to manage and confront new problems (6 to 8 sessions).

Monson 2012 described a Cognitive Behavioural Conjoint Therapy (CBCT) protocol which comprised 15 sessions organised in three phases: (1) establishing a rationale for therapy and safety within the relationship, involving psychoeducation about facilitating a shared sense of safety through recognition of early signs of conflict and conflict management strategies (twice-weekly sessions); (2) enhanced dyadic communication skills training to identify and share feelings and thought patterns (twice-weekly sessions); (3) developing propensities to approach rather than avoid thoughts that may contribute to PTSD symptoms (weekly sessions).

Sautter 2015 described a Structured Approach Therapy (SAT) protocol comprising 12 sessions organised in three phases: (1) psychoeducation and strategies for facilitating a shared sense of safe-



ty through recognising early signs of conflict and conflict management strategies (twice-weekly sessions); (2) enhanced dyadic communication skills to identify and share feelings and symptomatic thought patterns (twice-weekly sessions); (3) development of propensities to approach rather than avoid thoughts that may contribute to PTSD symptoms (weekly sessions).

In three studies, clinicians who delivered the intervention were therapists with postgraduate-level clinical training or post-graduate students under the supervision of trained clinicians (Glynn 1999; Monson 2012; Sautter 2015). Ahmady 2009 did not report details on the delivery of the intervention.

Comparison groups

Description of a comparison group was available for three studies.

Glynn 1999's individual therapy control included a 9-week directed therapeutic exposure (DTE), whereby BFT was delivered as an adjunct therapy following the DTE trial (i.e. the two therapies were not run simultaneously). The DTE included twice-weekly 90-minute sessions over a 9-week period (18 sessions in total) that proceeded from building therapeutic alliance and identifying the two most anxiety-provoking events for purposes of the subsequent re-exposure and cognitive restructuring stage. The latter involved a review of the traumatizing events in detail to permit extinction of arousal associated with memories and relevant cues. After the patient had completed at least six trials of exposure on each of the two traumatising events, the therapist allocated 15 minutes of each session to cognitive restructuring of memories, correcting distortions and normalizing trauma affects and behaviour. Glynn 1999 also included a wait-list condition which was not considered in this review (see Data collection and analysis).

Monson 2012 used a 3-month waiting list control condition. Sautter 2015 employed an active comparator which comprised PTSD Family Education (PFE). The latter comprised 12 weekly sessions which were equal to the target intervention (SAT) in terms of number and duration. The aim was to educate the veteran and their partner about PTSD through lectures, discussions and written materials. Clinicians providing PFE were instructed to avoid delivering skills training and other therapeutic interventions.

Outcomes

Three studies reported data on PTSD severity and dyadic adjustment (or relationship satisfaction) as reported by the primary patient with PTSD (Glynn 1999; Monson 2012; Sautter 2015). Two studies also reported data on dyadic adjustment/relationship satisfaction and psychological symptoms (depression, anxiety) as reported by the partner, as well as the primary patient with PTSD (Monson 2012; Sautter 2015). Ahmady 2009 reported data on dyadic adjustment and not on other outcomes.

Adverse events reported in two studies were instances of intimate partner violence and treatment dropouts (Monson 2012; Sautter 2015). Glynn 1999 also reported dropout rates. On all psychosocial outcome measures described in this section, higher scores indicate greater symptom severity.

Primary outcome 1: severity of PTSD symptoms

Three studies — Glynn 1999, Monson 2012 and Sautter 2015 — operationalised overall PTSD symptom severity using the CAPS (Blake 1995; Weathers 2001), although Glynn 1999 reported findings relat-

ing to the baseline assessment only. Ahmady 2009 used the PCL to measure PTSD severity (Weathers 1993), but also reported comparisons conducted at baseline only.

Primary outcome 2: dyadic adjustment/relationship satisfaction as reported by primary patient and partner

All four studies reported data relating to dyadic adjustment/relationship satisfaction. Ahmady 2009 used the ENRICH marital satisfaction scale (EMS; Fowers 1993) which consists of 15 questions about different aspects of marital adjustment. Ahmady 2009 did not report details on the method of scoring of these items and they did not report the means and standard deviations for scores (rather, they reported mean differences for intervention and control groups at post-treatment).

Monson 2012 and Sautter 2015 used the Dyadic Adjustment Scale (DAS; Spanier 1976) to assess relationship adjustment, as reported by both the primary patient with PTSD and their partners. Glynn 1999 also used the DAS which was reported by the primary patient and at baseline only. The DAS is a 32-item self-report measure with scores ranging from 0 to 151, with higher values indicating higher relationship satisfaction. When DAS scores were reported by both the primary patient and their partner (Monson 2012; Sautter 2015), we used the arithmetic mean of scores (and pooled variance) for purposes of analyses.

Secondary outcome 1: family member severity of depression

Two studies reported findings relating to the severity of depression for partners (Monson 2012; Sautter 2015). Sautter 2015 used partner reports on the Center for Epidemiologic Studies Depression Scale (CES-D; Radloff 1977), which is a 20-item self-report measure designed to assess depressive symptoms in non-clinical settings. Monson 2012 used partner reports on the Beck Depression Inventory (BDI; Beck 1988).

Secondary outcome 2: family member severity of anxiety

Sautter 2015 reported state anxiety symptoms for partners which were measured using the state subscale of the Spielberger State—Trait Anxiety Inventory (Spielberger 1988). This subscale (STAI-State) consists of 20-items which are self-reported. Monson 2012 also used the Spielberger 1988 measure to assess partner anxiety, but determined trait (rather than state) anxiety using the 20-item STAI-Trait subscale.

Secondary outcome 3: severity of co-occurring depression or anxiety of the person with PTSD

Sautter 2015 measured depression severity for the primary patient with PTSD using the Center for Epidemiologic Scale for Depression (CES-D; Radloff 1977), while anxiety symptoms were measured using the STAI-State (Spielberger 1988). Monson 2012 used STAI-Trait (Spielberger 1988) to measure trait anxiety and the BDI (Beck 1988) to measure depression severity for the primary patient with PTSD.

Secondary outcome 4: overall family functioning

No studies measured overall family functioning or specific characteristics of family interaction (e.g. communication).

Secondary outcome 5: treatment dropout

We used treatment dropout rates as a proxy measure of treatment acceptability; they were defined as the proportion of participants in treatment and control conditions that provided data on the



most immediate post-treatment assessment. Glynn 1999, Monson 2012 and Sautter 2015 reported data which informed calculation of treatment dropout rates, while Ahmady 2009 did not.

Secondary outcome 6: instances of severe aggression

Instances of severe aggression were considered as a type of adverse event. In Monson 2012, endorsement of any severe physically or sexually aggressive behaviour as defined by the Conflict Tactics Scale–Revised (CTS2; Straus 1996) in the past year excluded couples from the study. Sautter 2015's exclusion criteria for both partners included physical aggression with injury to a partner during domestic violence as also measured on the Physical Assault subscale of the CTS2. Both studies reported one incident of intimate partner violence that occurred during the trials.

Excluded studies

We excluded ten studies following review of the full-text, as they did not satisfy the inclusion criteria with the following primary reasons: Three studies (Cahoon 1984; Knox 2016; Landy 2015) did not allocate participants randomly into two or more groups. Four studies (Holditch-Davis 2014; Jones 2004; Jones 2012; Kersting 2013) did not include couple's or family therapy and the remaining studies did not measure PTSD for adult participants: King 2000 included measure of PTSD for maltreated children and two studies (Heinrichs 2012; Zimmermann 2016) involved couple's in the context of cancer treatment without a PTSD measure. More detail of the excluded studies is available in the Characteristics of excluded studies table.

Ongoing studies

There is one ongoing study detailed below.

Cognitive behavioural conjoint therapy (CBCT) Project

This randomised controlled trial commenced in 2016 with an estimated completion date in 2020 (NCT02720016). The study aims to enrol 180 couples (360 participants) in which one partner is a PTSD-positive veteran. The aim of the trial is to compare home-based CBCT to two active comparators: office-based CBCT and PTSD family education (PFE).

Primary outcome measures

- 1. PTSD symptoms as measured by CAPS at post-treatment and 3-month and 6-month follow-up.
- 2. Relationship satisfaction as measured by Couples Satisfaction Index (CDI) at mid- and post-treatment, 3-month and 6-month follow-up.
- Functional impairment as measured by Inventory of Psychosocial Functioning (IPF) at post-treatment and 3-month and 6month follow-up.
- 4. Client Satisfaction Questionnaire (CSQ) at post-treatment.

Secondary outcome measures

- 1. PTSD Checklist-5 (PCL-5) at mid- and post-treatment, 3-month and 6-month follow-up.
- 2. Beck Depression Inventory-II (BDI-2) at mid- and post-treatment, 3-month and 6-month follow-up.
- 3. State-Trait Anger Inventory (STAXI) at mid- and post-treatment, 3-month and 6-month follow-up.

4. Conflict Tactics Scale Short Form (CTS-2S) at mid- and post-treatment, 3-month and 6-month follow-up.

Studies awaiting classification

There are three studies awaiting classification.

1. Effects of mindfulness-based cognitive-behavioral conjoint therapy on post-traumatic stress disorder and relationship function

We identified this randomised controlled trial, commenced in 2010, in the initial search as an ongoing study and the outcomes were first published in ClinicalTrials.gov (NCT01035788). The goal of this study was to examine the effects of a mindfulness-based adaptation of CBCT for PTSD (MB-PTSD). Forty-six OEF-OIF Veterans and their intimate partners (n = 92) were randomized to MB-CBCT for PTSD and a control condition that teaches communication skills drawn from the first seven sessions of the Couples Behavioural CT manual. Formal publication of the study is pending at the time of submission of this review. We contacted the authors for information about the study methodology and conduct and expect to include the results in the updated version of this review.

Primary outcome measures

1. Clinician-Administered PTSD Scale (CAPS)

Secondary outcomes measures

- 1. PTSD Checklist (PCL) self-report, veteran only
- 2. Dyadic Adjustment Scale (DAS) self-report, veteran and partner
- 3. Beck Depression Inventory II (BDI) self-report, veteran and partner
- 4. State-Trait Anxiety Inventory State Subscale (STAI-S) self-report, veteran and partner

2. UCLA Welcome Back Veterans Family Resilience Center Couples Counseling for Combat Veterans

This trial protocol (NCT01627548) for a pilot study was identified in the initial search, and while it reports PTSD as an inclusion criteria, the protocol uses couple's communication as the only study outcome (rather than PTSD or other mental health measures). The trial was registered on ClinicalTrials.gov in June 2012 and the protocol contains a very limited amount of information about the intended methodology with no results published on the website or elsewhere. We contacted the authors for more information but could not access any unpublished information.

3. Individual PE vs couples' CBT for combat-related post-traumatic stress disorder

This clinical trial commenced in 2011 with data collection reportedly finalised in August 2016 (NCT02336971). The study has 64 couples enrolled in which one of the members is a combat-veteran with PTSD. Each couple has been randomised into one of two cognitive-behavioural therapies developed specifically as a treatment for PTSD - either prolonged exposure (PE) or cognitive-behavioural couples therapy (CBCT). We contacted the authors for more information and they confirmed that the study is completed and is currently in manuscript writing phase. The main outcome measures are as follows.

Primary outcome measures

1. PTSD symptoms, as measured by the CAPS and PCL at post-treatment (approximately 12 weeks).



Secondary outcome measures

- 1. PTSD symptoms, as measured by the CAPS and PCL at 3-month, 6-month and 12-month follow-up.
- 2. Relationship outcomes, as measured by the Couples Satisfaction Index at post-treatment (approximately 12 weeks), and 3-month, 6-month and 12-month follow-up.

Risk of bias in included studies

For details of the risk of bias judgements for each study, see Characteristics of included studies. A graphical representation of the overall risk of bias in included studies is presented in Figure 2 and Figure 3.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

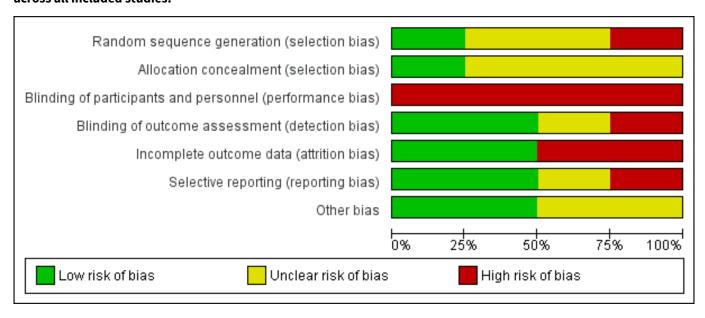
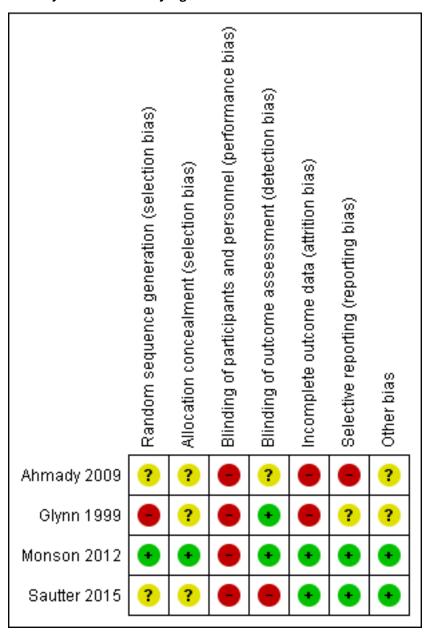




Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Allocation

Only Monson 2012 reported that the randomisation sequence was adequately concealed and both Glynn 1999 and Monson 2012 reported the randomisation method used in their studies; thus we classified Monson 2012 at low risk and Glynn 1999 at high risk of selection bias. Selection bias was unclear for Sautter 2015 and Ahmady 2009.

Blinding

None of the studies reported blinding of therapists and patients (which is generally not feasible in studies of psychosocial interventions), and thus we classified all at high risk of bias. Outcome assessors were blinded in Monson 2012 and Glynn 1999, but blinding was not reported in Sautter 2015 or Ahmady 2009; we therefore classi-

fied them at unclear risk of bias. We considered all self-report measures to produce a high risk of bias.

Incomplete outcome data

Completeness of the outcome data for each main outcome, including attrition and exclusions from the analysis were reported in Glynn 1999, Monson 2012 and Sautter 2015. While all 29 veterans in both groups completed the DTE component of the trial in Glynn 1999, of the 17 family units who were randomised to the adjunctive condition, only 13 (76.5%) participated in the family therapy component. Dropout reasons included changes in work schedules (n = 2) and transportation problems (n = 2). From the 57 couples initially enrolled in Sautter 2015's study, 43 (75.4%) completed post-treatment assessments. Reasons for discontinuing included relocation (n = 2), separation (n = 2), medical problems (n = 1), domestic violence (n = 1) and in relation to eight couples, no reason was provid-



ed. From the 40 couples in Monson 2012's study, 35 (87.5%) completed post-treatment assessments. Reasons for dropping out included psychosis (n=1), domestic violence (n=1) and separation (n=1), with no specific reasons given in relation to two couples which dropped out.

Intention-to-treat (ITT) analyses were also reported in Monson 2012 and Sautter 2015 for all outcomes but no detailed ITT strategy was included in the publications; we classified them at low risk of incomplete outcome data. In the absence of ITT analyses, we classified Glynn 1999 at high risk of attrition bias; and because Ahmady 2009 did not report numbers of participants in relation to the study outcomes, we classified it at unclear risk of attrition bias.

Selective reporting

Protocols were only available for Monson 2012 and Sautter 2015 and all pre-specified outcomes were reported for these studies. As such, selective reporting bias was classified as low for both studies. Glynn 1999 and Ahmady 2009 were not associated with published protocols and were thus classified as unclear risk of bias.

Other potential sources of bias

There were no other obvious bias in the four studies included in the review. Glynn 1999, Monson 2012 and Sautter 2015 provided funding sources and no conflict of interests were declared (or detected) in relation to any of the trials according to the information reported.

Effects of interventions

See: Summary of findings for the main comparison Stand-alone couple or family therapy compared to no treatment for post-traumatic stress disorder (PTSD); Summary of findings 2 Stand-alone couple or family therapy compared to other structured or non-specific intervention for post-traumatic stress disorder (PTSD); Summary of findings 3 Adjunctive couple or family therapy compared to structured or non-specific individual therapy alone for post-traumatic stress disorder (PTSD)

Comparison 1: stand-alone couple or family therapy versus no treatment

Two studies including 100 couples (200 participants) contributed data to this comparison (Ahmady 2009; Monson 2012). See also: Summary of findings for the main comparison.

1.1 Severity of PTSD symptoms

Data on PTSD severity from one study of 40 couples (n = 80 participants) produced an overall effect for CBCT, relative to the waitlist control, which was significantly different from zero (SMD -1.12, 95% CI -1.79 to -0.45; Analysis 1.1) (Monson 2012). The point estimate for the SMD indicated a large effect and potential benefit of CBCT. Given that only one study was available, it was not possible to appraise statistical heterogeneity for the analyses.

1.2 Dyadic adjustment

Data on dyadic adjustment as reported by the primary participant and their partner across two studies involving 100 couples (200 participants) produced an overall effect for CBCT, relative to the waitlist control, that was not significantly different from zero (SMD 1.07, 95% CI -0.17 to 2.31; $I^2 = 88\%$; Analysis 1.2) (Ahmady 2009; Monson 2012). Although the point estimate for the SMD suggested a very large effect and potential benefit of the intervention, the wide con-

fidence interval indicates high levels of imprecision. The largest effect was derived from one study which did not report group means at post treatment, but rather reported the mean difference between pre- and post-intervention for both intervention and control groups, which we thus used for purposes of analysis (Ahmady 2009).

1.3 Family member severity of depression

Data on partners' depressive symptoms from one study of 40 couples (80 participants) produced an overall effect for CBCT, relative to the wait-list control, which was not significantly different from zero (SMD 0.28, 95% CI –0.35 to 0.90; Analysis 1.3) (Monson 2012). The point estimate for the SMD suggested a small effect and potential benefit of wait-list condition although the confidence interval indicates high levels of imprecision. Given that only one study was available, it was not possible to appraise statistical heterogeneity for the analysis.

1.4 Family member severity of anxiety

Data on partners' anxiety symptoms from one study of 40 couples (80 participants) produced an overall effect for CBCT, relative to the wait-list control, which was not significantly different from zero (SMD 0.15, 95% CI –0.47 to 0.77; Analysis 1.4) (Monson 2012). The point estimate for the SMD suggested a small effect and potential benefit of wait-list condition, although the wide confidence interval indicates high levels of imprecision. Given that only one study was available, it was not possible to appraise statistical heterogeneity for the analysis.

1.5 Severity of depression for the person with PTSD

Data on the severity of depression for the primary participant with PTSD from one study of 40 couples (80 participants) produced an overall effect of CBCT, relative to the wait-list control, which was significantly different from zero (SMD –0.66, 95% CI –1.30 to –0.02; Analysis 1.5) (Monson 2012). The point estimate for the SMD indicated a moderate to large effect and potential benefit of CBCT. Given that only one study was available, it was not possible to appraise statistical heterogeneity for the analysis.

1.6 Severity of anxiety for the person with PTSD

Data on the severity of anxiety for the primary participants with PTSD from one study of 40 couples (80 participants) produced an overall effect of CBCT, relative to the wait-list control, that was significantly different from zero (SMD -0.93, 95% CI -1.58 to -0.27; Analysis 1.6) (Monson 2012). The point estimate for the SMD indicated a large effect and potential benefit of CBCT. Given that only one study was available, it was not possible to appraise statistical heterogeneity for the analysis.

1.7 Family functioning

There were no studies of a stand-alone couple or family therapy for PTSD versus no treatment which provided data on this outcome.

1.8 Treatment dropout

Data on treatment dropout from one study of 40 couples (80 participants) showed no significant difference between CBCT and wait-list control conditions (OR 0.41, 95% CI 0.09 to 1.95; Analysis 1.7) (Monson 2012). The point estimate for the OR suggested a small effect and lower rates of dropout for wait-list control condition, although the confidence interval suggested high levels of imprecision.



Comparison 2: stand-alone couple or family therapy versus standard care

There were no eligible studies that compared couple or family therapies for PTSD to standard care or a 'treatment as usual' conditions.

Comparison 3: stand-alone couple or family therapy versus other structured or non-specific intervention

One study with 57 couples (114 participants) contributed data to this comparison (Sautter 2015). See also: Summary of findings for the main comparison. Given that only one study was available, it was not possible to appraise statistical heterogeneity for any of the analyses situated under this comparison.

3.1 Severity of PTSD symptoms

Data on PTSD severity from one study of 57 couples (114 participants) produced an overall effect for SAT, relative to PFE, that was significantly different from zero (SMD –1.32, 95% CI –1.90 to –0.74; Analysis 2.1) (Sautter 2015). The point estimate for the SMD indicated a very large effect and potential benefit of SAT.

3.2 Dyadic adjustment

Data on dyadic adjustment from one study of 57 couples (114 participants) produced an overall effect for SAT, relative to PFE (SMD 0.01, 95% CI –0.51 to 0.53; Analysis 2.2) (Sautter 2015) with the confidence interval indicating high levels of imprecision.

3.3 Family member severity of depression

Data on partners' depression symptoms from one study of 57 couples (114 participants) produced an overall effect for the SAT, relative to PFE, that was not significantly different from zero (SMD 0.21, 95% CI –0.31 to 0.73; Analysis 2.3) (Sautter 2015). The point estimate for the SMD suggested a small effect and potential benefit of PFE, although the confidence interval indicates high levels of imprecision.

3.4 Family member severity of anxiety

Data on partners' anxiety symptoms from one study of 57 couples (114 participants) produced an overall effect for the SAT, relative to PFE, that was not significantly different from zero (SMD –0.16, 95% CI –0.68 to 0.36; Analysis 2.4) (Sautter 2015). The point estimate for the SMD suggested a small effect and potential benefit of PFE, although the confidence interval suggested that zero effect was also plausible.

3.5 Severity of depression for the person with PTSD

Data on the severity of depression for the primary patient with PTSD from one study of 57 couples (114 participants) produced an overall effect of SAT, relative to PFE, that was not significantly different from zero (SMD -0.28, 95% CI -0.81 to 0.24; Analysis 2.5) (Sautter 2015). The point estimate for the SMD indicated a small effect and potential benefit of SAT, although the confidence interval indicates high levels of imprecision.

3.6 Severity of anxiety for the person with PTSD

Data on the severity of anxiety for the primary patient with PTSD from one study of 57 couples (114 participants) produced an overall effect for SAT, relative to PFE, that was not significantly different from zero (SMD -0.34, 95% CI -0.87 to 0.18; Analysis 2.6) (Sautter 2015). The point estimate for the SMD indicated a small effect and

potential benefit of SAT, although the confidence interval indicates high levels of imprecision.

3.7 Family functioning

The one eligible study which was organised under this comparison did not evaluate overall family functioning and no analyses could be conducted for this outcome.

3.8 Treatment dropout

Data on treatment dropout from one study of 57 couples (114 participants) showed no significant difference between SAT and PFE conditions (OR 0.95, 95% CI 0.29 to 3.19; Analysis 2.7) (Sautter 2015). The point estimate for the OR suggested a small effect and lower rates of dropout for wait-list control condition, although the confidence interval indicates high levels of imprecision.

Comparison 4: adjunctive couple or family therapy versus standard care

There were no eligible studies that compared adjunctive couple or family therapies to standard care or 'treatment as usual' conditions.

Comparison 5: adjunctive couple or family therapy versus structured or non-specific individual therapy alone

There was one eligible study of 29 family-dyads (58 participants) under this comparison (Glynn 1999). However, the study did not report any relevant post-treatment data (Means and SDs) for the outcomes and we could not include them in the meta-analyses. The main report on this study describes three outcomes at post-treatment: (1) a social adjustment score (SAS), reported by the primary patient with PTSD; (2) a composite score for PTSD-positive symptoms using scores derived from three different scales (M-PTSD, CAPS, IOE); and (3) a composite score on PTSD-negative symptoms using scores derived from these three scales (M-PTSD, CAPS, IOE). We could not retrieve the actual scale scores for PTSD symptom severity on the basis of the information provided by the authors (published and unpublished data). The study authors concluded that there were no statistically significant differences between the DTE and DTE plus behavioural family therapy (BFT) conditions on positive or negative PTSD symptomatology or social adjustment. Of the outcomes specified in this review, Glynn 1999 provided data on treatment dropout only.

5.1 Treatment dropout

Data on treatment dropout from Glynn 1999 of 29 family units (58 participants) showed a significant difference between DTE and the adjunct treatment (DTE + BFT) conditions (OR 14.13, 95% CI 0.71 to 279.83; Analysis 3.1). The point estimate for the OR suggested a large effect with lower rates of dropout for DTE condition. However, the confidence interval for this comparison was extremely wide suggesting high levels of imprecision.

Subgroup analyses

There was an insufficient number of studies available to conduct subgroup analyses for the current version of the review.

Sensitivity analyses

We were only able to conduct a small selection of the planned sensitivity analyses.



Outcome data from multiple informants were excluded for Monson 2012 and Sautter 2015. We ran sensitivity analyses for Comparisons 1 and 3 for dyadic adjustment excluding the partner data. The Monson 2012 study showed an overall effect for the CBCT group, relative to the wait list condition, that was significantly different from zero (SMD 0.65, 95% CI 0.01 to 1.29). In Sautter 2015, after excluding the partner responses, there were no differences in dyadic adjustment, reported by the persons with PTSD, between the intervention group and the active comparator (SMD 0.16, 95% CI –0.36 to 0.68).

We were not able to address sensitivity analyses as planned for cluster randomised trials (excluding cluster randomised trials or varying the ICC during analyses) as there were none identified in this review. Similarly, we were not able to complete sensitivity analyses excluding cross-over trials as none were identified. Sensitivity analyses excluding imputed values or including 'completers only' were not performed as this data was not available in the studies in this review.

Reporting bias

We detected no reporting bias in relation to the two studies as reported in Selective reporting (reporting bias).

DISCUSSION

Summary of main results

The main aim of this review was to identify and synthesise evidence for the effects of couple and family therapies for PTSD. A comprehensive systematic search identified four RCTs (involving 186 couples/family units and 372 individuals) that were eligible for the review, although there were only two of these studies that provided sufficient data for analyses across a range of outcomes. These data supported analyses under three different comparisons: (1) standalone couple or family therapy versus no treatment; (2) standalone couple or family therapy versus other structured or non-specific intervention; and (3) adjunctive couple or family therapy versus structured or non-specific individual therapy alone. It is important to note that while the studies used different names for the trialled family interventions (CBCT, BFT, SAT), the content and organisation of these interventions were highly similar.

The results from analyses under Comparison 1 and 2 indicated that stand-alone couples' interventions based largely on cognitive-be-havioural principles were associated with some potential improvements in individual PTSD symptoms for the primary presenting patient, as well as their other mental health problems. In contrast, however, there was limited evidence of parallel improvements in reports of dyadic adjustment or the psychological problems of intimate partners. The only analyses possible under Comparison 3 addressed treatment dropout and there was little evidence pertaining to the potential benefits of couple or family therapies when utilised as an adjunct to individual PTSD treatment. We viewed dropout rate as a proxy measure of treatment acceptability in this review, and with 65% of family units completing the post-treatment measures for the family therapy condition, we concluded that the treatment acceptability for the adjunct intervention was moderate to low.

There were no eligible trials and thus evidence which considered other types of couple or family therapies, including those which are based on psychodynamic or systems-based theories or clinical approaches. Although there was substantial variability across studies in terms of risk of bias, there was a downgrade in certainty (we grad-

ed the overall evidence as low or very low-quality) given the small amount of evidence currently available.

Overall completeness and applicability of evidence

The included studies suggested that couple and family therapies produced meaningful improvements in individual symptoms for the primary presenting patient with PTSD, while there was limited evidence of change in dyadic adjustment of psychological problems for intimate partners. These conclusions were based, however, on a comprehensive search which identified only four RCTs, and only two of these provided data across multiple outcomes that were sufficient for analysis. There were therefore very few relevant studies in an absolute sense, and thus limited evidence overall which indicates the presence of absence of benefits for individuals or family members from couple or family therapies for PTSD.

The two main studies which we analysed both considered ostensibly similar disorder-specific and stand-alone therapies (although compared to different control conditions), which were based on cognitive-behavioural principles and addressed similar target populations and contexts; that is, war veterans (mainly) with PTSD and their partners attending veterans' mental health services. Therefore the available findings relate primarily to PTSD symptoms and family problems which are linked (presumably) to military experiences, and there is limited applicability to other forms of trauma, such as exposure to violence or abuse, natural disasters or physical injuries.

The review identified only one trial which considered a behaviourally focused family-based therapy that was adjunctive to individualised treatment, and this study did not report sufficient information to address the primary aims of this review. Thus it remains unclear whether couple- or family-based therapies have beneficial effects on PTSD or related interpersonal problems when integrated with a programme of individual treatment. This is notwithstanding that the inclusion of family members in treatment has been included in the treatment guidelines for PTSD for well over a decade (Foa 2008).

In contrast, there were no randomised trials of other types of couple or family therapies, including those which are based on alternative theoretical models (e.g. psychodynamic theory), and there is little evidence to illustrate the potential effects of these interventions. These include interventions based on family systems theory, such as Strategic Family Therapy (Minuchin 1974), which could foreseeably have stronger effects on dyadic adjustment and the psychological problems of intimate partners. There is also no evidence available from comparative studies to indicate whether different types of couple- or family-based therapies may be more or less helpful in the treatment of PTSD and associated family problems.

Quality of the evidence

Overall, the evidence was of low to very low-quality as measured by the GRADE framework. This primarily reflected a downgrade in certainty given the small number of available studies. That is, there were only four trials that were eligible for this review, and only two reported data across multiple outcomes (including PTSD symptom severity for the primary patient) that were sufficient for analyses. Furthermore, these two trials involved comparisons with different control conditions, and could not be integrated in the same analy-



ses that could formally appraise the statistical heterogeneity of findings.

While one of the eligible studies received classifications of low risk of bias on most metrics (which the exception of blinding of participants and personnel, which is unsurprising for clinical trials of psychosocial interventions) (Monson 2012), the limited amount of evidence necessarily required that certainty was downgraded to low or very low across analyses. The two studies which did not report sufficient data for analyses across most outcomes were also classified as high or unclear risk of bias according to most metrics.

Potential biases in the review process

We searched thoroughly all relevant outlets and strictly adhered to the protocol in the process of study identification, selection, data extraction and entry, and analysis. We only considered published studies, which may perpetuate publication biases. We found registered protocols for two reportedly completed studies that were missing a peer-reviewed outcome publication (NCT01035788; NCT02336971a): this may be indicative of high publication bias, given the small number of studies available overall. We also note that it was a limitation of the review that some potential outcomes were not included in the protocol including suicidality, sexual functioning and sexual satisfaction. While these were not measured in any of the included studies, we may consider a wider range of family-level outcomes in the updates of the review.

Agreements and disagreements with other studies or reviews

To our knowledge, there are no other reviews of couples' and family therapy for PTSD. Other relevant reviews have examined individually focused therapies for PTSD in the context of both adult (Bisson 2013) and child or adolescent populations (Gillies 2016), and interventions focused on the prevention of PTSD (Roberts 2009). These have generally concluded that treatments based on cognitive behavioural principles are efficacious when compared to control conditions, and such findings are consistent with outcomes of the current review which were also based mainly on studies of cognitive-behavioural therapies delivered using a couple-based format. The effect sizes from our review were slightly smaller than those reported for individually oriented psychological therapies for adult PTSD (Bisson 2013), although any such comparisons should be viewed cautiously given the small number of studies, and thus the lack of precision of point estimates in this review.

AUTHORS' CONCLUSIONS

Implications for practice

The available evidence, while modest in quantity and low in quality, points to some potential benefits of disorder-specific treatments for couples which are based on cognitive behavioural principles and aim mainly to improve individual PTSD symptoms. Against our expectations, however, the benefits were not as clear for improving relationship quality or the mental health of family members, which are also negatively impacted by PTSD. These interpersonal problems and consequences of PTSD are arguably where couple or family interventions should have particular benefit, and thus the absence of preliminary support for such effects might raise questions about the unique value of couple interventions, relative to individual treatments that have a stronger evidence base. However, as noted previously, there were few studies in this review which

also examined a homogenous collection of cognitive-behavioural treatments, and these did not consider a range of alternative intervention models (e.g. based on family systems theory; Minuchin 1974) which might have stronger dyadic or interpersonal benefits.

Given the lack of studies comparing couple and family therapies to individually-based or other structured treatments, there is insufficient evidence to indicate whether couple-based approaches offer benefit over other types of intervention. There is also insufficient evidence to determine whether there are any meaningful differences in the effects of different types of couple and family therapies (including generic versus disorder-specific couple or family therapies).

Even though family therapy is included in the treatment guidelines for PTSD, the current review does not yet support a strong evidence-based rationale for including couple or family therapy components in the standard treatment for PTSD, either as adjunctive or stand-alone intervention. While there is preliminary evidence that couple-based approaches could be beneficial for the individual patient, clinicians working with clients who suffer PTSD should adopt cautious approaches to working with couples that is based on clinical judgement, rather than strong empirical evidence. Some of the included studies outlined risk of Intimate Partner Violence (IPV) during treatment and this warrants careful monitoring of the safety and well-being of family members. In addition to the risk of ongoing IPV in families, other reasons to preclude family members from the treatment for PTSD include family members' own mental health problems, such as their own PTSD, or misuse of substances. A thorough assessment process before the inclusion of family/couple therapy for PTSD is recommended, involving clinical interviews with relevant family member(s), with a strong emphasis on patient preferences in treatment planning. Clinicians who deliver trauma-focused therapies should be trained and educated about all potential benefits and limitations of family and couple-based treatments for PTSD.

Implications for research

The review identified potential benefits of couples-based therapies for PTSD, but few relevant studies, and it thus indicates a strong need for additional trials. These should involve samples which are large enough to detect effects which are small to moderate in magnitude, and define the effects of interventions in terms of individual PTSD symptoms, as well as measures of overall family well-being or functioning and other relational outcomes (e.g. family member mental health, relationship satisfaction) that are negatively impacted by PTSD.

Given the potentially unique contribution of couple and family therapies to improving relational outcomes, there is a particular need for trials of couple and family therapies which are adjunctive to individual PTSD treatment. These adjunctive components should be carefully developed using co-design methodologies in order to maximise acceptability, and involve PTSD clients, family members, and service providers and clinicians. Future trials should also involve rigorous and transparent implementation guidelines and fidelity assessment to locate the potential pitfalls of including a family component in the course of treatment for PTSD.

The studies in this review focused mainly on samples affected by military or combat-related trauma, and future trials should examine the effects of couple or family therapies in the context of other



types of trauma. These might include, for example, traumatic stress linked to grief and bereavement, child abuse, and diverse types of violence (victims of crime, torture). It may be that couple and family therapies have variable effects according to different types of trauma exposure, such as those which have a major interpersonal dimension (e.g. interpersonal violence). Again, careful planning and co-design of interventions with trauma-affected individuals should inform the development of therapy components.

While treatments based on cognitive behavioural principles are known to benefit individual and family well-being in a number of settings (e.g. Pavuluri 2004; Wood 2006), the effects of other treatment models for families and partners of PTSD sufferers should be further explored. Comparative trials of different types of couple or family therapies could also help illustrate the relative benefits of these approaches to intervention. For example, while no emotionally focused therapies (EFT) were included in the review, EFT has been suggested as particularly beneficial for the treatment of PTSD in a relational or family context (e.g. Blow 2015) and we hope to in-

clude new trials of EFT-based modalities in subsequent updates to this review.

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CHARACTERISTICS OF STUDIES

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| Methods | Study design: randomised controlled trial |
|---|--|
| Participants Sample size: 120 PTSD (60) and their partners (60) | |
| | Age: PTSD mean 41.2 (SD 4.2) years, partners mean 36.5 (SD 5.4) years |
| | Sex: not reported |
| | Location: Iran, two major veterans' affairs clinics in Tehran: Baqiyatallah and Sadr hospitals |

Intervention: cognitive behavioural couples' therapy (CBCT)

^{*} Indicates the major publication for the study



| Ahmady 2009 (Continued) | Co-morbidities: spina tions were excluded | l cord injuries and other injuries affecting sexual functioning and opium addic- | | | | | |
|---|---|--|--|--|--|--|--|
| Outcomes | Timepoints: only post-treatment | | | | | | |
| | Primary (and only) ou | atcome: ENRICH marital adjustment test | | | | | |
| Notes | Dates: 2007 to 2008 | | | | | | |
| | Significant amount of i | information missing in the publication. | | | | | |
| Risk of bias | | | | | | | |
| Bias | Authors' judgement | Support for judgement | | | | | |
| Random sequence generation (selection bias) | Unclear risk | Not reported | | | | | |
| Allocation concealment (selection bias) | Unclear risk | Not reported | | | | | |
| Blinding of participants and personnel (perfor- mance bias) All outcomes | High risk | Participants seem aware that they were receiving treatment | | | | | |
| Blinding of outcome assessment (detection bias) All outcomes | Unclear risk | Not reported | | | | | |
| Incomplete outcome data (attrition bias) All outcomes | High risk | Primary outcome (PTSD severity) missing | | | | | |
| Selective reporting (reporting bias) | High risk | No protocol available | | | | | |

Glynn 1999

Other bias

| Methods | Study design: randomised controlled trial |
|---------------|--|
| Participants | Sample size: 29 PTSD-diagnosed Vietnam veterans and their family members (58 participants) |
| | Age: PTSD mean 37.11 (SD 11.27) years, family members' age not reported |
| | Sex: PTSD 100% male, family members not reported |
| | Location: Veterans Affairs Medical Center, West Los Angeles |
| Interventions | Intervention 1: direct therapeutic exposure (DTE) |
| | Intervention 2: behavioural family therapy (BFT) as an adjunct therapy |
| | Comorbidities: severe cardiovascular disease, organic brain, psychotic, or severe dissociative disorder, current substance dependence, and physical aggression to self or others within the preceding year excluded |

Crucial information missing in the publication

Unclear risk



| Glynn 1999 (Continued) | Adjunctive medication: 81% of the veterans on psychotropic medication, participants to maintain a stable medication regimen during the trial |
|------------------------|---|
| Outcomes | Timepoints for assessment: baseline, post treatment and 6-month follow-up |
| | Primary outcome: PTSD positive symptoms, PTSD negative symptoms (composite scores using selected CAPS, M-PTSD and IOE subscales) |
| | Secondary outcome: Social Adjustment Scale (SAS) |
| Notes | Funding: VA Health Services and Research Development Merit Review Grant IIR 006 |
| | Declarations of interests: n/a |
| | Dates: n/a, prior to 1997 |
| | Published data does not contain enough information to be included in the meta-analysis |
| | |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | High risk | Randomisation sequential balancing strategy with randomisation odds to permit 50% likelihood for one adjunct therapy group and 25% likelihood for the two other groups (individual therapy group and wait list condition) |
| Allocation concealment (selection bias) | Unclear risk | Not reported |
| Blinding of participants and personnel (perfor- mance bias) All outcomes | High risk | No blinding, participants and personnel were aware of intervention provided |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Assessors were unaware of which group the participants belonged |
| Incomplete outcome data (attrition bias) All outcomes | High risk | Most measures from baseline not reported at follow-up |
| Selective reporting (reporting bias) | Unclear risk | No protocol or trial registration available |
| Other bias | Unclear risk | A great deal of missing information in the publication |

Monson 2012

| Methods | Study design: randomised controlled study | |
|--------------|---|--|
| Participants | Sample size: 40 PTSD-diagnosed people and their partners (80 participants) | |
| | Age: PTSD mean 37.11 (SD 11.27) years, partner mean 37.82 (SD 11.55) years | |
| | Sex: PTSD 25.0% male, partners 67.5% male | |



| Monson 2012 (Continued) | Location: Department of Veterans Affairs outpatient hospital in Boston, USA and a university-based research centre in Toronto, Canada. |
|-------------------------|---|
| Interventions | Intervention: Cognitive behavioural conjoint therapy (CBCT) |
| | Co-morbidities: substance dependence, current bipolar and psychotic disorder excluded |
| | Adjunctive therapy: other concurrent couple or individual therapies excluded |
| | Adjunctive medication: participants asked to maintain a stable psychotropic medication regimen during the trial |
| Outcomes | Timepoints for assessment: baseline, mid-treatment, post-treatment and 3-month follow-up |
| | Primary outcome: CAPS |
| | Secondary outcome: DAS, PCL, BDI and Stai-Trait |
| Notes | Funding: National Institute of Mental Health |
| | Declarations of interest: full COI included |
| | Dates: 2008 to 2012 |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|--|
| Random sequence generation (selection bias) | Low risk | A computer random number generator for random assignment |
| Allocation concealment (selection bias) | Low risk | "Allocation results were concealed with separate privacy envelopes that were opened when a couple was deemed to participate" |
| Blinding of participants and personnel (perfor- mance bias) All outcomes | High risk | No blinding, participants and personnel were aware of intervention provided |
| Blinding of outcome assessment (detection bias) All outcomes | Low risk | Low for primary outcomes (clinician administered) and high for secondary outcomes (self-report) |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | All outcomes reported for the whole sample, intention-to-treat analysis and handling of missing data reported |
| Selective reporting (reporting bias) | Low risk | Protocol available and all pre-specified outcomes reported |
| Other bias | Low risk | n/a |

Sautter 2015

| Methods | Study design: randomised controlled trial |
|--------------|---|
| Participants | Sample size: 57 PTSD-diagnosed veterans and their partners (114 participants) |



| Sautter 2015 (Continued) | | | |
|---|--|--|--|
| , | Age: PTSD mean 33.12 (SD 6.56) years, partners mean 32.21 (SD 7.71) years | | |
| | Sex: PTSD 98.2% male, partners 1.8% male | | |
| | Location: Southeast Louisiana Veterans Affairs Health Care, USA. | | |
| Interventions | Intervention: Structural approach therapy (SAT) | | |
| | Co-morbidities: n/a | | |
| | Adjunctive therapy: other concurrent couple therapies excluded. | | |
| | Adjunctive medication: 57.1% of the veterans on psychotropic medication, participants to maintain a stable medication regimen during the trial. | | |
| Outcomes | Timepoints for assessment: baseline, post-treatment and 12-week follow-up. | | |
| | Primary outcome: CAPS | | |
| | Secondary outcomes: PCL, DA, STAI-State, CES-D | | |

Funding: in part by MERIT Review grant (B6756R) from the VA Rehabilitation and Development pro-

gram and Supplemental Funding Award from the South Central Mental Illness Research Education and

Declarations of interest: none declared

Clinical Center to Professor Sautter.

Dates: 2010 to 2013

Risk of bias

Notes

| Bias | Authors' judgement | Support for judgement |
|---|--------------------|---|
| Random sequence generation (selection bias) | Unclear risk | Not reported |
| Allocation concealment (selection bias) | Unclear risk | Not reported |
| Blinding of participants and personnel (perfor- mance bias) All outcomes | High risk | No blinding, participants and personnel aware of the intervention provided |
| Blinding of outcome assessment (detection bias) All outcomes | High risk | Unclear for clinician-administered CAPS and high for the self-report measures |
| Incomplete outcome data (attrition bias) All outcomes | Low risk | Intention-to-treat analyses and handling of missing data reported |
| Selective reporting (reporting bias) | Low risk | Protocol available and all pre-specified outcome measures reported |
| Other bias | Low risk | n/a |

BDI: Beck Depression Inventory

CAPS: Clinician- Administered PTSD Scale

CBCT: cognitive behavioural conjoint/couple's therapy



CES-D: Center for Epidemiological Studies Depression Scale

DAS: Depression, Anxiety and Stress Scale

IOE: Impact of Events Scale

M-PTSD: Mississippi Scale for Combat-Related Posttraumatic Stress Disorder

PCL: PTSD Checklist

PTSD: post-traumatic stress disorder

SD: standard deviation

Stai-Trait: State-Trait Anxiety Inventory

Characteristics of excluded studies [ordered by study ID]

| Study | Reason for exclusion | |
|---------------------|--|--|
| Cahoon 1984 | Allocation: Non-random, no comparison group | |
| | Participants: Vietnam veterans and their spouses | |
| | Intervention: Couple's group therapy | |
| Heinrichs 2012 | Allocation: Randomised | |
| | Participants: Couples in the context of cancer treatment, no PTSD measurement | |
| | Intervention: Couple-based skills training vs control group | |
| Holditch-Davis 2014 | Allocation: Randomised | |
| | Participants: Mothers of pre-term infants | |
| | Interventions: Auditory–tactile–visual–vestibular (ATVV) intervention and kangaroo care (KC) and control group (no couple's/family therapy) | |
| Jones 2004 | Allocation: Randomised | |
| | Participants: Family members of patients in ICU | |
| | Intervention: 6-week self-help manual containing information about recovery from ICU, psychological information and practical advice for the family member vs control group (no couple's/family therapy) | |
| Jones 2012 | Allocation: Non-random, no comparison group | |
| | Participants: Family members of patients in ICU | |
| | Intervention: Provision of the patient diary on their PTSD-related symptoms to the family member vs control group (no couple's/family therapy) | |
| Kersting 2013 | Allocation: Randomised | |
| | Participants: Parents who have lost their child during pregnancy | |
| | Intervention: Brief internet-based intervention vs control group (no couple's/family therapy) | |
| King 2000 | Allocation: Randomised | |
| | Participants: Sexually abused children with PTSD (no adult participants with PTSD) | |
| | Intervention: Family Cognitive-Behavioral Treatment (FBCT) vs control group | |
| Knox 2016 | Allocation: Non-random, participants were allocated based on a need assessment. | |
| | Participants: Married military members and military spouses who had experienced a traumatic event | |



| Study | Reason for exclusion | |
|-----------------|---|--|
| | Interventions: Emotionally Focused Therapy (EFT), Eye Movement Desensitization and Reprocessing (EMDR) and control group. | |
| Landy 2015 | Allocation: Non-random | |
| | Participants: Parents with PTSD | |
| | Interventions: Cognitive-Behavioral Conjoint Therapy (CBCT), no control group | |
| Zimmermann 2016 | Allocation: Not clear | |
| | Participants: Couples where one person is diagnosed with cancer (no PTSD measure) | |
| | Intervention: Couples-based skills training | |

Characteristics of studies awaiting assessment [ordered by study ID]

NCT01035788

| Methods | Study design: randomised controlled trial |
|---------------|--|
| Participants | Sample size: 92: 46 PTSD-diagnosed veterans and their partners |
| | Age: mean 39.9 (SD 10.3) years |
| | Sex: PTSD 89.1% males, 10.9% females |
| | Location: VA Medical Center, Indianapolis, US |
| Interventions | Intervention 1: mindfulness-based cognitive behavioural conjoint therapy (CBCT) for PTSD |
| | Intervention 2: active comparator, CBCT-PTSD communication component |
| | Co-morbidities: IPV, current suicidal/homicidal intent or self-injury, cognitive impairment, current substance dependence, PTSD diagnosis in the partner, uncontrolled psychotic of bipolar disorder excluded |
| Outcomes | Timepoints for assessment: baseline, post-treatment (10 weeks after session 1) |
| | Primary outcome: CAPS |
| | Secondary outcome: DAS, PCL, BDI and Stai-Trait |
| Notes | Trial completed in 2015, main outcomes now available (most recent update November 2018) on ClinicalTrials.gov, and authors communicate that a primary paper will be submitted in 2019. It is likely this study will be included in the updated review. |

NCT01627548

| Methods | Study design: randomised controlled trial |
|--------------|--|
| Participants | Sample size: 24 (unclear whether this is the number of couples or individuals) |
| | Age: 18 years and above |
| | Sex: All sexes were eligible |



| NCT01627548 (Continued) | Location: UCLA Welcome Back Veterans Center |
|-------------------------|--|
| Interventions | Intervention: Structured Approach Therapy (SAT), 12 weekly 50 minute sessions |
| | Control: Wait-list (delayed intervention) for 4 months |
| | Co-morbidities: IPV, substance dependence, past 3 month psychotic symptoms excluded |
| Outcomes | Timepoints for assessment: baseline, post-treatment (4-6 months) |
| | Primary outcome: Improved couples communication as measured by standardised assessments |
| | Secondary outcome: n/a |
| Notes | Trial registered in 2012, data collection due to finish 2013 with no updates after 2013 and no publication |

NCT02336971

| Methods | Study design: randomised controlled trial |
|---------------|--|
| Participants | 64 couples (128 individuals) |
| Interventions | Intervention 1: individual PE |
| | Intervention 2: couple's CBT |
| | Co-morbidities: Recent suicidal ideation alcohol dependence, cognitive impairment, PTSD diagnosis in the partner, uncontrolled psychotic of bipolar disorder excluded |
| Outcomes | Primary outcome: CAPS, PCL at 12 weeks |
| | Secondary outcome: CAPS, PCL at 3, 6, 12 months and Couple's Satisfaction Index at 12 weeks, 3, 6, and 12 months. |
| Notes | Trial completed in 2016, pending publication |

BDI: Beck Depression Inventory

CBCT: cognitive behavioural conjoint therapy CAPS: Clinician- Administered PTSD Scale DAS: Depression, Anxiety and Stress Scale

IPV: intimate partner violence

PCL: PTSD Checklist

PTSD: post-traumatic stress disorder

SD: standard deviation

Stai-Trait: State-Trait Anxiety Inventory

Characteristics of ongoing studies [ordered by study ID]

NCT02720016

| Trial name or title | Cognitive-Behavioral Conjoint Therapy (CBCT) Project |
|---------------------|--|
| Methods | Study design: randomised controlled trial |
| Participants | 360 participants (estimated enrolment) |



| NCT02720016 (Continued) | |
|-------------------------|---|
| Interventions | Intervention 1: CBCT-home based (CBCT-HB) |
| | Intervention 2: CBCT-office based (CBCT-OB) (active comparator) |
| | Intervention 3: PTSD family education (PFE) (active comparator) |
| Outcomes | Primary outcomes: CAPS, Couples Satisfaction Index (CSI), Inventory of Psychosocial Functioning (IPF); Client Satisfaction Questionnaire (CSQ), Working Alliance Inventory- short form (WAI-S) |
| | Secondary outcomes: PCL, BDI, State-Trait Anger Expression Inventory (STAXI), Conflict Tactics Scale Short Form (CTS-2S) |
| Starting date | October 2016 |
| Contact information | Daniel Barlam, Leslie Morland |
| Notes | Estimated study completion date: 2020 |

BDI: Beck Depression Inventory

CAPS: Clinician- Administered PTSD Scale CBCT: cognitive behavioural conjoint therapy DAS: Depression, Anxiety and Stress Scale

PCL: PTSD Checklist

PTSD: post-traumatic stress disorder Stai-Trait: State-Trait Anxiety Inventory

DATA AND ANALYSES

Comparison 1. Stand-alone couple or family therapy versus no treatment

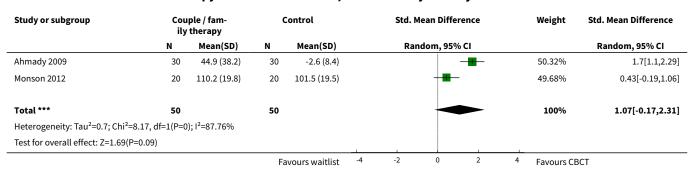
| Outcome or subgroup title | No. of studies | No. of partici- pants | Statistical method | Effect size |
|---|-------------------|-----------------------------|---|----------------------|
| 1 Severity of PTSD symptoms | 1 | 40 | Std. Mean Difference (IV, Random, 95% CI) | -1.12 [-1.79, -0.45] |
| 2 Dyadic adjustment | 2 | 100 | Std. Mean Difference (IV, Random, 95% CI) | 1.07 [-0.17, 2.31] |
| 3 Family member severity of depression | 1 | 40 | Std. Mean Difference (IV, Fixed, 95% CI) | 0.28 [-0.35, 0.90] |
| 4 Family member severity of anxiety | 1 | 40 | Std. Mean Difference (IV, Fixed, 95% CI) | 0.15 [-0.47, 0.77] |
| 5 Severity of depression | 1 | 40 | Std. Mean Difference (IV, Random, 95% CI) | -0.66 [-1.30, -0.02] |
| 6 Severity of anxiety | 1 | 40 | Std. Mean Difference (IV, Random, 95% CI) | -0.93 [-1.58, -0.27] |
| 7 Treatment dropout (treatment acceptability) | 1 | 40 | Odds Ratio (M-H, Random, 95% CI) | 0.41 [0.09, 1.95] |



Analysis 1.1. Comparison 1 Stand-alone couple or family therapy versus no treatment, Outcome 1 Severity of PTSD symptoms.

| Study or subgroup | Couple / fam- ily therapy | | Control | | | Std. Mean Difference | | | | Weight | Std. Mean Difference |
|--------------------------------------|------------------------------|-------------|---------|--------------|----|----------------------|-------------|---|---|------------|----------------------|
| | N | Mean(SD) | N | Mean(SD) | | Ran | dom, 95% CI | | | | Random, 95% CI |
| Monson 2012 | 20 | 33.5 (24.4) | 20 | 60.8 (23.4) | | - | | | | 100% | -1.12[-1.79,-0.45] |
| Total *** | 20 | | 20 | | | • | - | | | 100% | -1.12[-1.79,-0.45] |
| Heterogeneity: Not applicable | | | | | | | | | | | |
| Test for overall effect: Z=3.27(P=0) | | | | | | | | | | | |
| | | | ı | Favours CBCT | -4 | -2 | 0 | 2 | 4 | Favours wa | aiting list |

Analysis 1.2. Comparison 1 Stand-alone couple or family therapy versus no treatment, Outcome 2 Dyadic adjustment.



Analysis 1.3. Comparison 1 Stand-alone couple or family therapy versus no treatment, Outcome 3 Family member severity of depression.

| Study or subgroup | Couple / fam- ily therapy | | Control | | | Std. Mean Difference | | | Weight | Std. Mean Difference |
|---|------------------------------|-----------|---------|--------------|----|----------------------|-------------|---|---------------|----------------------|
| | N | Mean(SD) | N | Mean(SD) | | Fix | red, 95% CI | | | Fixed, 95% CI |
| Monson 2012 | 20 | 9.5 (8.7) | 20 | 7.2 (8) | | | | | 100% | 0.28[-0.35,0.9] |
| Total *** | 20 | | 20 | | | | • | | 100% | 0.28[-0.35,0.9] |
| Heterogeneity: Not applicable | | | | | | | | | | |
| Test for overall effect: Z=0.87(P=0.39) | | | | | | 1 | | | | |
| | | | | Favours CBCT | -4 | -2 | 0 2 | 4 | Favours waitl | ist |



Analysis 1.4. Comparison 1 Stand-alone couple or family therapy versus no treatment, Outcome 4 Family member severity of anxiety.

| Study or subgroup | Couple / fam- ily therapy | | Control | | | Std. Mean Difference | | | | Weight ! | Std. Mean Difference |
|---|------------------------------|-------------|---------|-------------|----|----------------------|------------|---|---|----------------|----------------------|
| | N | Mean(SD) | N | Mean(SD) | | Fi | xed, 95% C | I | | | Fixed, 95% CI |
| Monson 2012 | 20 | 37.8 (11.5) | 20 | 36.1 (10.8) | | | | | | 100% | 0.15[-0.47,0.77] |
| Total *** | 20 | | 20 | | | | • | | | 100% | 0.15[-0.47,0.77] |
| Heterogeneity: Not applicable | | | | | | | | | | | |
| Test for overall effect: Z=0.47(P=0.64) | | | | | | | | | | | |
| | | | | avours CBCT | -4 | -2 | 0 | 2 | 4 | Favours waitli | st |

Analysis 1.5. Comparison 1 Stand-alone couple or family therapy versus no treatment, Outcome 5 Severity of depression.

| Study or subgroup | Couple / fam- ily therapy | | Control | | | Std. M | ean Difference | | Weight | Std. Mean Difference |
|---|------------------------------|-------------|---------|--------------|----|--------|----------------|---|----------------|----------------------|
| | N | Mean(SD) | N | Mean(SD) | | Ran | dom, 95% CI | | | Random, 95% CI |
| Monson 2012 | 20 | 12.2 (12.4) | 20 | 20.3 (11.8) | | - | | | 100% | -0.66[-1.3,-0.02] |
| Total *** | 20 | | 20 | | | 4 | • | | 100% | -0.66[-1.3,-0.02] |
| Heterogeneity: Not applicable | | | | | | | | | | |
| Test for overall effect: Z=2.03(P=0.04) | | | | | | | | | | |
| | | | | Favours CBCT | -4 | -2 | 0 2 | 4 | Favours waitli | st |

Analysis 1.6. Comparison 1 Stand-alone couple or family therapy versus no treatment, Outcome 6 Severity of anxiety.

| Study or subgroup | | Couple / fam- ily therapy | | Control | | Std. M | ean Differenc | e | Weight | Std. Mean Difference |
|--|------------------|------------------------------|----|--------------|----|----------|---------------|-----|-----------|----------------------|
| | N | Mean(SD) | N | Mean(SD) | | Ran | dom, 95% CI | | | Random, 95% CI |
| Monson 2012 | 20 | 38.7 (14.3) | 20 | 51.7 (13.4) | | - | | | 100% | -0.93[-1.58,-0.27] |
| Total *** | 20 | | 20 | | | ◄ | > | | 100% | -0.93[-1.58,-0.27] |
| Heterogeneity: Tau ² =0; Chi ² = | 0, df=0(P<0.0001 | .); I ² =100% | | | | | | | | |
| Test for overall effect: Z=2.77 | (P=0.01) | | | | | | | | | |
| | | | | Favours CBCT | -4 | -2 | 0 2 | 2 4 | Favours w | aitlist |

Analysis 1.7. Comparison 1 Stand-alone couple or family therapy versus no treatment, Outcome 7 Treatment dropout (treatment acceptability).

| Study or subgroup | Couple / fam- ily therapy | Control | | Odds Ratio | | | Weight | Odds Ratio |
|-------------------|------------------------------|--------------|----------|--------------|-------|----|----------------------|---------------------|
| | n/N | n/N | М-Н | , Random, 95 | 5% CI | | | M-H, Random, 95% CI |
| Monson 2012 | 14/20 | 17/20 | | - | | | 100% | 0.41[0.09,1.95] |
| Total (95% CI) | 20 | 20 | | | | | 100% | 0.41[0.09,1.95] |
| | | Favours CBCT | 0.02 0.1 | 1 | 10 | 50 | Favours waiting list | |



| Study or subgroup | Couple / fam- ily therapy | Control | | | Odds Ratio | | | Weight | Odds Ratio |
|---------------------------------|------------------------------|--------------|------|------|------------|-------|----|----------------------|---------------------|
| | n/N | n/N | _ | М-Н, | Random, 9 | 5% CI | | | M-H, Random, 95% CI |
| Total events: 14 (Couple / fai | mily therapy), 17 (Control) | | | | | | | | |
| Heterogeneity: Not applicab | le | | | | | | | | |
| Test for overall effect: Z=1.12 | 2(P=0.26) | | | | | | | | |
| | | Favours CBCT | 0.02 | 0.1 | 1 | 10 | 50 | Favours waiting list | |

Comparison 2. Stand-alone couple or family therapy versus other structured or non-specific intervention

| No. of studies | No. of partici- pants | Statistical method | Effect size |
|-------------------|-----------------------------|---|---|
| 1 | 57 | Std. Mean Difference (IV, Random, 95% CI) | -1.32 [-1.90, -0.74] |
| 1 | 57 | Std. Mean Difference (IV, Random, 95% CI) | 0.01 [-0.51, 0.53] |
| 1 | 57 | Std. Mean Difference (IV, Fixed, 95% CI) | 0.21 [-0.31, 0.73] |
| 1 | 57 | Std. Mean Difference (IV, Fixed, 95% CI) | -0.16 [-0.68, 0.36] |
| 1 | 57 | Std. Mean Difference (IV, Random, 95% CI) | -0.28 [-0.81, 0.24] |
| 1 | 57 | Std. Mean Difference (IV, Random, 95% CI) | -0.34 [-0.87, 0.18] |
| 1 | 57 | Odds Ratio (M-H, Random, 95% CI) | 0.95 [0.29, 3.19] |
| | 1 1 1 1 1 1 | studies participants 1 57 1 57 1 57 1 57 1 57 1 57 1 57 | studiesparticipants157Std. Mean Difference (IV, Random, 95% CI)157Std. Mean Difference (IV, Random, 95% CI)157Std. Mean Difference (IV, Fixed, 95% CI)157Std. Mean Difference (IV, Fixed, 95% CI)157Std. Mean Difference (IV, Random, 95% CI)157Std. Mean Difference (IV, Random, 95% CI) |

Analysis 2.1. Comparison 2 Stand-alone couple or family therapy versus other structured or non-specific intervention, Outcome 1 Severity of PTSD symptoms.

| Study or subgroup | Couple / fam- ily therapy | | Control | | | Std. Mea | an Difference | Weight | Std. Mean Difference |
|---|------------------------------|-------------|---------|-------------|----|----------|---------------|--------------|----------------------|
| | N | Mean(SD) | N | Mean(SD) | | Rando | om, 95% CI | | Random, 95% CI |
| Sautter 2015 | 29 | 44.6 (20.4) | 28 | 71.9 (20.4) | | - | | 100% | -1.32[-1.9,-0.74] |
| Total *** | 29 | | 28 | | | • | | 100% | -1.32[-1.9,-0.74] |
| Heterogeneity: Not applicable | | | | | | | | | |
| Test for overall effect: Z=4.49(P<0.000 | 1) | | | | | | | | |
| | | | | Favours SAT | -4 | -2 | 0 2 | 4 Favours PF | E |



Analysis 2.2. Comparison 2 Stand-alone couple or family therapy versus other structured or non-specific intervention, Outcome 2 Dyadic adjustment.

| Study or subgroup | r subgroup Couple / fam- ily therapy | | Control | | | Std. M | lean Differe | nce | | Weight | Std. Mean Difference |
|---|---|--------------|---------|--------------|----|--------|--------------|-----|---|-------------|----------------------|
| | N | Mean(SD) | N | Mean(SD) | | Ran | ndom, 95% C | :1 | | | Random, 95% CI |
| Sautter 2015 | 29 | 105.5 (20.7) | 28 | 105.3 (20.6) | | | | | | 100% | 0.01[-0.51,0.53] |
| Total *** | 29 | | 28 | | | | • | | | 100% | 0.01[-0.51,0.53] |
| Heterogeneity: Not applicable | | | | | | | | | | | |
| Test for overall effect: Z=0.03(P=0.97) | | | | | 1 | 1 | | | | | |
| | | | | Favours SAT | -4 | -2 | 0 | 2 | 4 | Favours PFE | |

Analysis 2.3. Comparison 2 Stand-alone couple or family therapy versus other structured or non-specific intervention, Outcome 3 Family member severity of depression.

| Study or subgroup | Couple / fam- ily therapy | | Control | | | Std. M | lean Differenc | e | | Weight | Std. Mean Difference |
|---|------------------------------|-------------|---------|-------------|----|--------|----------------|---|---|-------------|----------------------|
| | N | Mean(SD) | N | Mean(SD) | | Fi | xed, 95% CI | | | | Fixed, 95% CI |
| Sautter 2015 | 29 | 18.6 (14.6) | 28 | 15.5 (14.4) | | | | | | 100% | 0.21[-0.31,0.73] |
| Total *** | 29 | | 28 | | | | • | | | 100% | 0.21[-0.31,0.73] |
| Heterogeneity: Not applicable | | | | | | | | | | | |
| Test for overall effect: Z=0.78(P=0.44) | | | | | | | | | | | |
| | | | | Favours SAT | -4 | -2 | 0 2 | 2 | 4 | Favours PFE | |

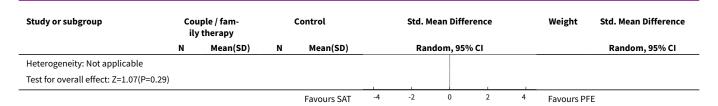
Analysis 2.4. Comparison 2 Stand-alone couple or family therapy versus other structured or non-specific intervention, Outcome 4 Family member severity of anxiety.

| Study or subgroup | Couple / fam- ily therapy | | Control | | | Std. M | lean Diffe | rence | | Weight | Std. Mean Difference |
|---|------------------------------|-------------|---------|-------------|----|--------|------------|-------|---|-------------|----------------------|
| | N | Mean(SD) | N | Mean(SD) | | Fi | xed, 95% | CI | | | Fixed, 95% CI |
| Sautter 2015 | 29 | 33.9 (14.7) | 28 | 36.3 (14.8) | | | | | | 100% | -0.16[-0.68,0.36] |
| Total *** | 29 | | 28 | | | | • | | | 100% | -0.16[-0.68,0.36] |
| Heterogeneity: Not applicable | | | | | | | | | | | |
| Test for overall effect: Z=0.61(P=0.54) | | | | | | | | | | | |
| | | | | Favours SAT | -4 | -2 | 0 | 2 | 4 | Favours PFE | |

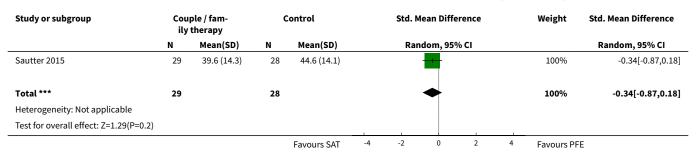
Analysis 2.5. Comparison 2 Stand-alone couple or family therapy versus other structured or non-specific intervention, Outcome 5 Severity of depression.

| Study or subgroup | | ple / fam- C therapy | | Control | | Std. N | Mean Diffe | erence | | Weight | Std. Mean Difference |
|-------------------|----|-------------------------|----|-------------|----|--------|------------|--------|---|-------------|----------------------|
| | N | Mean(SD) | N | Mean(SD) | | Rai | ndom, 95° | % CI | | | Random, 95% CI |
| Sautter 2015 | 29 | 24.7 (13.1) | 28 | 28.5 (13.1) | | | | | | 100% | -0.28[-0.81,0.24] |
| Total *** | 29 | | 28 | | | | • | | | 100% | -0.28[-0.81,0.24] |
| | | | | Favours SAT | -4 | -2 | 0 | 2 | 4 | Favours PFE | |

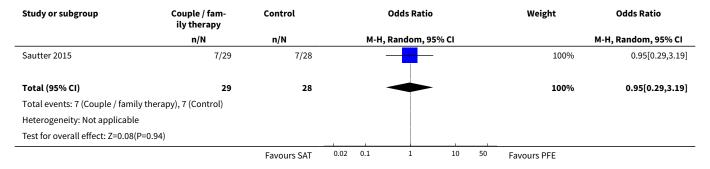




Analysis 2.6. Comparison 2 Stand-alone couple or family therapy versus other structured or non-specific intervention, Outcome 6 Severity of anxiety.



Analysis 2.7. Comparison 2 Stand-alone couple or family therapy versus other structured or non-specific intervention, Outcome 7 Treatment dropout (treatment acceptability).



Comparison 3. Adjunctive couple or family therapy versus structured or non-specific individual therapy alone

| Outcome or subgroup title | No. of studies | No. of par- ticipants | Statistical method | Effect size |
|---|-------------------|--------------------------|-------------------------------------|----------------------|
| 1 Treatment dropout (treatment acceptability) | 1 | 29 | Odds Ratio (M-H, Random, 95% CI) | 14.13 [0.71, 279.83] |



Analysis 3.1. Comparison 3 Adjunctive couple or family therapy versus structured or non-specific individual therapy alone, Outcome 1 Treatment dropout (treatment acceptability).

| Study or subgroup | Couple / fam- ily therapy | Control | | 0 | dds Ratio | | Weight | Odds Ratio |
|---------------------------------------|------------------------------|------------------|-------|--------|--------------|-----|------------------------|---------------------|
| | n/N | n/N | | M-H, R | andom, 95% (| CI | | M-H, Random, 95% CI |
| Glynn 1999 | 6/17 | 0/12 | | | | - | 100% | 14.13[0.71,279.83] |
| Total (95% CI) | 17 | 12 | | | | | 100% | 14.13[0.71,279.83] |
| Total events: 6 (Couple / family the | erapy), 0 (Control) | | | | | | | |
| Heterogeneity: Not applicable | | | | | | | | |
| Test for overall effect: Z=1.74(P=0.0 | 08) | | | | | | | |
| | Favours i | ndividual treatm | 0.005 | 0.1 | 1 10 | 200 | Favours adj family the | rap |

APPENDICES

Appendix 1. Details of the CCMDCTR

Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR)

The Cochrane Common Mental Disorders Group maintains an archived specialised register of RCTs, the CCMDCTR. This register contains over 40,000 reference records (reports of RCTs) for anxiety disorders, depression, bipolar disorder, eating disorders, self-harm and other mental disorders within the scope of this Group. The CCMDCTR is a partially studies-based register with more than 50 percent of reference records tagged to around 12,500 individually PICO-coded study records. Reports of trials for inclusion in the register were collated from (weekly) generic searches of key bibliographic databases to June 2016, which included: Ovid MEDLINE (1950 onwards), Embase (1974 onwards) and PsycINFO (1967 onwards), Cochrane Central Register of Controlled Trials (CENTRAL) and review-specific searches of additional databases. Reports of trials were also sourced from international trial registries, drug companies, the handsearching of key journals, conference proceedings and other (non-Cochrane) systematic reviews and meta-analyses. Details of CCMD's core search strategies (used to identify RCTs) can be found on the Cochrane Common Mental Disorders website, with an example of the core MEDLINE search displayed in Appendix 1.

The CCMDCTR is hosted and maintained on the new Cochrane Register of Studies (CRS) meta-register, which allows for left- and right-hand truncation of search terms. The register fell out of date in June 2016 when the Editorial Group moved from the University of Bristol to the University of York.

The search strategy listed below is the weekly OVID MEDLINE search which was used to inform Cochrane Common Mental Disorders specialised register. It was based on a list of terms for all conditions within the scope of Cochrane Common Mental Disorders plus a sensitive RCT filter.

1. [MeSH Headings]:

eating disorders/ or anorexia nervosa/ or binge-eating disorder/ or bulimia nervosa/ or female athlete triad syndrome/ or pica/ or hyperphagia/ or bulimia/ or self-injurious behavior/ or self mutilation/ or suicide/ or suicidal ideation/ or suicide, attempted/ or mood disorders/ or affective disorders, psychotic/ or bipolar disorder/ or cyclothymic disorder/ or depressive disorder/ or depression, postpartum/ or depressive disorder, major/ or depressive disorder, treatment-resistant/ or dysthymic disorder/ or seasonal affective disorder/ or neurotic disorders/ or depression/ or adjustment disorders/ or exp antidepressive agents/ or anxiety disorders/ or agoraphobia/ or neurocirculatory asthenia/ or obsessive-compulsive disorder/ or obsessive hoarding/ or panic disorder/ or phobic disorders/ or stress disorders, traumatic/ or combat disorders/ or stress disorders, post-traumatic/ or stress disorders, traumatic, acute/ or anxiety/ or anxiety, castration/ or koro/ or anxiety, separation/ or panic/ or exp anti-anxiety agents/ or somatoform disorders/ or body dysmorphic disorders/ or conversion disorder/ or hypochondriasis/ or neurasthenia/ or hysteria/ or munchausen syndrome by proxy/ or munchausen syndrome/ or fatigue syndrome, chronic/ or obsessive behavior/ or compulsive behavior/ or behavior, addictive/ or impulse control disorders/ or firesetting behavior/ or gambling/ or trichotillomania/ or stress, psychological/ or burnout, professional/ or sexual dysfunction, psychological/ or vaginismus/ or Anhedonia/ or Affective Symptoms/ or *Mental Disorders/

2. [Title/ Author Keywords]:

(eating disorder* or anorexia nervosa or bulimi* or binge eat* or (self adj (injur* or mutilat*)) or suicide* or suicidal or parasuicid* or mood disorder* or affective disorder* or bipolar i or bipolar ii or (bipolar and (affective or disorder*)) or mania or manic or cyclothymic* or depression or depressive or dysthymi* or neurotic or neurosis or adjustment disorder* or antidepress* or anxiety disorder* or agoraphobia or obsess* or compulsi* or panic or phobi* or ptsd or posttrauma* or post trauma* or combat or somatoform or somati#ation or medical*



unexplained or body dysmorphi* or conversion disorder or hypochondria* or neurastheni* or hysteria or munchausen or chronic fatigue* or gambling or trichotillomania or vaginismus or anhedoni* or affective symptoms or mental disorder* or mental health).ti,kf.

3. [RCT filter]:

(controlled clinical trial.pt. or randomized controlled trial.pt. or (randomi#ed or randomi#ation).ab,ti. or randomly.ab. or (random* adj3 (administ* or allocat* or assign* or class* or control* or determine* or divide* or distribut* or expose* or fashion or number* or place* or recruit* or subsitut* or treat*)).ab. or placebo*.ab,ti. or drug therapy.fs. or trial.ab,ti. or groups.ab. or (control* adj3 (trial* or study or studies)).ab,ti. or ((singl* or doubl* or tripl* or trebl*) adj3 (blind* or mask* or dummy*)).mp. or clinical trial, phase ii/ or clinical trial, phase iv/ or randomized controlled trial/ or pragmatic clinical trial/ or (quasi adj (experimental or random*)).ti,ab. or ((waitlist* or treatment as usual or TAU) adj3 (control or group)).ab.)

4. (1 and 2 and 3)

Records were screened for reports of RCTs within the scope of the Cochrane Common Mental Disorders Group. Secondary reports of RCTs were tagged to the appropriate study record.

Similar weekly search alerts were also conducted on OVID Embase and PsycINFO, using relevant subject headings (controlled vocabularies) and search syntax, as appropriate to each resource.

A quarterly search of the Cochrane Central Register of Controlled Trials (CENTRAL) was conducted c/o the Cochrane Register of Studies Online (CRSO).

Appendix 2. Other database searches (to March 2018)

In March 2018, records retrieved from a much larger search, for a suite of PTSD reviews, were screened for trials relevant to this review.

The search was based on population or psychological debriefing (only) (+ RCT filter, where appropriate), details below.

Date of search: 3 March 2018 Date limits: 1980 onwards

Database hits:

- 1. CENTRAL (2028)
- 2. MEDLINE (1742)
- 3. Embase (3319)
- 4. PsycINFO (1449)
- 5. PILOTS (879)

Total = 9417 Duplicates removed = 4620 Studies screened for RCTs = 4797 Records excluded = 3632

RCT records identified = 1165

Databases: CENTRAL

Cochrane Central Register of Controlled Trials: Issue 2 of 12, February 2018

Date Searched: March 3rd 2018

#1 MeSH descriptor: [Stress Disorders, Post-Traumatic] this term only (1492)

#2 (PTSD or ((posttrauma* or post-trauma* or post trauma*) near/3 (stress* or disorder* or psych* or symptom*)) or acute stress disorder* or combat disorder* or war neuros*) (5065)

#3 (((acute or traumatic) near/1 stress*) and (expos* or psyc*)) (1525)

#4 (traumatised near/1 (victim* or survivor*)) 2

#5 (traumatized near/1 (victim* or survivor*)) 4

#6 (trauma* near/2 (event* or memor* or flashback* or nightmare*)) 553

#7 ((trauma* or posttrauma* or post-trauma* or victim* or survivor*) and (exposure near/3 (therap* or psychotherap* or training or counsel*))) 417

#8 MeSH descriptor: [Crisis Intervention] this term only 166

#9 (critical incident near/1 (stress or debrief* or de-brief*)) 24

#10 (debriefing or de-briefing) 328

#11 (crisis intervention* or CISD) 1003

#12 ((stress or group* or psychological or crisis) near/3 (debrief* or de-brief*)) 107

#13 (trauma* near/2 (event* or memor* or flashback* or nightmare*)) 553

#14 (EMDR or (eye movement desensitization and reprocessing)) 225



#15 (EMDR or (eye movement desensitisation and reprocessing)) 197

#16 (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15)

#17 MeSH descriptor: [Stress Disorders, Post-Traumatic] this term only

Publication Year from 2014 to 2018 (2893)

File: VO1 CENTRAL n2028.txt

Databases: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present

Date Searched: March 3rd 2018

1 Stress Disorders, Post-Traumatic/ 27503

- 2 (PTSD or ((posttrauma* or post-trauma* or post trauma*) adj3 (stress* or disorder* or psych* or symptom?)) or acute stress disorder* or combat disorder* or war neuros*).ti,ab,kf. 31111
- 3 (((acute or traumatic) adj stress*) and (expos* or psyc*)).ti,ab,kf. 10567
- 4 (traumati#ed adj (victim? or survivor?)).ti,ab,kf. 34
- 5 (trauma* adj2 (event? or memor* or flashback* or nightmare?)).ti,ab,kf. 8174
- 6 ((trauma* or posttrauma* or post-trauma* or victim* or survivor?) and (exposure adj3 (therap* or psychotherap* or training or counsel*))).ti,ab,kf,hw. 901

7 Crisis Intervention/ 5457

- 8 (critical incident adj (stress or debrief* or de-brief*)).ti,ab,kf. 223
- 9 (debriefing or de-briefing).ti,kf. 577
- 10 (crisis intervention? or CISD).ti,ab,kf.1744
- 11 ((stress or group? or psychological or crisis) adj3 (debrief* or de-brief*)).ti,ab,kf. 406
- 12 (trauma* adj2 (event? or memor* or flashback* or nightmare?)).ti,kf. 1150
- 13 (EMDR or (eye movement desensiti#ation and reprocessing)).ti,ab,kf,sh. 510
- 14 (1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13) 52168
- 15 randomized controlled trial.pt. 454849
- 16 controlled clinical trial.pt. 92204
- 17 randomized.ab. 404382
- 18 placebo.ab. 186843
- 19 clinical trials as topic.sh. 182777
- 20 randomly.ab. 285994
- 21 trial.ti. 178689
- 22 (15 or 16 or 17 or 18 or 19 or 20 or 21) 1136215
- 23 (14 and 22) 4000
- 24 (2014* or 2015* or 2016* or 2017* or 2018*).yr,dt,ed,ep. 5444042
- 25 (23 and 24) 1742

Ovid Embase

March 3rd 2018

- 1 posttraumatic stress disorder/ 48854
- 2 "trauma and stressor related disorders"/ $34962\,$
- 3 combat disorders/ 26663
- 4 psychological trauma/5351
- 5 stress disorders, post-traumatic/ 16743
- 6 stress disorders, traumatic, acute/751
- 7 (PTSD or ((posttrauma* or post-trauma* or post trauma*) adj3 (stress* or disorder* or psych* or symptom?)) or acute stress disorder* or combat disorder* or war neuros*).ti,ab,kw. 39945
- 8 (((acute or traumatic) adj stress*) and (expos* or psyc*)).ti,ab,kw. 15122
- 9 (traumati#ed adj (victim? or survivor?)).ti,ab,kw. 51
- 10 (trauma* adj2 (event? or memor* or flashback* or nightmare?)).ti,ab,kw. 10514
- 11 (EMDR or (eye movement desensiti#ation and reprocessing)).ti,kw. 527
- 12 ((trauma* or posttrauma* or post-trauma* or victim* or survivor?) and (exposure adj3 (therap* or psychotherap* or training or counsel*))).ti,ab,kw. 1096
- 13 (critical incident adj (stress or debrief* or de-brief*)).ti,ab,kw. 275
- 14 (debriefing or de-briefing).ti,ab,kw. 4133
- 15 (crisis intervention? or CISD).ti,ab,kw. 2273
- 16 ((stress or group? or psychological or crisis) adj3 (debrief* or de-brief*)).ti,ab,kw. 602



17 (trauma* adj2 (event? or memor* or flashback* or nightmare?)).ti,ab,kw. 10514

18 (1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17) 74063

19 crossover-procedure/ or double-blind procedure/ or randomized controlled trial/ or single-blind procedure/ or (random* or factorial* or crossover* or cross over* or placebo* or (doubl* adj blind*) or (singl* adj blind*) or assign* or allocat* or volunteer*).tw. 1970074 20 (18 and 19) 7601

21 (2014* or 2015* or 2016* or 2017* or 2018*).yr,dc. 7084132

22 (20 and 21) 3319

Ovid PsycINFO

Date Searched: March 3rd 2018

1 posttraumatic stress disorder/ or complex ptsd/ or desnos/ or acute stress disorder/ or combat experience/ or "debriefing (psychological)"/ or emotional trauma/ or post-traumatic stress/ or exp stress reactions/ or traumatic neurosis/ 50806

2 exp disasters/8186

3 (PTSD or ((posttrauma* or post-trauma* or post trauma*) adj3 (stress* or disorder* or psych* or symptom?)) or acute stress disorder* or combat disorder* or war neuros*).ti,ab. 38985

- 4 (((acute or traumatic) adj stress*) and (expos* or psyc*)).ti,ab. 16755
- 5 (traumati#ed adj (victim? or survivor?)).ti,ab. 68
- 6 (trauma* adj2 (event? or memor* or flashback* or nightmare?)).ti,ab. 11819
- 7 (EMDR or (eye movement desensiti#ation and reprocessing)).ti,ab. 1640
- 8 ((trauma* or posttrauma* or post-trauma* or victim* or survivor?) and (exposure adj3 (therap* or psychotherap* or training or counsel*))).ti,ab. 1086

9 crisis intervention/3314

- 10 (critical incident adj (stress or debrief* or de-brief*)).ti,ab. 443
- 11 (debriefing or de-briefing).ti,ab. 2186
- 12 (crisis intervention? or CISD).ti,ab. 3505
- 13 ((stress or group? or psychological or crisis) adj3 (debrief* or de-brief*)).ti,ab. 596
- 14 (trauma* adj2 (event? or memor* or flashback* or nightmare?)).ti,ab. 11819
- 15 (1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14) 80813
- 16 clinical trials.sh. 10820
- 17 (randomi#ed or randomi#ation or randomi#ing).ti,ab,id. 72509
- 18 (RCT or at random or (random* adj3 (assign* or allocat* or control* or crossover or cross-over or design* or divide* or division or number))).ti,ab,id. 82020
- 19 (control* and (trial or study or group) and (placebo or waitlist* or wait* list* or ((treatment or care) adj2 usual))).ti,ab,id,hw.25590
- 20 ((single or double or triple or treble) adj2 (blind* or mask* or dummy)).ti,ab,id. 24054
- 21 trial.ti. 25583
- 22 placebo.ti,ab,id,hw. 37267
- 23 treatment outcome.md. 18762
- 24 treatment efficacy evaluation.sh. 21858
- 25 mental health program evaluation.sh. 2028
- 26 (16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25) 169119
- 27 (15 and 26) 4124
- 28 (2014* or 2015* or 2016* or 2017* or 2018*).yr,dc,mo. 782907
- 29 (27 and 28) 1449

Database: PILOTS: Published International Literature On Traumatic Stress

Date Searched: March 3rd 2018

Search Strategy

Set#: S1 Searched for: ti((posttrauma* near/4 (stress* or disorder* or psych* or symptom*))) OR ab((posttrauma* near/4 (stress* or disorder* or psych* or symptom*))) Results: 16999*

Set#: S2 Searched for: ti((post-trauma* near/4 (stress* or disorder* or psych* or symptom*))) OR ab((post-trauma* near/4 (stress* or disorder* or psych* or symptom*))) Results: 6647°

Set#: S3 Searched for: ti((post trauma* near/4 (stress* or disorder* or psych* or symptom*))) OR ab((post trauma* near/4 (stress* or disorder* or psych* or symptom*))) Results: 7214°

Set#: S4 Searched for: ti((PTSD or acute stress disorder* or combat disorder* or war neuros*)) OR ab((PTSD or acute stress disorder* or combat disorder* or war neuros*)) Results: 30435*

Set#: S5 Searched for: ti((((acute or traumatic) near/2 stress*) and (expos* or psyc*))) OR ab((((acute or traumatic) near/2 stress*) and (expos* or psyc*))) Results: 2341°

Set#: S6 Searched for: ti((traumatised near/2 (victim* or survivor*))) OR ab((traumatised near/2 (victim* or survivor*))) Results: 84°



Set#: S7 Searched for: ti((trauma* near/3 (event* or memor* or flashback* or nightmare*))) OR ab((trauma* near/3 (event* or memor* or flashback* or nightmare*))) Results: 6974°

Set#: S8 Searched for: ti(((trauma* or posttrauma* or post-trauma* or victim* or survivor*) and (exposure near/4 (therap* or psychotherap* or training or counsel*)))) OR ab(((trauma* or posttrauma* or post-trauma* or victim* or survivor*) and (exposure near/4 (therap* or psychotherap* or training or counsel*))))) Results: 787°

Set#: S9 Searched for: ti((critical incident near/2 (stress or debrief* or de-brief*))) OR ab((critical incident near/2 (stress or debrief* or de-brief*))) Results: 385°

Set#: S10 Searched for: ti((debriefing or de-briefing)) OR ab((debriefing or de-briefing)) Results: 685°

Set#: S11 Searched for: ti((crisis intervention* or CISD)) OR ab((crisis intervention* or CISD)) Results: 784°

Set#: S12 Searched for: ti(((stress or group* or psychological or crisis) near/4 (debrief* or de-brief*))) OR ab(((stress or group* or psychological or crisis) near/4 (debrief* or de-brief*))) Results: 464°

Set#: S13 Searched for: ti((trauma* near/3 (event* or memor* or flashback* or nightmare*))) OR ab((trauma* near/3 (event* or memor* or flashback* or nightmare*))) Results: 6974°

Set#: S14 Searched for: ti((EMDR or (eye movement desensitisation and reprocessing))) OR ab((EMDR or (eye movement desensitisation and reprocessing))) Results: 888°

Set#: S15 Searched for: ti((EMDR or (eye movement desensitiZation and reprocessing))) OR ab((EMDR or (eye movement desensitiZation and reprocessing))) Results: 888°

Set#: S16 Searched for: (s1 or s2 or s3 or s4 or s5 or s6 or s7 or s8 or s9 or s10 or s11 or s12 or s13 or s14 or s15)

Results: 36840*

Set#: S17 Searched for: MAINSUBJECT.EXACT("Randomized Clinical Trial") Results: 1210°

Set#: S18 Searched for: ab((randomized or randomised or placebo or randomly)) Results: 2931°

Set#: S19 Searched for: ti(trial) Results: 784°

Set#: S20 Searched for: (S17 or S18 or S19) Results: 3226°

Set#: S21 Searched for: S16 and s20 Results: 2654°

* Duplicates are removed from your search, but included in your result count.

° Duplicates are removed from your search and from your result count.

Appendix 3. Other database searches (Feb 2019)

In February 2019 a further (targeted) update search was conducted for RCTs, using search terms for condition and intervention.

Date of search: 22-February-2019

- 1. CENTRAL, (2018 to Issue 2, 2019), n = 145
- 2. MEDLINE (2018 to 21-Feb-2019), n = 39
- 3. Embase (2018 to 2019, week 07), n = 64
- 4. PsycINFO (2018 to February Week 1, 2019), n = 45
- 5. PTSDpubs (2018 to 22-Feb-2019), n = 24
- 6. PTSDpubs (Dissertation & Theses) (all years to date), n = 78
- 7. Trial Registries (all years to date), n = 19

[The Proquest database PILOTS was renamed to PTSDpubs in January 2019]

Total = 414 Duplicates removed = 87 To Screen, n = 327

Cochrane Central Register of Controlled Trials (CENTRAL) Issue 2 of 12, 2019

#1 MeSH descriptor: [Couples Therapy] this term only

#2 (("Group Therapy") or (Psychotherapy near/2 Group)) and (couple* or partner* or marriage or marital or husband* or wife or wives* or spous* or family or families or multi-family or conjoint or interpersonal or relations* or significant other or (child* and parent*)):TI,AB,KW #3 ((couple* or partner* or marriage or marital or husband* or wife or wives* or spous* or family or families or multi-family or conjoint or interpersonal or relations* or "significant other" or (child* NEAR parent*)) NEAR/3 (therap* or psychotherap* or counsel* or treat* or intervention*)):TI,AB,KW

#4 (#1 OR #2 OR #3)

#5 MeSH descriptor: [Trauma and Stressor Related Disorders] explode all trees

#6 (PTSD or ((posttrauma* or post-trauma* or post trauma*) NEAR (stress* or disorder* or psych* or symptom*)) or ("acute stress" NEXT disorder) or (combat NEXT disorder*) or (war NEXT neuros*)):TI,AB,KW

#7 (#5 or #6)

#8 (#4 and #7) n = 468 trials



Date limited 01/01/2018 to 22/02/2019, n = 145

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to February 21, 2019> Search Strategy:

-

1 exp Couples Therapy/ (2063)

2 Psychotherapy, Group/ and (couple* or partner* or marriage or marital or husband* or wife or wives* or spous* or family or families or multi-family or conjoint or interpersonal or relations* or significant other or (child* and parent*)).ti,ab,kf,hw. (4836)

3 ((couple* or partner* or marriage or marital or husband* or wife or wives* or spous* or family or families or multi-family or conjoint or interpersonal or relations* or significant other or (child* and parent*)) adj7 (therap* or psychotherap* or counsel* or treat* or intervention*)).ti,ab,kf. (125231)

4 or/1-3 (128970)

5 Stress Disorders, Post-Traumatic/ (29434)

6 (PTSD or ((posttrauma* or post-trauma* or post trauma*) adj3 (stress* or disorder* or psych* or symptom?)) or acute stress disorder* or combat disorder* or war neuros*).ti,ab,kf. (34083)

75 or 6 (42315)

8 randomized controlled trial.pt. (476462)

9 controlled clinical trial.pt. (92918)

10 (randomized or randomised).ti,ab,kf. (560894)

11 (RCT or randomized or randomised).ti,ab,kf. (564299)

12 randomly.ab. (305737)

13 placebo.ab. (195505)

14 clinical trials as topic.sh. (186060)

15 trial.ti. (194452)

16 or/8-15 (1241438)

17 4 and 7 and 16 (345)

18 (2018* or 2019*).yr,dp,dt,ep,ez. (1671137)

19 17 and 18 (39)

Ovid Embase <1974 to 2019 Week 07>

Search Strategy:

.....

1 couple therapy/ (308)

2 group therapy/ and (couple* or partner* or marriage or marital or husband* or wife or wives* or spous* or family or families or multi-family or conjoint or interpersonal or relations* or significant other or (child* and parent*)).ti,ab,kw,hw. (5920)

3 ((couple* or partner* or marriage or marital or husband* or wife or wives* or spous* or family or families or multi-family or conjoint or interpersonal or relations* or significant other or (child* and parent*)) adj7 (therap* or psychotherap* or counsel* or treat* or intervention*)).ti,ab,kw. (176198)

4 or/1-3 (179609)

5 posttraumatic stress disorder/ (53155)

6 (PTSD or ((posttrauma* or post-trauma* or post trauma*) adj3 (stress* or disorder* or psych* or symptom?)) or acute stress disorder* or combat disorder* or war neuros*).ti,ab,kw. (43952)

75 or 6 (60139)

8 crossover-procedure/ or double-blind procedure/ or randomized controlled trial/ or single-blind procedure/ or (random* or factorial* or crossover* or cross over* or placebo* or (doubl* adj blind*) or (singl* adj blind*) or assign* or allocat* or volunteer*).tw. (2112246) 9 4 and 7 and 8 (463)

10 (2018* or 2019*).dc,dd,dp,yr. (2088349)

119 and 10 (64)

Ovid PsycINFO <1806 to February Week 1 2019>

Search Strategy:

1 couples therapy/ (4249)

2 family therapy/ or conjoint therapy/ or strategic family therapy/ or structural family therapy/ (21413)

3 marriage counseling/ (4677)



4 (exp group psychotherapy/ or group intervention/) and (couple* or partner* or marriage or marital or husband* or wife or wives* or spous* or family or families or multi-family or conjoint or interpersonal or relations* or significant other or (child* and parent*)).ti,ab,id,hw. (8496) 5 ((couple* or partner* or marriage or marital or husband* or wife or wives* or spous* or family or families or multi-family or conjoint or interpersonal or relations* or significant other or (child* and parent*)) adj7 (therap* or psychotherap* or counsel* or treat* or intervention*)).ti,ab,id. (142872)

6 or/1-5 (148986)

7 posttraumatic stress disorder/ or complex ptsd/ or desnos/ (30247)

8 post-traumatic stress/ or acute stress disorder/ (897)

9 exp Combat Experience/ or exp Traumatic Neurosis/ (3032)

10 (PTSD or ((posttrauma* or post-trauma* or post trauma*) adj3 (stress* or disorder* or psych* or symptom?)) or acute stress disorder* or combat disorder* or war neuros*).ti,ab,id. (42801)

11 or/7-10 (45372)

12 clinical trials.sh. (11241)

13 (randomi#ed or randomi#ation or randomi#ing).ti,ab,id. (77564)

14 (RCT or at random or (random* adj3 (assign* or allocat* or control* or crossover or cross-over or design* or divide* or division or number))).ti,ab,id. (87047)

15 (control* and (trial or study or group) and (placebo or waitlist* or wait* list* or ((treatment or care) adj2 usual))).ti,ab,id,hw. (26945)

16 ((single or double or triple or treble) adj2 (blind* or mask* or dummy)).ti,ab,id. (24877)

17 trial.ti. (27336)

18 placebo.ti,ab,id,hw. (38406)

19 treatment outcome.md. (19321)

20 treatment efficacy evaluation.sh. (22634)

21 mental health program evaluation.sh. (2057)

22 or/12-21 (177418)

23 6 and 11 and 22 (374)

24 (2018* or 2019*).yr,an. (164112)

25 23 and 24 (45)

PTSDPubs (formerly PILOTS) (22-February-2019)

S1 MAINSUBJECT.EXACT("Conjoint Therapy") OR MAINSUBJECT.EXACT("Family Therapy") OR MAINSUBJECT.EXACT("Behavioral Couples Therapy") 622

S2 MAINSUBJECT.EXACT.EXPLODE("Group Psychotherapy") AND noft((couple* OR partner* OR marriage OR marital OR husband* OR wife OR wives* OR spous* OR family OR families OR multi-family OR conjoint OR interpersonal OR relations* OR "significant other" OR (child* AND parent*))) 648

S3 noft(((couple* OR partner* OR marriage OR marrial OR husband* OR wife OR wives* OR spous* OR family OR families OR multi-family OR conjoint OR interpersonal OR relations*) N/3 (therap* OR psychotherap* OR counsel* OR treat* OR intervention*))) 2241

S4 noft(("significant other") N/3 (therap* OR psychotherap* OR counsel* OR treat* OR intervention*)) 3

S5 noft((parent*) N/3 (therap* OR psychotherap* OR counsel* OR treat* OR intervention*)) AND noft((child*) N/3 (therap* OR psychotherap* OR counsel* OR treat* OR intervention*)) 187

S6 (S1 OR S2 OR S3 OR S4 OR S5) 2775

S7 MAINSUBJECT.EXACT("Randomized Clinical Trial") 1302

S8 MAINSUBJECT.EXACT("Clinical Trial") 270

S9 MAINSUBJECT.EXACT("Treatment Efficacy") 5692

\$10 noft((randomized or randomised or randomization or randomisation or randomizing or randomising)) 2453

S11 noft(RCT or "at random") OR noft(random* N/3 (assign* or allocat* or control* or crossover or cross-over or design* or divide* or division or number)) 2041

S12 noft((control* and (trial or study or group) and (placebo or waitlist* or wait* list*))) OR noft((control* AND (trial or study or group))) and noft((treatment N/2 usual) or (care N/2 usual)) 870

S13 ti(trial) 862

S14 ti(placebo) OR ab(placebo) 530

S15 (S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14) 6921

S16 (S6 AND S15) 753

S17 MAINSUBJECT.EXACT.EXPLODE("PTSD") OR MAINSUBJECT.EXACT.EXPLODE("Acute Stress Disorder") OR MAINSUBJECT.EXACT.EX-PLODE("Traumatic Neuroses") 40082

S18 noft(PTSD) OR noft((posttrauma* OR post-trauma* OR "post trauma*") N/3 (stress* OR disorder* OR psych* OR symptom*)) 41658 S19 noft(("acute stress disorder*" or "combat disorder*" or "war neuros*")) 1633

S20 (S17 OR S18 OR S19) 43415

S21 (S16 AND S20) 592

S22 (S16 AND S20) [Date] Limits Applied (2018-2019) 24

S23 (S16 AND S20) [Publication Type] Limits Applied (Dissertations & Theses) 78



S24 (S22 OR S23) 102

Clinical Trials Registers (22-February-2019)

ClinicalTrials.gov n = 13

Advanced Search > Interventional Studies

Condition: PTSD OR "posttraumatic stress" OR "post traumatic stress"

Other terms: "Couple Therapy" OR "Couples Therapy" OR "Conjoint Therapy" OR "Family Therapy" OR "Families Therapy"

Other synonyms applied:

 $Condition: post-traumatic stress \ disorder, post-traumatic neuroses, combat \ fatigue, combat \ neuroses, post \ traumatic stress \ syndrome, traumatic neurosis$

Intervention: counseling families, family counseling, family psychotherapy

WHO International Clinical Trials Registry Platform (ICTRP) n = 6

PTSD AND Couple Therapy OR PTSD AND Couples Therapy OR PTSD AND Conjoint Therapy OR PTSD AND Family Therapy OR PTSD AND Families Therapy

Multiple synonyms applied

CONTRIBUTIONS OF AUTHORS

Aino Suomi led the review conceptualised by Sean Cowlishaw. Aino Suomi, Sean Cowlishaw and Stephanie Taplin carried out the screening for the systematic review. Aino Suomi and Sean Cowlishaw extracted the data and ran the analyses. Aino Suomi, Sean Cowlishaw, Stephanie Taplin, Lynette Evans and Bryan Rodgers all contributed to the conduct and writing of the review.

DECLARATIONS OF INTEREST

AS: none

LE: none

BR: none

ST: none

SC: none

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Salary support (BR)

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The differences between protocol and review are as follows.

- 1. We excluded two databases: Web of Science and LILACS. After piloting the search we found that they did not add any relevant studies to the screening but resulted in a large number of irrelevant publications.
- 2. We added search term "significant other".
- 3. We changed the primary outcome 'severity of psychological symptoms of family members' to two separate primary outcomes: 'family member severity of depression' and 'family member severity of anxiety'. It is anticipated that identical psychological measures would be administered to both the primary participant and the family member within each study and the revised outcomes now better reflect the current and future studies included in the review.
- 4. We amended comparison 3 to better reflect the published literature by replacing 'individual psychological therapy' with 'intervention'.
- 5. We did not include a follow-up assessment for any of the outcomes after post-treatment. Given that there was only one study in each comparison, the follow-up assessments would not have added the intended value to the analyses. We will consider adding this in when more studies become available.
- 6. We added Stephanie Taplin as an author.