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**Interventions to Reduce  
Distress in Adult Victims of  
Sexual Violence and Rape: A  
Systematic Review**

Cheryl Regehr, Ramona Alaggia, Jane Dennis, Annabel  
Pitts, Michael Saini



**THE CAMPBELL COLLABORATION**

# Colophon

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# Executive summary/Abstract

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## BACKGROUND

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Beginning with the articulation of Rape Trauma Syndrome (Burgess 1974), the traumatic aftermath of sexual assault on victims has become a focus of social and legal policy, scholarly inquiry, and mental health interventions. The wide variety of psychosocial treatment modalities for victims of sexual violence reported in the literature and used in practice are predominantly based on psychodynamic, cognitive-behavioural or feminist-informed theoretical frameworks. Some modalities have been specifically designed for victims of sexual violence while others have been adapted from use with other traumatized populations. Although there is evidence of effective treatments for addressing traumatic stress in victims of many types of trauma, modalities specific to victims of sexual assault have not been systematically tested. Evidence suggests that trauma associated with rape or sexual assault differs from trauma stemming from other experiences, in part due to the strong element of self-blame, the individualized nature of this type of trauma, social support and social acceptance factors, and the higher incidence of concurrent depression. Therefore, it is critical to examine the effectiveness of interventions specific to victims of sexual violence and rape.

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## OBJECTIVES

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To examine the effectiveness of psychotherapeutic interventions in reducing symptoms of distress and trauma for victims of sexual assault and rape.

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## SEARCH STRATEGY

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Both published and unpublished work was considered eligible for the review. Electronic searches were conducted in June 2009 and in April 2011 within the following databases: Cochrane Central Register of Controlled Trials (CENTRAL); Cochrane Database of Systematic Reviews (CDSR); MEDLINE; EMBASE; EMBASE Classic; All EBM Reviews; PsycINFO; ASSIA (Applied Social Sciences Indexes and Abstracts); ERIC; Social Sciences Abstracts; Social Services Abstracts; Social Sciences Citation Index; Criminal Justice Abstracts; Violence and Abuse Abstracts; Social Work Abstracts; Dissertation Abstracts International (DAI); CINAHL; Gender

Studies Database; and Contemporary Women's Issues. Reference lists of all relevant articles were also screened and requests for additional studies made to authors and key informants. To supplement the electronic searches, seven journals relevant to the sexual assault, rape or sexual violence were hand-searched up to April 2009: Journal of Traumatic Stress; Journal of Interpersonal Violence; Victims and Offenders; Trauma Abuse and Violence; Violence against Women; American Journal of Psychiatry; and British Journal of Psychiatry.

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## **SELECTION CRITERIA**

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Studies were eligible for the review if (a) the allocation of study participants to experimental or control groups was by random allocation or quasi-experimental parallel cohort design; (b) participants were adults who had experienced sexual assault or rape as adults; and (c) the intervention specifically focused on victims of sexual assault or rape. Studies with participants that identified primarily as victims of childhood sexual abuse were not included.

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## **DATA COLLECTION AND ANALYSIS**

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Two review authors screened abstracts and read the full-text of all eligible articles. Standardised mean differences with 95% confidence intervals were calculated for all relevant outcomes.

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## **RESULTS**

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Six studies including 405 participants met eligibility criteria, with data from 358 participants available for analysis. Two of the studies evaluated Cognitive Processing Therapy (CPT, totalling 80 participants); three evaluated Prolonged Exposure (PE, n= 94); two evaluated Stress Inoculation Therapy (SIT, n=26); one evaluated Supportive Psychotherapy (SP, n=12) and two examined Eye Movement Desensitization Reprocessing therapy (EMDR, n=34). Meta-analysis comparing all treatments against no treatment for the randomized controlled trials revealed significant results for PTSD symptoms, both independently observed [SMD -1.81 (95% CI -2.90 to -0.72, four studies)] and self-reported [SMD -1.90 (95% CI -2.73 to -1.07, three studies)] at post-treatment. Meta-analyses of relevant outcomes from the six included studies revealed that all the treatments had a statistically significant effect on PTSD and depression symptoms in comparison to the control groups at post-test. The four studies that included anxiety as an outcome also showed significant improvements. Other outcomes that demonstrated improvements included guilt (following CPT and to a lesser extent, PE) and dissociation (following EMDR treatment).



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## **AUTHORS' CONCLUSIONS**

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Results of this systematic review provide tentative evidence that cognitive and behavioural interventions, in particular Cognitive Processing Therapy, Prolonged Exposure therapy, Stress Inoculation Therapy, and Eye Movement Desensitization and Reprocessing can be associated with decreased symptoms of Post-Traumatic Stress Disorder (PTSD), depression and anxiety in victims of rape and sexual assault. There is a need for further well-designed controlled studies which differentiate victims of sexual assault and rape from other traumatic events.

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# 1 Background

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## 1.1 DESCRIPTION OF THE CONDITION

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### 1.1.1 Prevalence

Estimates of the incidence and prevalence of rape and other forms of sexual assault vary depending on how terms are defined, what types of sexual assaults are included, the time frame during which the data are collected, sampling methods used, age and gender of the population studied, and the location of the sample. Commonly used methods include surveys of individuals to ascertain their experiences of victimization and compilations of crimes collected from policing services, courts or correctional facilities, all of which will provide different perspectives on the scope of the problem (Burgess 2012). Further, as few countries have undertaken studies that comprehensively document the prevalence of rape and sexual assault, worldwide incidence is difficult to determine (British Council, 2006).

In the United Kingdom, Painter 1991 reported that 1 in 4 women experienced rape or attempted rape. A national random sample of 6,926 women in Sweden found that 1 in 6, or 16% of the respondents, had experienced sexual violence by a former husband or cohabitant and that 1 in 4, or 25% of the respondents, had been subject to sexual violence by a man outside a relationship (Lundgren 2002). In a similar study in Ghana, Coker et al (1999) randomly sampled 2,069 women and adolescent girls and found that 1 in 3, or 33% of the respondents, had been touched against their will and that 1 in 5, or 21% of the respondents, had been raped. The WHO *World Report on Violence and Health* reports that percentages of women who experienced sexual assault in the previous five years ranged from 8% in Brazil and 6% in Albania, to 0.8% in Botswana (Krug 2002).

In the United States, The National Institute of Justice (NIJ) Special Report on the Extent, Nature, and Consequences of Rape Victimization: Findings from the National Violence Against Women Survey (NVAWS) (Tjaden 2006) reported that 17.6% of surveyed women and 3% of surveyed men were raped at some time in their lives. Extrapolating from the data, the NVAWS estimated that 17.7 million women and 2.8 million men were forcibly raped at some time in their lives, with more than 300,000 women and more than 92,000 men forcibly raped in the year prior to the survey. Similarly, an earlier survey of households in Los Angeles, reported lifetime prevalence of sexual assault of 16.7% for women and 9.4% for men (Burnham 1988). A national random sample of women found that 12.7% reported a history of rape and 14.3% reported other forms of sexual assault (Resick 1993).

The US National Crime Victimization Survey (2009) revealed that females between the ages of 16 and 19 are four times more likely to report on the survey instrument that they have experienced sexual assault, rape or attempted rape. This is confirmed by high rates of sexual violence reported by women in college samples. Koss 1987 found in their survey of 6,000 students from 32 colleges that 50% of the respondents indicated having experienced some form of sexual violence after age 14, and 27.5% reported having been raped. In a subsequent study with 2,700 college women, 15% reported rape and 12% reported attempted rape since age 14 (Koss 1989). Gross and colleagues (2006) reported that 27% of a sample of college women had experienced some form of unwanted sexual contact (ranging from kissing and petting to intercourse) since entering college. Thus, while estimates vary, sexual assault affects a nontrivial percentage of the population, suggesting a strong rationale for developing, implementing and evaluating interventions specific to the needs of these victims.

### **1.1.2 Consequences**

Being sexually assaulted or raped is undeniably a distressing event, often producing a range of negative effects. Post-Traumatic Stress Disorder (PTSD), depression, anxiety, fear and self-blame, as well as problems with social and work adjustment and with sexual functioning have all been clearly documented as associated with rape trauma in numerous studies and reviews (Campbell 2009; Campbell 2005; Elliot 2004; Resick 1983; Rothbaum 1992).

*Post Traumatic Stress Disorder (PTSD):* First and foremost, sexual assault and rape survivors are at significantly increased risk of developing (PTSD) (Campbell 2009). PTSD has been reported in almost 50% of individuals who have been raped (Feeny 2004), and rape survivors appear to be the largest group of persons experiencing PTSD (Foa 1998). Symptoms of PTSD fall into three clusters: re-experiencing of intrusive thoughts, emotions or physiological distress upon exposure to cues of the event; avoidance of thoughts or stimuli that are reminiscent of the event; and biological, emotional or cognitive arousal (APA 2000). However, in a large percentage of people PTSD does not persist and rather symptoms diminish over time. For instance, Rothbaum 1992 reported that while 94% of the 95 rape victims in their study met the criteria for PTSD at one week post-rape, this reduced to 47% at 94 days post-rape. Nevertheless, it has been suggested that symptoms of PTSD become relatively persistent if present three months after the rape event. Given the proportion of trauma symptoms that spontaneously remit in the early stages post assault, controlled studies that take into account time elapsed since the rape are necessary when evaluating the efficacy of interventions.

*Other symptoms:* Victims of rape exhibit depression, fear and anxiety, problems with social and work adjustment, and problems with sexual functioning subsequent to their assault (Resick 1983). Reported rates of depression range from 68-74% in the first four weeks post sexual assault, but diminish to normal levels within a few months in the majority of victims (Regehr 1998). Nickerson (2012) recently examined the comorbid relationship between PTSD, depression and anxiety in 126 women during the first four weeks post-sexual assault. This time-lagged

mediation analysis revealed that PTSD fully mediated the relationship between time and symptoms of depression and anxiety, underlining that PTSD is a primary outcome of rape trauma.

*Consequences of rape in comparison with other traumatic events:* While there appears to be similarity of response between individuals exposed to a broad range of traumatic events that includes rape, life-threatening accidents and disasters (Rothbaum 1996), the consequences associated with rape may differ from other forms of trauma because of the strong element of self-blame, societal blame, stigma and revictimization in the criminal justice system; such factors appear to lead to a higher incidence of concurrent depression and an increased risk of suicide (Campbell 2009; Connor 1997; Kimerling 2002; Najdowski 2011). Breslau (1991) reported that the incidence of PTSD was highest after rape (49%, SE 12.2), and greater than for other forms of sexual assault (23%, SE 10.8). The incidence of PTSD was 15% (SE 13.7) after being shot or stabbed, 16.8% (SE 6.2) after other kinds of serious accident, 3.8 (SE 3.0) following a natural disaster, and 2.3% (SE 1.3) after a serious car accident.

### **1.1.3 Existing evidence**

A significant literature on the treatment of individuals who have been exposed to traumatic events can be identified. Although the vast majority of such studies are not empirically-based (Solomon 2002), a number of experimental studies with samples that include victims of rape and sexual assault have been reported.

Stein et al (2006) systematically reviewed pharmacotherapy for PTSD, grouping adult victims of sexual violence with other trauma sufferers. In this analysis of 35 randomized control trials (RCTs), individuals on a variety of medications (including SSRIs, TCAs and MOAIs) experienced greater symptom reduction than individuals in the placebo condition in 13 studies. Bisson (2007) completed a Cochrane review of psychological treatments for symptoms of PTSD and found evidence that individual Trauma-Focused Cognitive Behavioural Therapy/Exposure Therapy (TFCBT), Eye Movement Desensitisation and Reprocessing (EMDR), Stress Management, and group Trauma-Focused Cognitive Behavioural Therapy/Exposure Therapy were all effective. TFCBT, EMDR and stress management demonstrated the greater efficacy than the other forms of treatment examined. Sherman 1998 completed a meta-analysis of controlled and clinical trials of psychotherapeutic treatments for PTSD, including samples of combat veterans, crime-related victims, severe bereavement sufferers, and victims of rape. This review examined both cognitive and psychodynamic treatments in both group and individual settings, and found the overall impact of psychotherapy on PTSD and psychiatric symptomatology was significant ( $d = 0.52$ ,  $r = 0.25$ ) with a 95% confidence interval suggesting that the true effect lies between 0.39 and 0.68.

While previous reviews contribute to knowledge about the efficacy of treatments for PTSD, they are of limited use in the current analysis as they have combined outcomes from adult victims of sexual assault and rape with outcomes from other populations experiencing PTSD symptoms. Stein 2006, for example, provided no specific data synthesis or sub group

analyses for participants who had been victims of rape, and Bisson 2007 made no restriction on the basis of the type of traumatic event in a review with disparate samples that included war veterans, female assault survivors, refugees, police officers, and mixed groups of individuals who had experienced road traffic accidents, assaults, bereavement and industrial accidents.

The potential for interventions to exert an iatrogenic effect in trauma victims has also been observed. Studies with mixed samples have demonstrated that whereas some interventions may be helpful with certain trauma groups, they can lead to a worsening of symptoms in others (Bisson 1997; Mayou 2000; Regehr 2001). It is thus important therefore for a systematic review to distinguish carefully the outcomes of adult victims of sexual assault from the outcomes of other trauma victims to examine any possible iatrogenic effects specific to this population.

A further criticism is that the above reviews do not always exclude studies that employ single group designs, with the consequence that any spontaneous remission will not be accounted for (Falsetti 1997; Foa 1993; Foa 1998; Taylor 2009; Vickerman 2009).

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## **1.2 DESCRIPTION OF THE INTERVENTION**

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Models of therapy used to assist victims in recovery from trauma are predominantly based on psychodynamic, cognitive and behavioural framework. An additional model that is less clearly defined is referred to as 'supportive therapy'. Due to the specific nature of sexual violence, these models are, when applied to this type of trauma, often informed by feminist frameworks that recognize the need for re-establishing appropriate boundaries in relationships, promoting self-determination, and empowerment of the victim to move from victim to survivor. Feminist-informed approaches view sexual victimization as a crime against the self and highlight the contribution of a society that condones violence (Bass 1992; Myers Avis 1992; Solomon 1992). Their goal is to help the victim understand that such violence is a societal problem and not an individual problem, thereby reducing self-blame and guilt (Enns 1993; Koss 1991). Although feminist theories may underpin different models of treatment, there is no clear definition of a feminist treatment model. The feminist treatment approach is not therefore included as a separate category of intervention in this review.

### **1.2.1 Psychodynamic**

Psychodynamic psychotherapy has the longest history as a method for dealing with trauma in various forms including sexual assault and rape. Psychodynamic theory underpins this therapeutic approach. The psychodynamic perspective is distinguished by its focus on expression of emotions, exploration of avoidance of distressing emotions, examining past experiences, wishes and fantasies, identification of defense mechanisms, working through interpersonal relationships and using the therapy relationship to resolve intra-psychic conflicts and interpersonal struggles (Shedler, 2010). An important premise of psychodynamic psychotherapy is the idea that bringing the client's conflicts and psychic

tensions from the unconscious into the conscious will lead to healthier functioning (Robbins, Chatterjee & Canda, 2011). Therefore the aim of the therapy is to uncover unconscious motives and conflicts through talking about past experiences, defense mechanisms and repetitive patterns / themes in order to set the stage for change.

Traumatic events are seen as impacting on the sense of self in relation to others, and may force a survivor to relive earlier struggles over autonomy, identity and intimacy. Recovery requires reestablishment of a sense of self and relationships with others (Herman 1992, 1997; van der Kolk 1994; van der Kolk McFarlane 1996). The emphasis is on internal defenses, interpersonal interactions, or developmental considerations, with the intention of bringing these parts into closer communication. Despite the long history and extensive use of psychodynamic models, they have little empirical support (Taylor 2009; Vickerman 2009). Research emphasises theory (Bohleber 2007; Evans 1978; Rose 1991; Straker, Watson 2002), and reports on case studies (Barnett 2001; Fosha 2006; Friedberg 1997; Pole 2006; Wren 2003) and clinical reflections (Schottenbauer 2006), rather than RCTs. However, Shedler's (2010) recent review of the scientific literature found some evidence for psychodynamic psychotherapy as an empirically supported therapy which is worth noting for future considerations of this approach.

### **1.2.2 Cognitive and Behavioral**

Cognitive-behavioural models of treatment cover a range of specific approaches including Exposure Therapy or Prolonged Exposure (ET/PE), Stress Inoculation Training (SIT), Cognitive Processing Therapy (CPT), and Eye Movement De-Sensitization and Reprocessing (EMDR). Cognitive-behavioural therapy incorporates cognitive, behavioural, and social learning theory components, to explain functioning as a product of reciprocal interactions between personal and environmental variables. Behavioral interventions often focus on control of physical stress reactions through controlled breathing or muscle relaxation. Cognitive therapy aims to assist individuals to identify and modify trauma-related dysfunctional beliefs that influence response to stimuli and subsequent physiological and psychological distress.

Prolonged Exposure (PE) is a manualized treatment developed by Foa and colleagues to treat post-traumatic stress disorder (Foa 1993). The treatment is characterized by the following four elements: education about common reactions to trauma; training in relaxing breathing; repeated in vivo exposure to stimuli that provoke anxiety due to their association with a traumatic event; and repeated imaginal exposure to traumatic memories (Foa 2007). "The aim of in vivo and imaginal exposure, as explained to clients in the overall rationale for treatment, is to enhance emotional processing of traumatic events by helping them face trauma memories and the situations that are associated with them." (Foa 2007, p. 3).

Stress Inoculation Training, developed by Michenbaum (1977), involves three interlocking and overlapping phases: 1) education regarding sources of stress, including irrational thinking, and ways to reduce psychological and physiological stress; 2) coping skills, including relaxation training and cognitive restructuring; 3) application of new strategies to

real or simulated situations. The model was later modified to include covert modeling, role playing and guided self-dialogue specifically to treat rape victims (Rothbaum 2000).

Assertiveness Training (AT) intervention models for victims of sexual violence incorporate skills building exercises from Lange and Jakubowski's (1976) work (Responsible Assertive Behavior) as well as techniques derived from Rational Emotive Therapy (Ellis 1977). Interpersonal problems that arise following sexual trauma are viewed to stem in part from non-assertive cognitions. Through behavioral rehearsal, clients are helped to speak assertively to others about their assault(s), both in terms of correcting blaming attitudes and asking for social support (Rothbaum 2000).

Cognitive Processing Therapy (CPT) was developed by Resick and Schnicke as an intervention which "elicit memories of the event and then directly confronts conflicts and maladaptive beliefs" (Resick 1993a p.17). CPT consists of two integrated components: 1) exposure of the client to his/her own trauma memories, often through writing and reading aloud a detailed account of the event which includes sensory details and 2) cognitive therapy (Resick 1993a; Resick 1993b). Cognitive components of the intervention include the identification of maladaptive cognitions and the differentiation of thoughts from feelings. Some researchers have reported that exposure therapy in combination with SIT or cognitive therapy yields the most positive results (Hembree 2003). Others have reported that inoculation does not necessarily enhance other cognitive methods, which are equally effective when provided alone (Harvey 2003; Tarrier 1999a,b).

Eye Movement Desensitization and Reprocessing (EMDR) (Shapiro 1996) incorporates desensitization through therapeutic exposure and the repetitive redirecting of attention. EMDR is a manualized training program that involves several elements: 1) the client is asked to imagine one aspect of the traumatic experience and in doing so, to experience the negative sensations associated with the event; 2) the client visually tracks an object moving back and forth, generally the therapist's fingers; 3) the client rates her level of distress on a ten point scale; 4) steps 1 to 3 are repeated until the level of distress diminishes to 0 or 1; 5) the client imagines a preferred memory or belief while tracking the therapist's fingers (Rothbaum 2005). The goal is to foster cognitive and emotional changes related to the traumatic experience. EMDR remains controversial intervention. It has been suggested that the theoretical foundation has not been well developed (e.g. Rothbaum 2005), and that it is no more effective than other exposure techniques. T Relatively few controlled studies have been conducted, and findings have been mixed (Deville 1999; Ironson 2002; Lee 2002; Taylor 2003).

Cognitive-behavioural techniques have been extensively evaluated and found to be effective in reducing symptoms of PTSD in a wide variety of populations (Bisson 2007; Foa 1991; Follette 1998; Harvey 2003; Resick 1993; Rothbaum 1996; Sherman 1998; Taylor 2009). It is important to note that exposure methods have been associated with high rates of discontinuation from therapy ('dropout'). This association has been identified as an area of concern. It is possible that those with higher levels of symptoms are less able to tolerate the

treatment, and therefore discontinue early. From a treatment standpoint, those providing treatment based on exposure methods tend to be more selective in their criteria for inclusion. It has been suggested that this model of treatment should be used only when a sound therapeutic alliance has been formed and a thorough assessment has been completed (Calhoun 1991).

### **1.2.3 Supportive approaches**

Supportive psychotherapy (SP) and supportive counseling (SC) are provided in both individual and group modalities. Victims are given the opportunity to describe their traumatic experience, the symptoms they experience as a result of the traumatic event, and the reactions of others. The treatment aims to normalize experiences, offer a safe, supportive environment, and to promote helpful approaches to managing symptoms and situations (Resick 1988).

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## **1.3 HOW THE INTERVENTION MIGHT WORK**

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Prolonged exposure and stress inoculation training have their foundations in learning theories; that is, “fear is acquired through classical conditioning and maintained via operant conditioning” (Meadows 1998, p. 101). Thus, stimuli invoke fear responses due to their association with the traumatic event. Avoidance strategies reduce the exposure and thereby the fear response, but do not directly confront the fear itself. Exposure therapies break the association between the stimulus and the response, extinguishing the association through repeated exposure. Emotional processing theory has also been applied to PE and SIT models of treatment. From this perspective, activation of the fear response is paired with introduction of corrective information which then alter cognitions about the fear invoking stimuli (Meadows 1998).

Cognitive-behavioural techniques such as CPT and EMDR take additional account of the cognitive factors that play a significant role in the onset, severity and outcomes of PTSD symptoms after sexual assault (Foa 1997; Foa 1989; Koss 2004; Jaycox 2002). Resick 1993 argued that an approach that elicits memories of the events and directly confronts conflicts and maladaptive beliefs may be more effective in alleviating PTSD symptoms than prolonged exposure alone; whereas prolonged exposure activates the memory structure, it does not provide direct information that might correct the misattributes common among rape victims (Resick 1992). In contrast to original models of CBT, Resick (1993) proposes that symptoms of PTSD occur as a result of conflicts between pre-existing schemata and traumatic experiences. Further, victims deal with the discrepancies through avoidance. CPT incorporates an exposure component which requires clients to confront the trauma related cognitions and then works to confront and modify maladaptive beliefs.

Shapiro (1996) describes the adaptive information processing model that underpins EMDR. In this model, maladaptive responses block adaptive information process and subsequently impede healing from traumatic events. If the block is removed, the traumatic event can be processed and functionally integrated. Information processing is activated and accelerated



when attention is focused on external an external cue. Further, this method relies on repeated exposure to fear invoking stimuli which attenuates and extinguishes fear (Rothbaum 1997). It has been suggested that the repetitive redirecting of attention induces a neurobiological state similar to REM sleep, and that this state is one which supports the cortical integration of traumatic memories (Stickgold 2002).

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#### **1.4 WHY IT IS IMPORTANT TO DO THIS REVIEW**

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The number of adults who experience sexual assault is significant. Studies have found that as many as one in four women in the UK have experienced rape or attempted rape, and that more than 12% of women in the USA reported a history of rape. The US National Crime Victimization Survey (2009) revealed that women between the ages of 16 and 19 are four times more likely to report that they have experienced sexual assault, rape or attempted rape.

The experience of being sexually assaulted is associated with a variety of symptoms, including PTSD, depression, anxiety, fear, guilt, problems with social adjustment, and with sexual functioning. In addition, rape survivors appear to experience more acute and chronic physical health problems than do women who are not victimized.

Few of the treatment options for sexually assaulted individuals have been rigorously tested and there is currently an absence of clarity about which intervention is superior in addressing PTSD symptoms and post-traumatic depression. It is important to note that previous studies have been conducted primarily with middle class white Anglo-Saxon women in the USA; it is unknown how these therapeutic approaches work for individuals from other cultures, social classes, or sexual orientations, nor for those with different levels of psychological functioning and ability/disability. Similarly, it is unclear whether the effectiveness of interventions varies with the nature of the sexual assault (e.g., single vs. repeated, known vs. unknown perpetrators, assaults under “normal” living conditions vs. those that happen during other traumatic events such as war). The therapeutic approaches reviewed to date may not be as effective for all types of adult sexual assault survivors. Further research is needed to understand which forms of treatment are effective, and for whom.

Although the literature suggests there may be effective treatments for trauma and PTSD in general, there remains a substantial gap in the empirical evidence related to the effectiveness of various modalities to treat adult victims of rape and other forms of sexual assault. By systematically reviewing the current state of interventions to reduce distress post-rape and/or sexual assault, this review contributes to a research agenda to develop evidence-based guidelines for the treatment of distress.

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## 2 Objectives of the review

The objectives of this systematic review were to complete a comprehensive search of controlled and clinical trials of psychotherapeutic approaches to treatment for adult victims of sexual assault and rape, and to synthesize the results of these studies to assess treatment effects on outcomes related to distress and trauma. Specifically, the objectives were to estimate absolute and relative effects of:

- the combined group of psychotherapies on distress and trauma symptoms among adult victims of sexual assault and rape; and
- individual models of treatment on distress and trauma symptoms among adult victims of sexual assault and rape

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## 3 Methods

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### 3.1 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

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#### 3.1.1 Types of studies

Eligible studies for this review included experimental and quasi-experimental parallel cohort evaluations of psychological intervention programs to reduce distress in adult victims of sexual assault and rape. Studies were eligible for the review if they 1) used random assignment to create treatment and comparison or control groups, or 2) used parallel cohort designs in which groups were assessed at the same points in time. Single-group designs and single-subject designs were excluded.

Comparison conditions included “other treatment”, “no treatment” and “treatment as usual”. Given that studies vary in the method of constructing comparison groups and vary in their use of statistical controls to reduce the threat of selection bias, only studies using parallel cohort design in constructing a comparison/control group were eligible for the review.

#### 3.1.2 Types of participants

Eligible study participants were male or female adults who had been victims of sexual assault. Adulthood is defined as commencing at age 19 years. Sexual assault is defined as encompassing rape, attempted rape, forced oral sex, anal sex, penetration with objects, touching of intimate parts, and other types of threats or coercion in which unwanted sexual contact is attempted or occurs between the victim and offender. Rape refers to forced or attempted sexual intercourse with a male or female, by any offender. Individuals who were identified solely as victims of ongoing childhood sexual abuse were not included.

#### 3.1.3 Types of interventions

Any type of psychological and/or psychosocial intervention was eligible for inclusion in the review. These interventions may have included: behavioural techniques such as exposure, systematic desensitization, eye movement desensitization and reprocessing [reprogramming] (EMDR); cognitive behavioural therapy; cognitive therapy; relaxation; and psychodynamic therapy. We also identified an “other” category of interventions to ensure we remained flexible in the retrieval process.

Since the main objective was to compare psychosocial interventions to reduce distress, interventions exclusively based on pharmacology were excluded. Studies that compared psychosocial treatments to pharmacological treatment, and that combined psychosocial treatments with pharmacological treatments were eligible for inclusion.

### **3.1.4 Types of outcomes**

#### **3.1.4.1 Primary outcomes**

The primary outcome is **PTSD symptoms**, assessed by independent observer or self-report. Validated observer-rated instruments include the Clinician Administered PTSD Symptom Scale (CAPS; Blake 1995) and the PTSD Symptom Scale Interview (PSS-I; Foa 1993). Validated self-report measures include the Impact of Event Scale (IES; Horowitz 1979), the Rape Aftermath Symptom Test (RAST; Kilpatrick 1988) and the PTSD Symptom Scale - Self-Report (PSS-SR; Foa 1993).

#### **3.1.4.2 Secondary outcomes**

Secondary outcomes are:

- **Depression symptoms**, measured using instruments such as the Beck Depression Inventory (BDI; Beck 1961), a self-report measure.
- **Anxiety symptoms**, measured using instruments such as the Spielberger State Trait Anxiety Inventory (STAI; Spielberger 1983), a self-report measure.
- **Guilt**, measured using instruments such as the Trauma-Related Guilt Inventory (TRGI; Kubany 1996), a self-report measure.
- **Fear**, measured using instruments such as the Modified Fear Scale (MFS; Veronin & Kilpatrick, 1980), a self-report measure.

In a departure from the original protocol, we decided to include an additional secondary outcome on account of its clinical relevance:

- Dissociation symptoms, measured using instruments such as the Dissociative Experiences Scale (DES; Bernstein 1986), a self-report measure.

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## **3.2 SEARCH METHODS FOR IDENTIFICATION OF STUDIES**

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### **3.2.1 Electronic searches**

No restrictions were made regarding the date, location or language of potential studies for the review in an attempt to achieve a broad inclusion of studies from various disciplines, geographical locations and languages. Nineteen electronic databases were searched in 2009 and again in April 2011.

#### **Bibliographic Databases:**

1. Cochrane Central Register of Controlled Trials (CENTRAL)
2. Cochrane Database of Systematic Reviews (CDSR)
3. MEDLINE

4. EMBASE
5. EMBASE Classic
6. All EBM Reviews
7. PsycINFO
8. ASSIA (Applied Social Science Index and Abstracts)
9. ERIC
10. Social Sciences Abstracts
11. Social Services Abstracts
12. Social Sciences Citation Index
13. Criminal Justice Abstracts
14. Violence and Abuse Abstracts
15. Social Work Abstracts
16. Dissertation Abstracts International (DAI)
17. CINAHL (Cumulative Index to Nursing and Allied Health Literature)
18. Gender Studies Database
19. Contemporary Women's Issues

### **3.2.2 Search terms**

The search strategy was developed in consultation with the Campbell Collaboration Information Retrieval Specialist. Search terms are listed below for MEDLINE and PsycINFO.

#### **MEDLINE**

1. Rape/
2. Sex Offenses/
3. (sex\$ adj2 (abus\$ or offens\$ or attack\$ or viol\$ or assault\$ or victim\$ or surviv\$ or unwanted or unlawful or forc\$ or coerc\$)).tw.
4. (rape or raped or rapist or raping).tw.
5. or/1-4
6. anxiety/
7. exp anxiety disorders/
8. anx\$.tw.
9. ((post trauma\$ or posttrauma\$ or post-trauma\$) adj (stress or neuros#s)).tw.
10. ptsd.tw.
11. exp mood disorders/
12. Depression/
13. depress\$.tw.
14. traum\$.tw.
15. distress\$.tw.
16. or/6-15
17. exp Psychotherapy/
18. (psychotherap\$ or psychoeducat\$ or psychodynam\$ or psychoanaly\$ or psychosocial or psycho-social).tw.
19. ((behavio\$ or cognit\$ or general or social or supporti\$ or interpersonal or group or individual or brief or psycho\$ or dialectic\$ or mindful\$ or exposure or hypno\$ or

- wilderness or emotion-focus\$ or emotion focus\$ or solution- focus\$ or solution focus\$ or narrative\$) adj2(counsel\$ or support\$ or intervention\$ or program\$ or treatment\$)).tw.
20. relaxation.tw.
21. (eye movement\$ or emdr).tw.
22. desensitiz\$.tw.
23. cbt\$.tw.
24. dbt\$.tw.
25. therap\$.tw
26. or/17-25
27. 26 and 16 and 5

## **PsycINFO**

1. ((DE=(Rape)) or(DE=(Sex Offenses)) or(TI=(sex\* within 2 (abus\* or offens\* or attack\* or viol\* or assault\* or victim\* or surviv\* or unwanted or unlawful or forc\* or coerc\*))) or(AB=(sex\* within 2 (abus\* or offens\* or attack\* or viol\* or assault\* or victim\* or surviv\* or unwanted or unlawful or forced or coerc\*))) or(TI=(rape or raped or rapist or raping)) or(AB=(rape or raped or rapist or raping)))
2. ((DE=(Anxiety)) or(DE=(Anxiety Disorders)) or(TI=(anxi\*)) or(AB=(anxi\*)) or(TI=((post trauma\* or posttrauma\* or post-trauma\*) within 1 (stress or neuroses or neurosis))) or(AB=((post trauma\* or posttrauma\* or post-trauma\*) within 1 (stress or neuroses or neurosis))) or(TI=(ptsd)) or(AB=(ptsd)) or(DE=(Affective Disorders)) or(DE=(Depression)) or(TI=(depress\*)) or(AB=(depress\*)) or(TI=(traum\*)) or(AB=(traum\*)) or(TI=(distress\*)) or(AB=(distress\*)))
- 3.((DE=(Psychotherapy)) or(TI=(psychotherap\* or psychoeducat\* or psychodynam\* or psychoanaly\* or psychosocial or psycho-social)) or(AB=(psychotherap\* or psychoeducat\* or psychodynam\* or psychoanaly\* or psychosocial or psycho-social)) or(TI=(behavio\* or cognit\* or general or social or supporti\* or interpersonal or group or individual or brief or psycho\* or dialectic\* or mindful\* or exposure or hypno\* or wilderness or emotion- focus\* or emotion focus\* or solution-focus\* or solution focus\* or narrative\*) within 2 (counsel\* or support\* or intervention\* or program\* or treatment\*)) or(AB=(behavio\* or cognit\* or general or social or supporti\* or interpersonal or group or individual or brief or psycho\* or dialectic\* or mindful\* or exposure or hypno\* or wilderness or emotion-focus\* or emotion focus\* or solution-focus\* or solution focus\* or narrative\*) within 2 (counsel\* or support\* or intervention\* or program\* or treatment\*)) or(TI=(relaxation)) or(AB=(relaxation)) or(TI=(eye movement\* or emdr)) or(AB=(eye movement\* or emdr)) or(TI=(desensitiz\*)) or(AB=(desensitiz\*)) or(TI=(cbt\*)) or(AB=(cbt\*)) or(TI=(dbt\*)) or(AB=(dbt\*)) or(TI=(therap\*)) or(AB=(therap\*)))
4. (1 and 2 and 3)

### **3.2.3 Searching other resources**

#### **3.2.3.1 Reference lists**

We inspected the reference lists of all relevant articles that were obtained, including those from previously published reviews. Publications describing potentially relevant studies were identified, retrieved and assessed for possible inclusion.

#### **3.2.3.2 Personal communication**

Experts in the field were contacted by letter or email in attempt to locate additional relevant studies. A list of the inclusion criteria for the review together with a sample of relevant articles were sent to these key informants along with the request that they identify any relevant studies. The list of experts comprised principal investigators of eligible studies, program developers, and authors of previous reviews of relevant literature (including Edna Foa, Barbara Rothbaum, Ann Burgess, Patricia Resick, Heidi Resnick, Enrique Echeburua, Dean Kilpatrick and Ronald Acierno).

#### **3.2.3.3 Hand-searching journals**

Relevant international journals were hand-searched to identify relevant studies not found by electronic database searches. Specifically, the *Journal of Traumatic Stress* was searched from January 1988 to June 2009 (yielding two additional articles) and the *Journal of Interpersonal Violence* was searched from March 1986 (yielding a further two articles). *Victims and Offenders* was searched from January 2006; *Trauma Abuse and Violence* was searched from January 2000 to July 2009; *Violence Against Women* was searched from March 1995 to August 2009; *American Journal of Psychiatry* was searched from April 1994 to July 2009; and the *British Journal of Psychiatry* was searched from January 1988 to July 2009. These five journals yielded no additional articles.

#### **Grey Literature**

Special attention was made to identify relevant studies from within the grey literature. The following sources were examined: 1) conference proceedings; 2) research reports; 3) government reports; 4) book chapters; 5) dissertations; 6) policy documents; 7) personal networks; 8) web sites for research organizations; and 9) national rape crisis umbrella organizations. Two grey literature websites were searched: Grey.Net (<http://www.greynet.org/index.html>) and GrayLit Network (<http://graylit.osti.gov/>) yielding a total of 17 hits, of which nine duplicated articles previously identified using the initial search strategy.

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## **3.3 DATA COLLECTION AND ANALYSIS**

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### **3.3.1 Selection of studies**

Titles and abstracts of articles yielded by the searches were screened by two review authors independently to determine their eligibility for inclusion. To facilitate this screening, we used an online tool designed to facilitate and accelerate the execution of systematic reviews

(TrialStat's Systematic Review System (SRS) version 3.0). Screening was carried out by a two-stage procedure in terms of the inclusion and exclusion criteria identified in Section 3.1.

#### 1) Initial screening by inspection of title and abstract (stage 1)

This consisted of an initial screening to determine whether a study might be appropriate for the review based on the article's title and abstract alone. If there was insufficient information in the title and abstract to make such decisions, the article passed to the next screening level (stage 2). Any article for which there was disagreement between the two screeners was also passed to the next screening level. The two screeners considered the following questions:

- Does the population consist of adults who have experienced rape and or sexual assault? Yes / No
- Does the study population include individuals who identify solely as survivors of childhood sexual abuse? Yes/No
- Is there an intervention related to rape and or sexual assault experienced by the population included in the study? Yes / No
- Is there a parallel cohort (comparison or control group)? Yes / No
- Are the outcomes related to distress? Yes / No

#### 2) Screening by inspection of full copy (stage 2)

In the second stage, two authors independently reviewed full copies of articles to determine whether studies should remain in the review based on the inclusion and exclusion criteria. Screeners addressed of the same questions listed above for stage one. Specific reasons for exclusion at this stage were documented for each study. Any disagreements were resolved by a third review author.

### **3.3.2 Data extraction and management**

Study details were independently extracted by two review authors using a data extraction sheet (see Appendix 2). Any differences between coders were identified in attempt to ensure consistent extraction and management of the data and to establish inter-rater reliability, with discrepancies resolved by referral back to the primary source. Any disagreements were resolved by a third review author.

Details extracted included:

- 1) *Study*: information regarding the author(s); year of publication; source; country; and language;



- 2) *Characteristics of setting and participants*: eligibility criteria for participants; explanation of recruitment procedures, setting (country, location, clinical/non-clinical); demographic features of the sample;
- 3) *Sampling*: sample sizes for treatment and control; whether power analysis was used to determine sample size; allocation to the treatment and control; explanation of method used to generate the allocation;
- 4) *Research design*: nature of research design;
- 5) *Intervention data*: nature of interventions (for treatment and comparison/control groups); aim of intervention; length of intervention, whether manuals were used, whether fidelity checks were included, information on possible contamination reported;
- 6) *Outcome data*: primary and secondary outcomes, measures used, information on reliability/validity of measures; and
- 7) *Results*: attrition at post intervention and follow-up; number excluded from the analysis; length of follow-up; statistical methods; type of data effect size is based on; data needed for effect size calculations.

### **3.3.3 Assessment of risk of bias in included studies**

Two review authors independently assessed the risk of bias for each included study. In a change to the published protocol, which was based on an earlier version of the *Cochrane Handbook* (Higgins 2005), assessments were based on the “risk of bias” criteria established in the more recent *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins & Green, 2011). These focused on risk associated with the generation of allocation sequence, degree of allocation concealment, blinding of assessors, completeness of outcome data, and selective reporting of data.

### **3.3.4 Measures of treatment effect**

Continuous data

In all six studies included in the analysis, outcome data relevant to the inclusion criteria (PTSD, anxiety and depression) were measured on continuous scales. For these continuous scale data, the standard mean difference between the treatment and comparison groups was estimated based on the reported means and standard deviations for each group. Standard mean differences (SMD) allowed for comparisons to be made across studies when scales measured the same outcomes (for example, traumatic stress symptoms) in different ways. Given the small sample sizes in both the treatment and comparison groups, we calculated the Hedges' *g* statistic. Hedges' *g* is similar to the Cohen's *d*, but includes an adjustment for small sample bias. To pool SMDs, inverse variance methods were used to weight each effect size by the inverse of its variance to obtain an overall estimate. Confidence intervals of 95% were reported throughout (Hasselblad 1995).

### **3.3.5 Unit of analysis issues**

Allocation in each included study was at the individual level; no studies allocated by group or cluster.

For studies that included multiple follow-ups, we planned to divide these into the following intervals (up to 3 months, 3-6 months, more than 6 months) and to conduct separate meta-analyses for each interval. No long-term comparisons were possible, however, given that all included studies used a waitlist control condition.

### **3.3.6 Dealing with missing data and incomplete data**

In cases where data were missing, we contacted the primary authors of the study. Where available, we used intention-to-treat data. We consistently reported data on participants who dropped out following allocation both as raw numbers and as percentages of the sample overall, paying attention to whether reasons were given for dropout and whether dropout was evenly distributed between treatment and control conditions (see Risk of Bias tables).

### **3.3.7 Assessment of heterogeneity**

Our primary analysis involved an assessment of the effectiveness of eligible psychological treatments as defined by our protocol (whether cognitive behavioural or psychodynamic in nature and regardless of the degree to which exposure elements were incorporated). We initially pooled data for all eligible active treatment groups within each study against no-treatment control, using a formula to combine means and standard deviations (Higgins 2011, section 7.7.3.8)

Sub-group analyses of the effects of the different types of intervention (Cognitive-Processing Therapy, Prolonged Exposure, Stress Inoculation Therapy, Eye Movement Desensitization and Reprocessing) were conducted only if there were at least two studies per category.

To assess the extent of differences between trials, we assessed the degree of heterogeneity in three ways: by visual inspection of the forest plots; by performing the chi square test of heterogeneity (interpreting a significance level of  $p < 0.10$  as evidence of heterogeneity); and by examining the Tau and  $I^2$  statistics (Higgins 2011; section 9.5.2).

Tau describes the variance between studies. The  $I^2$  statistic describes approximately the proportion of variation in point estimates due to heterogeneity rather than sampling error: 0% to 40% indicates that only a small amount of the observed variation is due to true heterogeneity; 30% to 60% may indicate moderate heterogeneity; 50% to 90% may indicate substantial heterogeneity; and 75% to 100% may indicate considerable heterogeneity (Higgins 2011).

Given predicted heterogeneity, a random effects models model was employed.

Three sources of heterogeneity were identified *a priori*: a) baseline severity of depression or PTSD symptoms; b) format of delivery of treatment; and c) different measures used to test outcomes. It was not possible to assess the impact of these potential sources of heterogeneity given that there were only six included studies.

### **3.3.8 Assessment of reporting biases**

We did not draw a funnel plot to examine differences in treatment effects against their standard error because there were insufficient included studies for this to be meaningful.

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<sup>1</sup> All studies included data at three month follow up. Resick (1992) also included data at six months and Resick (2002) included data at nine months.

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## **3.4 DATA SYNTHESIS**

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At protocol stage, we planned to synthesise data from controlled studies with multiple eligible treatments by randomly selecting one treatment only per study to ensure that each study was independent. In response to subsequent statistical advice (Valentine & Higgins, personal correspondence, March to August 2012), we have instead divided the total number of control group participants between treatments when synthesising data from this type of trial. We also omitted formal meta-analysis of one older treatment (stress inoculation therapy) in favour of a narrative presentation.

### **3.4.1 Subgroup analysis, moderator analysis and investigation of heterogeneity**

There were too few studies to complete moderator analysis as planned at protocol stage. We assessed statistical heterogeneity in the outcome measures using the  $Q$ -statistic together with the associated  $p$ -value for each analysis, and the  $I^2$  statistic (Higgins 2002).

### **3.4.2 Sensitivity analysis**

We analysed the results of randomised controlled trials separately from those of other designs. Although we planned in the protocol to perform sensitivity analyses based on other aspects of trial quality, e.g. blinding of outcome assessors, there were insufficient included studies for these to be informative.

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# 4 Results

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## 4.1 RESULTS OF THE SEARCH

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The searches were conducted between April 16, 2009 and April 4, 2011 by AP, RW (Rachael Walisser), and MS. The following electronic databases were searched between April 16, 2009 and June 15, 2009: All EBM reviews (165 records); ASSIA (253); CINAHL (868); Criminal Justice Abstracts (174); Digital Dissertations (361); EMBASE (1240); ERIC (187); Gender Studies (104); MEDLINE (1151); PsycInfo (2536); Social Science Abstracts (240); Social Sciences Citation Index (600); Social Work Abstracts (134); Violence and Abuse Abstracts (17) and Dissertations and Theses (819). These electronic databases were searched again on April 4, 2011 covering the period between June 16, 2009 and April 4, 2011, but no additional studies meeting the inclusion criteria were identified. All citations were saved into separate folders in a Refworks account.

Grey literature searches were completed by AP and RW between June 6, 2009 and June 17, 2009. Hand searches of the Journal of Traumatic Stress; Journal of Interpersonal Violence; Victims and Offenders; Trauma Abuse and Violence; Violence against Women; American Journal of Psychiatry; and British Journal of Psychiatry was completed by AP between March 3, 2009 and May 10, 2009. MS completed an additional search between February 15, 2011 and April 4, 2011 of the grey literature using the same search terms but limiting from 2010 to 2011. No new studies matching the inclusion criteria were identified.

A search of the Metaregister of Clinical Trials (<http://www.controlled-trials.com/mrct/>) which indexes trial protocols and contains details on trials in the stage of recruitment or pre-publication write-up was conducted in April 2012 (JD) and a number of relevant trials close to completion/reporting were identified (see Table of Ongoing Studies).

Searching the literature resulted in 7,587 hits. After removing duplicates, a total of 5779 articles were subjected to stage one screening by two independent raters (AP and RW) ( $\kappa = .82$ ) with disagreements resolved by a third reviewer (MA). Fifty four titles passed this screening level and the full text retrieved to be subjected to the stage two screen where 44 titles were excluded. Ten studies were retained and

subjected to the data extraction process. Two of the studies that were initially excluded were subsequently included after reviewing the excluded studies table (see Table 8.2) and contacting the authors for further information. Following closer inspection during the data extraction phase, six of the ten studies were withdrawn because they included predominantly child victims (under the age of 19 years of age) of sexual abuse or adult victims of sexual abuse that occurred in childhood. Upon reexamination, two studies (Foa 1991 and Resick 1988) that had previously been excluded, were included in the analysis.

Ultimately, six studies with outcome data suitable for meta-analysis were included in the final review (see figure 1).

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## **4.2 DESCRIPTION OF THE STUDIES**

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Detailed description of the studies can be found in the “Characteristics of included studies tables” below.

### **4.2.1 Design**

Four of the six included studies are randomized controlled trials (Foa 1991; Rothbaum 1997; Resick 2002; Rothbaum 2005). Two studies (Resick 1988; Resick 1992) were of quasi-experimental design, involving non-randomised, “naturally occurring” waitlist control groups formed of treatment-seeking women who remained on the waiting lists at the (identical) center where treatment was conducted for the same period of weeks required for treatment to be delivered to other participants receiving active interventions.

All six studies are of parallel design with allocation at the level of the individual participant. In no study was any form of matching or stratifying by any participant characteristic undertaken by the investigators. In each case, active treatments were compared with a waitlist control group (WLC); this is an understandable requirement of many ethics committees, but inevitably limits the collection of controlled follow-up data. Two studies compared one active treatment with WLC (Resick 2002 and Rothbaum 1997); two studies compared two active treatments with WLC (Resick 2002 and Rothbaum 2005); and two studies compared three active treatments with WLC (Foa 1991 and Resick 1988).

### **4.2.2 Sample sizes**

The number of participants allocated to eligible treatment or no-treatment (waitlist) controls within the six included studies was 405; the total number completing was 370. The mean number of participants per study is 67.5. The mean number of participants per intervention or comparator group is 22.5 across the 18 active intervention arms described above.

Power calculations are mentioned in two studies only (Resick 1988; Resick 2002); in the former the authors calculated a need to recruit 80 participants per group (although the total number completing was 37); in the latter, the authors stated that a primary aim was to conduct a study of adequate power (p. 868).

### **4.2.3 Setting and recruitment**

Methods of recruitment varied little between the six studies. With the exception of Rothbaum 2005 (who can however be presumed to have used similar methods to her earlier study) all report the use of “victim assistance agencies” and most also took referrals from local professionals, posted advertisements in local newspapers or, in one case (Resick 1988), recruited from those previously involved “in a study of the response to rape (Rothbaum et al 1990)”.

All six studies were conducted in large urban settings within the USA. One study took place in Philadelphia, Pennsylvania (Foa 1991); three in St Louis, Missouri (Resick 1988; Resick 1992; Resick 2002) and two in Atlanta, Georgia (Rothbaum 1997, Rothbaum 2005). Treatment settings were generally specialist centers for trauma or anxiety based in universities, but not restricted to university enrollment and thus can be best described as outpatient settings. However, at least one set of researchers noted that participants in these studies (women who are survivors of sexual assault who also have diagnosis of PTSD) tend not to view themselves as “patients” in the way others with diagnoses of anxiety disorders do (Foa 1991, p. 722).

### **4.2.4 Participants**

#### **4.2.4.1 Inclusion and exclusion criteria**

Each of the six included studies required that participants had experienced a sexual assault (usually a “completed” rape) but Foa 1991 included individuals who had experienced an “attempted rape”, and that the most recent assault occurred at least three months previously “to allow for the natural decline in PTSD symptoms” (Kilpatrick & Calhoun, 1988; Rothbaum et al 1992; Rothbaum 1997). Two studies further required that participants meet DSM-III-R criteria for PTSD (Foa 1991 and Rothbaum 1997) or the formal criteria established by the CAPS developed by Blake et al 1988 (Resick 2002; Rothbaum 2005). The remaining two studies required simply that participants reported “problems with rape-related fear and anxiety” (Resick 1988) or “severe PTSD symptomatology” (Resick 1992).

Two studies explicitly excluded any woman who disclosed a history of incest (Resick 1988; Resick 1992); the more recent trials conducted by Resick 2002 and Rothbaum 2005 deviated from this criterion and allowed a wider sample without excluding any woman on grounds of trauma history or mental health issues (e.g. personality disorders in the case of Resick 2002 or general comorbid psychiatric diagnoses (schizophrenia apart) in the case of Rothbaum 2005), that might have excluded them

from other trials. Most studies excluded on the basis of severe psychopathology which was termed “competing” [with PTSD]. This included severe depression, parasuicidal behaviour, current alcohol or drug abuse, or domestic violence. Foa 1991 excluded any participant whose assault had been by a spouse or other family member; Resick required only that those who had experienced marital rape “must have been out of the relationship for at least six months”. Illiteracy (which would affect completion of self-report measures and also, in the case of interventions like CPT and PE, homework assignments which were part of treatment) was an exclusion criteria in some studies.

It was not always possible to establish the age at which the most recent rape had occurred, given that many of the participants had suffered more than one rape. An inclusion criterion for this review was that participants were not solely survivors of rapes suffered during childhood (a criterion which caused the exclusion of studies such as Hebert & Bergeron 2006,). Following communication with the primary investigator of the study in which this is most in question (Resick 2002), we are satisfied that women in that study who were attacked solely between the ages of 14 and 17 were in a minority, and that no woman who had been raped before that age (only) had been admitted as a participant (Resick 2012, personal communication). The most recent study (Rothbaum 2005) was problematic in that it defined rape in adulthood as rape occurring after the age of 12, and also allowed women with histories of rape before that age to be admitted as participants. We were, however, persuaded by the data provided that these cases were in a minority.

#### ***4.2.4.2 Age and ethnicity***

The average age of women included within this review was 32.2 years ; the range was large (see Characteristics of Included studies for details). Ethnicity was reported in five trials (combined n = 384) where approximately 75% identified themselves as “white”, approximately 20% as African American, and the remainder as Hispanic or “other.” One trial (Rothbaum 1997) reported no data for ethnicity and the subsequent trial by the same authors (Rothbaum 2005) broke data down only by “Caucasian” and “other”.

#### ***4.2.4.3 Mean years since most recent assault; other assault characteristics***

Data on mean length of time since the “index” or most recent rape experienced was collected for all participants but was presented in different ways. Means and standard deviations per study were as follows: 6.2 years (SD 6.7) for Foa 1991; 5.2 years (SD 7.7) for Resick 1988; 6.4 years (SD 6.9) for Resick 1992; 8.5 years (SD 8.5) for Resick 2002 and 5.2 years (SD 4.45) for the intervention group and 13 years (SD 8.9) in the control condition for Rothbaum 1997. Mean time since assault in months varied between treatment groups in the most recent trial (Rothbaum 2005) (EMDR: 145.9, SD 146.8; PE: 120.9, SD 94.1; WAIT: 162.9, SD 136.9). A minority of studies collected data on average numbers of rapes, which was skewed in one case by



repeated episodes of marital rape. Most studies presented data on whether the assailant(s) were strangers or acquainted with the woman; attacks by strangers were in the majority, apart from Rothbaum 2005. Whilst all six studies collected data on assaults within the baseline interview, three presented detailed data on nature of assault (Resick 1988; Foa 1991; Rothbaum 2005) which included data on duration, setting, whether a weapon was used and, in the case of the Foa 1991, how convinced the woman was that her life was under threat. Resick 1988 was the only study presenting data on apprehension, arrests, charges and/or convictions of perpetrators: here, conviction of the perpetrator was recorded in only 12% on cases.

#### **4.2.4.4 Baseline demographics**

All six studies collected data on mean years of education, level of income and occupation of participants; none reported any differences at baseline between groups although these factors were investigated as potential reasons for differential dropout (e.g. in Foa 1991). Information on alcohol and substance abuse was routinely collected at the initial assessments. Several studies excluded participants actively engaged in alternative psychotherapy (with the exception of Rothbaum 1997). Resick 1992 presented detailed data on previous psychotherapy for rape-related distress; Resick 2002 reported that 31% of participants were on psychotropic medication for the duration of the trial.

#### **4.2.4.5 Interventions**

The nature and theoretical underpinnings of most treatment programs, including crucial discussions of the role of exposure and of cognitive therapy, are discussed in the Background (above). Explicit details of treatment programs used in studies included within this review (such as individual session content and overall intensity and duration) can be found in the “Characteristics of Included Studies” tables, below. Only brief details are given here.

In all, six interventions were assessed across the six included studies : Stress Inoculation Training (SIT); Prolonged Exposure (PE); Supportive Counselling or Supportive Psychotherapy (SC or SP); Cognitive Processing Therapy (CPT); Assertiveness Training (AT); and Eye Movement Desensitization and Reprocessing (EMDR).

SIT is a treatment developed in the 1970s (Vernonen 1978). PE was developed by Foa and colleagues. Supportive Counselling was defined in Foa 1991 as the treatment routinely provided by a women’s group (Chapter of Women Organised Against Rape [Philadelphia]). Supportive Psychotherapy was delivered as a non-manualised treatment in which participants interacted and therapists were present largely as facilitators and presenters of information. CPT was developed by Resick &

Schnicke (1993). AT was delivered using both a manual (Lange 1976) and using principles from Rational Emotive Therapy (Ellis, 1977). EMDR was pioneered by Shapiro (1996).

Only one intervention (PE) was examined in three studies. No other intervention was examined in more than two studies. Two of the active interventions were delivered in group sessions in one study and individually in another, making subgroup analysis difficult (SIT was individually delivered in Foa 1991 and group-based in Resick 1988; CPT was individually delivered in Resick 2002 and group-based in Resick 1992). It must be emphasized that for most interventions assessed within this review, the numbers of participants allocated to or completing treatment are too small to allow robust conclusions to be drawn.

- EMDR (delivered individually) was examined in two small RCTs (Rothbaum 1997; with 10 completers in the EMDR arm; Rothbaum 2005; with 20 completers in the EMDR arm);
- Assertiveness Training (group format) was examined in one study (Resick 1988, with 13 completers in the AT arm).
- CPT was examined in two studies: Resick 1992 (group format, with 19 completers) and Resick 2002 (delivered individually, with 62 in the ITT sample);
- PE was examined in three studies (Foa 1991; Resick 2002; Rothbaum 2005; delivered individually, combined  $n = 92$ );
- SIT was examined in two studies (Foa 1991 (delivered individually),  $n = 14$  and Resick 1988 (group format),  $n = 12$ );
- Supportive Counselling/Supportive Psychotherapy were delivered in one study each (Resick 1988 (group format) and Foa 1991 (delivered individually)).

The duration and intensity of the treatment varied considerably between studies. The shortest therapeutic period was that used by Rothbaum in delivering EMDR (4 weeks of 1 session per week); the longest was by Resick 2002, with one introductory session followed by 12 x 90 minute sessions over 12 weeks. Data from post-treatment follow-up were not available for this review as the use of a WLC means that any follow-up data will, by definition, lack a control condition. We note, however, that each study considered at a minimum outcomes at three months (Foa 1991; Rothbaum 1997). Three studies additionally assessed outcomes at six months (Resick 1988; Resick 1992; Rothbaum 2005). Resick 2002 followed up at three and

nine months, and subsequently at intervals of between five and ten years (Resick 2011).

Because relatively few studies have been published prior to completion of our searches (April 2011) and the investigator communities are currently small and overlapping, the six included studies can usefully be seen as part of the “dialogues” underpinning research in the field more generally. As study succeeds study, efforts are made to correct previous compromising features of design or treatment content. Thus, the three most recent studies are RCTs and the trend is one of increasing sample size. The largest trial in the review (Resick 2002) also uses intention-to-treat analysis, and addresses at least two major issues considered contentious in previous studies. For example, authors of Foa 1991 commented that a weakness of Resick 1988 was that elements of exposure “overlapped” between treatment groups. The investigators subsequently addressed this by explicitly attempting to ensure that potential contamination between the key interventions (PE and CPT) were minimized by making “an effort not to introduce casual cognitive therapy” in the PE protocol or to conduct prolonged ...exposures in the CPT protocol” (Resick 2002, p. 868).

Each of the six included studies reported rigorous attempts to ensure treatment integrity and fidelity. In two cases (Foa 1991; Resick 1992) the treatments under investigation had not been manualised at the time the studies were undertaken, however, and the involvement by the program developer in those studies (and indeed all with the exception of Rothbaum 1997) should be noted. One consequence is that this review lacks evidence on CPT which does not derive directly from studies conducted by the program developer, although this is likely to be addressed in research currently in progress (see Table of Ongoing studies).

#### **4.2.4.6 Outcomes**

Three primary outcomes were assessed in the six included studies: post traumatic stress symptoms, depression symptoms and anxiety symptoms.

#### **4.2.4.7 Post-Traumatic Stress (PTSD) symptoms**

The measures commonly used to assess PTSD symptoms in research and clinical practice (Keene, Weathers & Foa, 2000; Stamm, 1996) can be divided into those that are clinician rated and those that are by self-report.

##### *Clinician administered PTSD Measures*

Four studies used clinician administered PTSD scales. Foa 1991 used the PTSD Symptom Scale Interview (PSS-I; Foa, Riggs, Dancu and Rothbaum, 1993) which was in development at the time of their study. This scale was subsequently used by Rothbaum 1997 and has good reported reliability and validity. Resick 2002 and Rothbaum 2005 used the Clinician Administered PTSD Scale (CAPS, Blake, et al,

1995). This measure developed by the US National Center for PTSD is designed for use by experienced clinicians and has been described as an exceptionally strong measure for classifying PTSD (Keene, Weathers & Foa, 2000).

#### *Self-reported PTSD Measures*

All six included studies used self-report measures to assess PTSD symptoms. Resick 1988, Resick 1992 and Rothbaum 1997 used the Impact of Event Scale (IES, Horowitz, Wilner and Alvarez, 1979) and Rothbaum 2005 used the revised version (IES-R, Weiss & Marmar, 1997). The original IES contained two of the symptom clusters required for a diagnosis of PTSD (intrusion and avoidance) while the revised version added hyperarousal, the third symptom cluster. These two versions of the IES have been used in hundreds of studies addressing trauma and thus provide excellent opportunities for comparison across populations. The PTSD Symptom Scale –Self Report (PSS-SR) was used in three studies (Foa, 1991; Resick, 2002; Rothbaum, 2005), In addition, Resick 1992 used the SCL-90 (Derogatis 1977) and Foa 1991 used the Rape Aftermath Symptom Test (RAST, Kilpatrick, 1988).

#### **4.2.4.8 Depression symptoms**

All six studies assessed depression using self-report measures. Five (Foa, 1991; Resick, 1992; 2002; Rothbaum 1997; 2005) used the Beck Depression Inventory (BDI, Beck et al, 1961) and one (Resick 1988) used the depression subscale of the SCL-90 (Derogatis, 1977). The Beck Depression Inventory assesses the presence and severity of affective, cognitive, motivational, vegetative and psychomotor components of depression.

#### **4.2.4.9 Anxiety symptoms**

Self-reported anxiety symptoms were assessed using the State Trait Anxiety Inventory (STAI, Spielberger 1993) in three studies (Foa 1991; Rothbaum 1997; and Rothbaum, 2005). The STAI is widely used as a research measure, has good reliability and validity, and is sensitive to change (Spielberger 1993). Resick 1998 used an adapted version of the SCL-90.

#### **4.2.4.10 Additional outcome measures**

*Guilt* – reported by Resick 2002 using the Trauma- Related Guilt Inventory (TRGI, Kubany et al, 1996, which includes subscales addressing guilt cognitions).

*Dissociation* – reported by Rothbaum 1997 and Rothbaum 2005 using the Dissociative Experiences Scale (DES, Bernstein 1986).

*Fear* – reported by Resick 1988 using the Modified Fear Scale (Veronin 1980).

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### **4.3 EXCLUDED STUDIES**

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Forty four titles were excluded. Six of the articles were not primary studies (reviews of the literature, conceptual papers); eight studies included non-sexual assault victims of trauma (in combination with adult victims of sexual assault and rape but did not include specific results based on types of trauma); seven studies included child victims under 18 years of age or combined samples that were either adult victims of rape or child victims of sexual abuse; fourteen studies did not have a control group (within group design, single system design or longitudinal); two studies did not include measures specific to trauma or distress; two studies used samples that had been victims of sexual assault and rape 72 hours prior to being included in the intervention; one study had a sample focused on borderline personalities; one study was qualitative; one study used non-equivalent groups (completers vs. non completers). During the data extraction phase, four studies were excluded based on the participants not meeting the inclusion criteria (total excluded n = 46). Two studies (Resick 1988; Rothbaum 2005) were subsequently reassigned to included status following review of the excluded tables and contact with primary authors. Details of excluded studies can be found in Table 8.2 and in Figure 1.

#### **4.3.1 Studies awaiting classification**

No studies have been identified for this category.

#### **4.3.2 Ongoing studies**

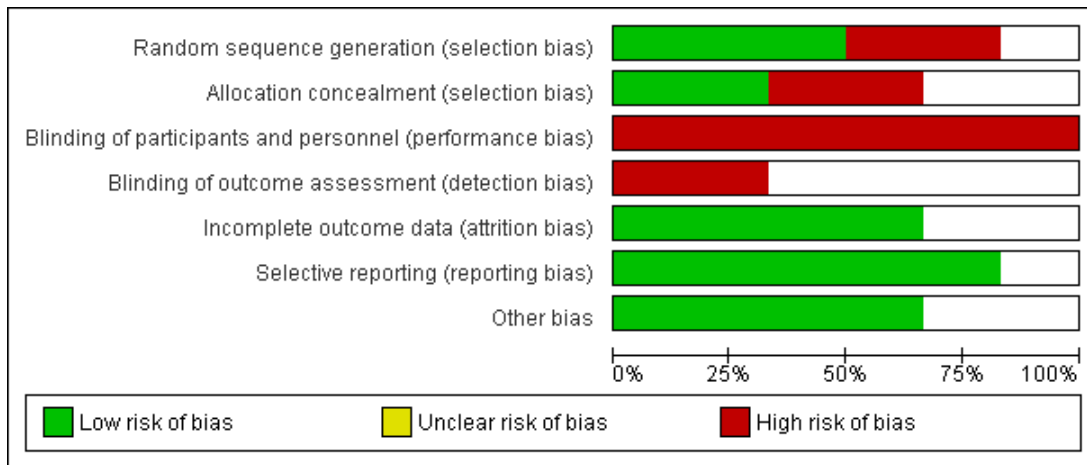
A total of four RCTs are currently registered that may contribute to future updates of this review. These are listed in section 9.2. Three of these (Galovski, Galovski, and Smith) are investigating the effectiveness of CPT with women who have experienced either physical or sexual violence. If a population of women who have experienced rape or sexual assault can be extracted, this would contribute to future updates of this review. The most promising study is that of Suris in which CPT is being evaluated as a means for reducing PTSD in victims of military sexual trauma.

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### **4.4 RISK OF BIAS IN INCLUDED STUDIES**

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We assessed the risk of bias in the six included studies following categories recommended in the Cochrane Handbook (Higgins 2008; 2011). Details of judgments are given in the Tables of Risk of Bias (below) and summarised in following graph.



#### 4.4.1 Sequence generation

The risk of bias was judged as high in two cases (Resick 1988; Resick 1992); the former employed alternate allocation for the active interventions and used a “naturally occurring” control group, and in the latter the formation of the control group was by collecting data from women who remained on a waiting list at the center for six weeks (a procedure of which the investigators themselves are highly critical).

Of the four trials claiming random assignment (Foa 1991; Resick 2002; Rothbaum 1997; Rothbaum 2005), no method is reported in the published papers; however, personal contact with primary investigators of each established that three studies employed random numbers tables and the fourth made use of a computerized random numbers generator. The latter three studies were judged as being at low risk of bias, but the former (Foa 1991) was rated as “unclear” due to an anomaly of the allocation process by which assignment of women to the control group was capped at ten participants.

#### 4.4.2 Allocation sequence concealment

For reasons described above, allocation was not concealed for Resick 1988 nor for Resick 1992. No method of allocation concealment was reported in any of the RCTs but personal correspondence with investigators resulted in a rating of low risk of bias for Resick 2002 where sealed numbered packets were used; of low risk of bias for Foa 1991 where the allocator was not aware of the randomization schedule (Foa 2012); and of ‘unclear’ for Rothbaum 1997 and Rothbaum 2005.

#### 4.4.3 Blinding of participants, personnel and outcome assessment

Blinding of participants or therapists involved in receiving or delivering psychological interventions is by definition impossible and all such trials are therefore at high risk of bias on this criterion. It can be argued that this increases the importance of blinding of outcome assessors where possible.

The risk of bias for both quasi-experimental studies (Resick 1988 and Resick 1992) was judged high on this criterion. All outcomes were by self-report in the older

study; most were by self-report in the latter and those which were not were only assessed by independent assessors in 8/19 cases in the active treatment arm; the rest of participants were assessed by their own therapists.

Blinding of outcome assessment was judged to be adequate for the primary outcome (PTSD symptoms) in all the included RCTs (Foa 1991; Resick 2002; Rothbaum 1997; Rothbaum 2005); the remaining outcomes were by self-report, yielding an assessment of 'unclear' risk of bias for these latter studies.

#### **4.4.4 Incomplete outcome data**

Investigators were rigorous in documenting dropouts from all studies and in several cases detailed assessments were made to compare the baseline characteristics of those leaving the study with those remaining. Only one study (Foa 1991) found a notable difference (those with lower incomes and working in "blue collar" jobs were more likely to leave treatment).

Rate of dropout varied between 14% to 30%. We assessed risk of bias to the results of this review on factors that included the evenness of distribution of dropout and the analytic method (e.g., intention to treat analysis).

In one study (Rothbaum 1997), 3/21 (14%) participants left the study early, but an assessment of low risk of bias was made as they departed prior to the start of intervention. The risk of bias in Resick 1988 and Rothbaum 2005 (where dropout was 14% and 18% respectively during the course of the trial but was evenly distributed between groups) was also judged as low, given that many of those participants in the former study who were labeled as dropouts and excluded from analysis were often excluded because they missed only two sessions and so might have been included in analysis in other studies. Conversely, the dropout in Resick 1992 occurred solely in the intervention arm (14%) and the uncertain relationship between those missing data and those of possibly noncontemporaneous allocation of the waiting list led to a judgment of "unclear" risk of bias.

The rate of dropout was highest (30%) in the study involving the greatest intensity and the longest duration of treatment (Resick 2002, which lasted three months and involved 13 sessions of which 12 consisted of 90 minutes of individual therapy). This study was assessed as low risk of bias for this criterion nonetheless, because of the investigators' use of an appropriate method of intention-to-treat analysis (last observation carried forward [LOCF]) which allowed us to use ITT sample data for our main analyses.

#### **4.4.5 Selective outcome reporting**

The trial protocol was available for only one included study (Resick 2002); nevertheless we judged the five of the included studies as being at a low risk of bias because all reasonable outcomes (including those prespecified in the published papers) appeared to be reported. Resick 1992 was assessed as at 'unclear' risk of

bias, given that results are reported for only two of the many measures used. Investigators report that “because the battery of instruments has changed over the past 5 years, the only measure that all of the comparison subjects and CPT subjects had in common was the SCL-90-R” (the figure of five years casting a further shadow over the comparability of participants in this nonrandomized trial).

#### **4.4.6 Other potential threats to validity**

We note that the six included studies were all conducted by overlapping sets of investigators, using interventions and even outcome measures developed by these same investigators (who were often, especially in earlier studies, intimately involved in training and supervision of those delivering treatment and also, delivering treatment themselves). This is both an indicator of the investigators’ commitment to this population and its wellbeing, and a potential source of bias that must be confronted in any assessment of evidence. The current ongoing research summarized in Section 9.2 may resolve this potential source of bias.

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## **4.5 EFFECTS OF THE INTERVENTIONS**

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Outcomes are reported in the order listed in the protocol. Results of meta-analysis of randomized controlled trials are presented separately from those of quasi-randomized studies.

The protocol for this review permitted comparisons between eligible treatments and no-treatment or waitlist control, and plans were made to assess long-term follow-up; however, as all studies which met inclusion criteria made use of a waitlist control group, all results are restricted to those available at the “end of treatment”.

Our primary analyses concern the effects of all psychological treatments versus none, as specified in the protocol.

The dataset is not yet sufficient to warrant true network analysis, but we present a number of subgroup analyses of results from RCTs of the most clinically relevant interventions (PE, EMDR and CPT). These we interpret with caution and with the benefit of statistical advice on the independence of data in multi-armed trials (Valentine 2012; Higgins 2012a; Higgins 2012b). Whilst acknowledging our methods are not ideal, we are aware that relative efficacy is of interest to this field and believe that this partially justifies our approach. We anticipate that in updated versions of this review there will be sufficient trials to conduct such a network meta-analysis in which direct and indirect comparisons will be made simultaneously (see Figure 2).

Outcomes are presented by comparison, grouped in the following order:



### **1. All treatments versus waitlist control (RCTs only)**

As planned in the protocol, effects of all treatments versus control were pooled to obtain overall estimates of effects on prespecified outcomes. Four RCTs (Foa et al 1991; Resick 2002; Rothbaum 1997 and Rothbaum 2005) yielded data suitable for meta-analysis for this comparison.

### **2. All treatments versus waitlist control (quasi-randomized trials only)**

Again, effects of all treatments versus control were pooled to obtain overall estimates of effects on prespecified outcomes. Two quasi-randomized studies contributed data for this comparison (Resick 1988 and Resick 1992).

### **3. Prolonged exposure (PE) versus waitlist control (RCT only)**

Three RCTs (Foa 1991, Resick 2002 and Rothbaum 2005) contributed data to this comparison. Where studies comprised more than one relevant active treatment arm against waitlist control (for example, Resick 2002) the number of the control group was divided in this and subsequent subgroup comparisons in order to mitigate the risk of inflated precision. In future updates of this review, we anticipate network analyses will replace these analyses.

### **4. Eye movement reprocessing (EMDR) versus waitlist control (RCT only)**

Two RCTs contributed data to this comparison (Rothbaum 1997 and Rothbaum 2005). Where studies comprised more than one relevant active treatment arm against waitlist control (for example, Rothbaum 2005) the number of the control group was divided in this and subsequent subgroup comparisons in order to mitigate the risk of inflated precision (see above).

### **5. Cognitive processing therapy (CPT) versus waitlist control (RCT only)**

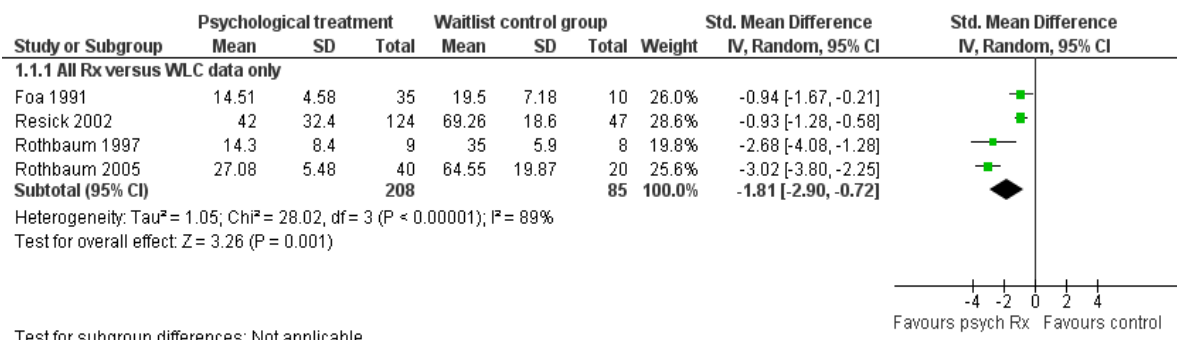
One RCT (Resick 2002) contributed data to this comparison. The number of the control group was reduced as described above to permit this analysis.

## 4.5.1 Results

### 1. All treatments versus waitlist control (RCTs only)

#### 1.1 PTSD symptoms (clinician assessed, totals)

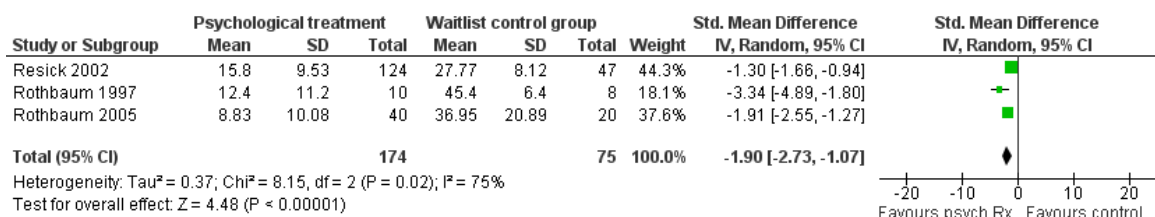
##### Analysis 1.1



Four studies (Foa 1991; Resick 2002; Rothbaum 1997; Rothbaum 2005) (combined n = 293) contribute data to a pooled analysis for the outcome of PTSD symptoms as measured by blinded independent assessor. Results are significant for treatment against WLC (SMD -1.81, 95% CI -2.90 to -0.72). Heterogeneity as assessed by the I<sup>2</sup> statistic is considerable (89%).

#### 1.2 PTSD symptoms (self-report measures, totals)

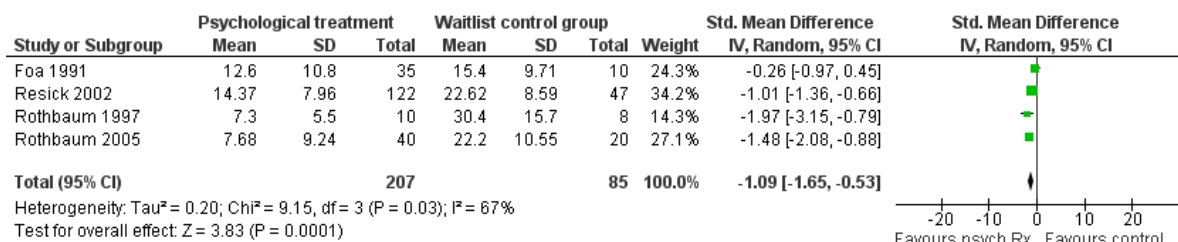
##### Analysis 1.2



Three studies (Resick 2002; Rothbaum 1997; Rothbaum 2005) (combined n = 249) contribute data to a pooled analysis for the outcome of PTSD symptoms as measured by self-report. Results are significant for treatment against WLC (SMD -1.9, 95% CI -2.73 to -1.07). Heterogeneity as assessed by the I<sup>2</sup> statistic is substantial (75%).

### 1.3 Depression symptoms (BDI)

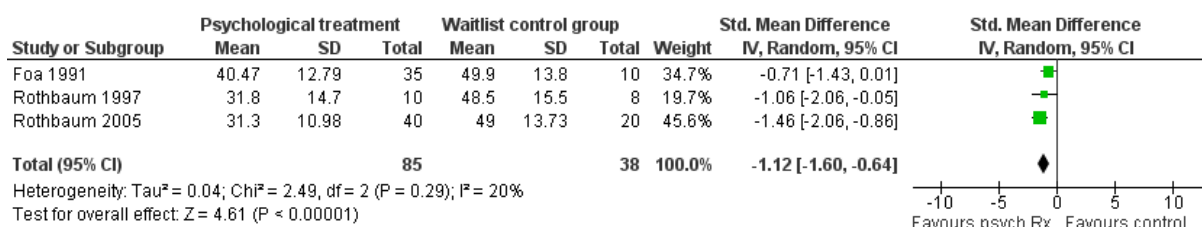
#### Analysis 1.3



Four studies (Foa 1991; Resick 2002; Rothbaum 1997; Rothbaum 2005) (combined n = 292) contribute data to a pooled analysis for the outcome of depression symptoms (self-report). Results are significant for treatment against WLC (SMD -1.09, 95% CI -1.65 to -0.53). Heterogeneity as assessed by the I<sup>2</sup> statistic is substantial (67%).

### 1.4 Anxiety (state)

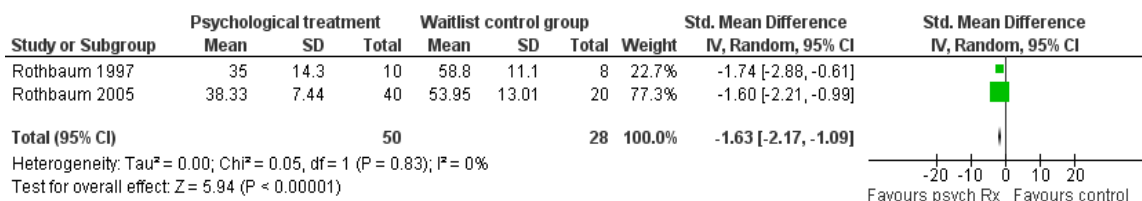
#### Analysis 1.4



Three studies (Resick 2002; Rothbaum 1997; Rothbaum 2005) (combined n = 123) contribute data to a pooled analysis for the symptoms as measured by self-report. Results are significant for treatment against WLC (SMD -1.12, 95% CI -1.60 to -0.64). Heterogeneity as assessed by the I<sup>2</sup> statistic is small (20%).

### 1.5 Anxiety (trait)

#### Analysis 1.5



Only two studies (Rothbaum 1997; Rothbaum 2005) (combined n = 78) measured anxiety as a trait. Results of pooled analysis are significant for treatment against WLC (SMD -1.63, 95% CI -2.17 to -1.09). Heterogeneity as assessed by the I<sup>2</sup> statistic is negligible (0%).

## 1.6 Guilt (TRGI: total)

### Analysis 1.6

Study or Subgroup	Psychological treatment			Waitlist control group			Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Resick 2002	1.55	1.15	123	2.33	1.06	39	100.0%	-0.69 [-1.06, -0.32]	
<b>Total (95% CI)</b>			<b>123</b>			<b>39</b>	<b>100.0%</b>	<b>-0.69 [-1.06, -0.32]</b>	

Heterogeneity: Not applicable  
Test for overall effect: Z = 3.66 (P = 0.0003)

One study (Resick 2002) reported data for guilt as measured by total scores on the TRGI (n = 164). Results of pooled analysis combining data from both active treatment groups are significant for treatment against a waitlist control (SMD -0.69, 95% CI -1.06 to -0.32).

## 1.7 Guilt (TRGI: hindsight bias subscale)

### Analysis 1.7

Study or Subgroup	Psychological treatment			Waitlist control group			Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Resick 2002	1.25	1.2	123	1.98	1.08	39	100.0%	-0.62 [-0.99, -0.25]	
<b>Total (95% CI)</b>			<b>123</b>			<b>39</b>	<b>100.0%</b>	<b>-0.62 [-0.99, -0.25]</b>	

Heterogeneity: Not applicable  
Test for overall effect: Z = 3.31 (P = 0.0009)

One study (Resick 2002) reported data for guilt as measured by the hindsight bias subscale on the TRGI (n = 164). Results of pooled analysis combining data from both active treatment groups are significant for treatment against a waitlist control (SMD -0.62, 95% CI -0.99 to -0.25).

## 1.8 Guilt (TGI: wrongdoing subscale)

### Analysis 1.8

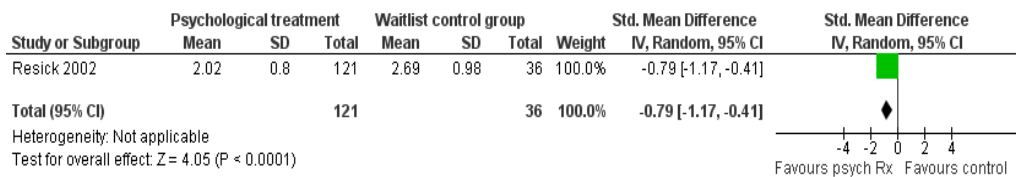
Study or Subgroup	Psychological treatment			Waitlist control group			Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Resick 2002	1.33	0.7	119	1.9	1.06	36	100.0%	-0.71 [-1.09, -0.33]	
<b>Total (95% CI)</b>			<b>119</b>			<b>36</b>	<b>100.0%</b>	<b>-0.71 [-1.09, -0.33]</b>	

Heterogeneity: Not applicable  
Test for overall effect: Z = 3.66 (P = 0.0003)

One study (Resick 2002) reported data for guilt as measured by the sense of wrongdoing subscale on the TRGI (n = 164). Results of pooled analysis combining data from both active treatment groups are significant for treatment against a waitlist control (SMD -0.71, 95% CI -1.09 to -0.33).

## 1.9 Guilt (TRGI : lack of justification subscale)

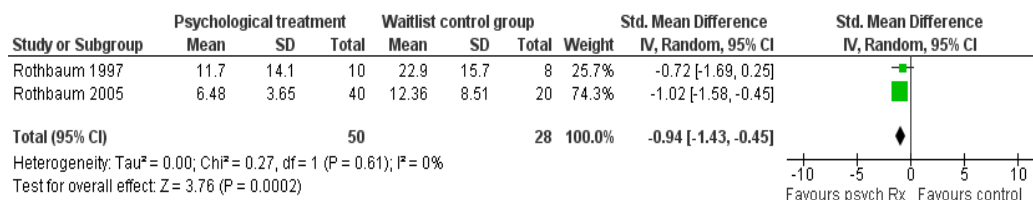
### Analysis 1.9



One study (Resick 2002) reported data for guilt as measured by the lack of justification subscale on the TRGI (n = 164). Results of pooled analysis combining data from both active treatment groups are significant for treatment against a waitlist control (SMD -0.79, 95% CI -1.17 to -0.41).

## 1.10 Dissociation symptoms (DES)

### Analysis 1.10

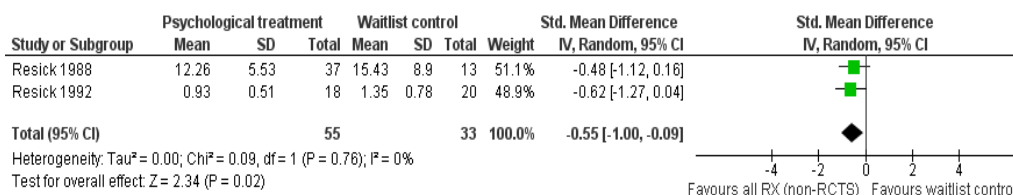


Only two studies (Rothbaum 1997; Rothbaum 2005) (combined n = 78) measured anxiety as a trait. Results of pooled analysis combining data from both active treatment groups are significant for treatment against a waitlist control (SMD -0.94, 95% CI -1.43 to -0.45) with no statistical heterogeneity (I<sup>2</sup> = 0%).

## 2. All treatments versus waitlist control (quasi-RCTs only)

### 2.1 PTSD symptoms (self-report only, combination of IES scale and the SCL-90)

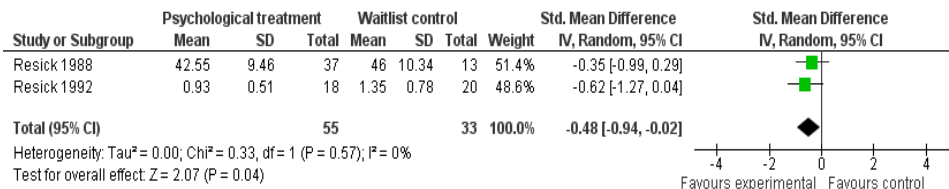
#### Analysis 2.1



Both studies of quasi-randomised design (Resick 1988 and Resick 1992, combined n = 88) contributed PTSD self-report data suitable for meta-analysis. Results are significant. Heterogeneity as assessed by the I<sup>2</sup> statistic is considerable (SMD -0.55, 95% CI -1.00 to 0.09; (I<sup>2</sup> = 76%).

## 2.2 Depression symptoms (as measured by the PSS)

### Analysis 2.2

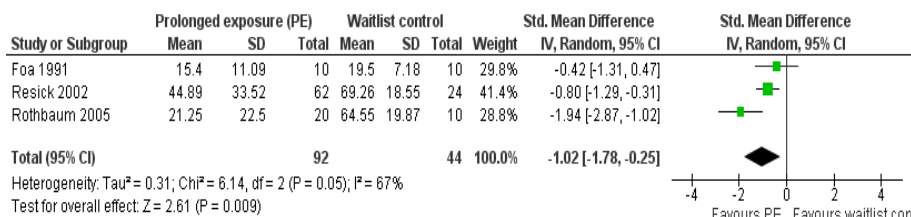


Both studies of quasi-randomised design (Resick 1988 and Resick 1992, combined n = 88) contributed self-report data for depression which were suitable for meta-analysis. Results are significant, with negligible statistical heterogeneity (SMD -0.48, 95% CI -0.94 to -0.02, I<sup>2</sup> = 0%).

## 3. Prolonged exposure (PE) versus waitlist control (RCT data only)

### 3.1. PTSD symptoms (clinician assessed)

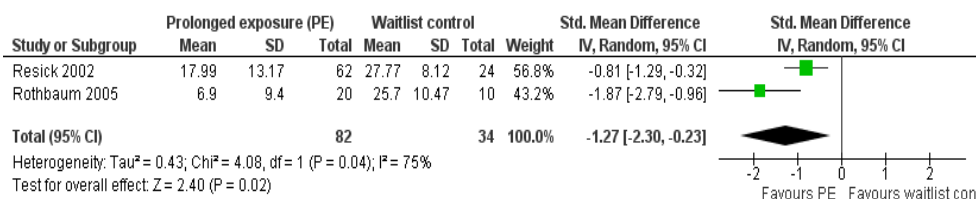
#### Analysis 3.1



Three studies contributed data to a comparison of the effects of Prolonged Exposure (PE) versus control on objective measures of PTSD. Results were significant (SMD -1.02, 95% CI -1.78 to -0.25). Heterogeneity as assessed by the I<sup>2</sup> statistic is substantial (I<sup>2</sup> = 67%).

### 3.2 PTSD symptoms (self-report measures)

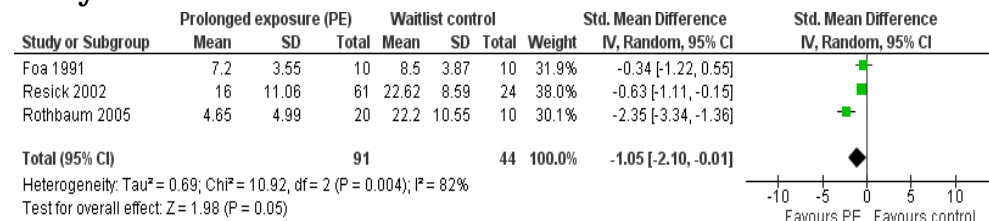
#### Analysis 3.2



Two of the studies assessing effects of PE measured PTSD by self-report. Pooled results show significant effects. Heterogeneity as assessed by the I<sup>2</sup> statistic is substantial (SMD -1.27; 95% CI -2.30 to -0.23, I<sup>2</sup> = 75%).

### 3.3 Depression symptoms (BDI)

#### Analysis 3.3

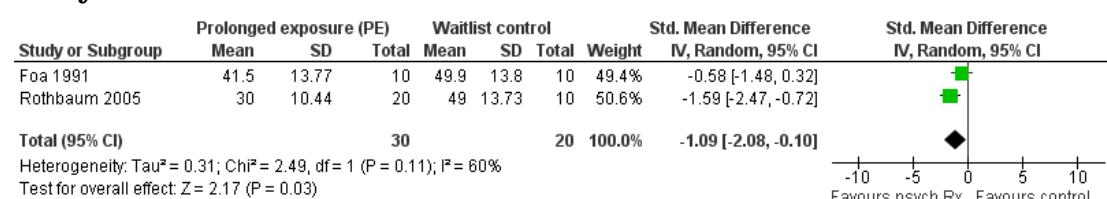


All three studies assessing the effects of PE measured depression using the BDI. Results are significant (SMD -1.05, 95% CI -2.10 to -0.01).

Heterogeneity as assessed by the I<sup>2</sup> statistic is considerable (I<sup>2</sup> = 82%).

### 3.4 Anxiety (state) symptoms

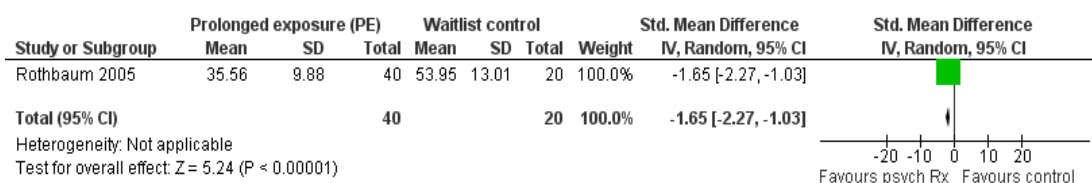
#### Analysis 3.4



Two studies assessing the effects of PE measured anxiety (state). Results are significant (SMD -1.09, 95% CI -2.08 to 0.10). Heterogeneity as assessed by the I<sup>2</sup> statistic is substantial (I<sup>2</sup> = 60%).

### 3.5 Anxiety (trait) symptoms

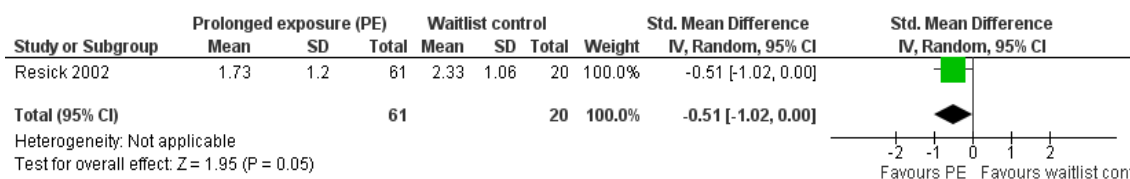
#### Analysis 3.5 (single study results)



One study (n = 60) compared PE versus WLC (Rothbaum 2005) for the outcome of anxiety (trait). Results are significant (SMD -1.65, 95% CI -2.27 to -1.03).

### 3.6 Guilt (TRGI: total)

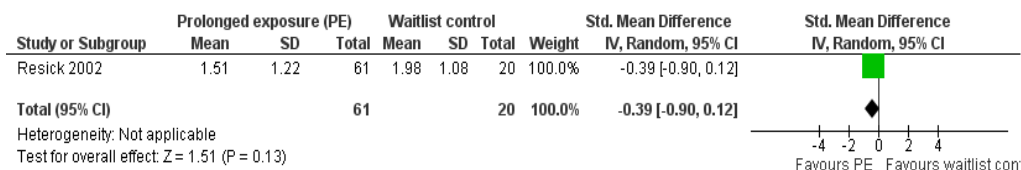
#### Analysis 3.6 (single study results)



One study (n = 81) compared PE versus WLC (Resick 2002) for the outcome of guilt (as measured by the TGRI: total score). Results are significant (SMD -0.51, 95% CI -1.02 to -0.00).

### 3.7 Guilt (TRGI: hindsight bias subscale)

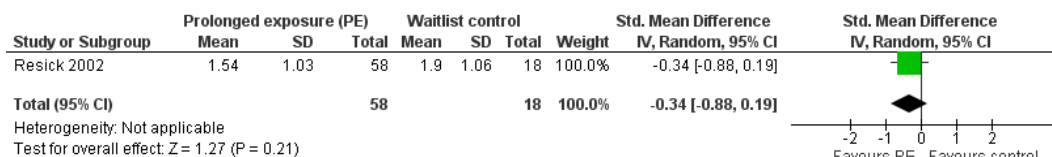
#### Analysis 3.7 (single study results)



One study (n = 81) compared PE versus WLC (Resick 2002) for the outcome of guilt/ hindsight bias (TGRI: subscale). Results are not significant (SMD -0.39, 95% CI -0.90 to -0.12).

### 3.8 Guilt (TGI: wrongdoing subscale)

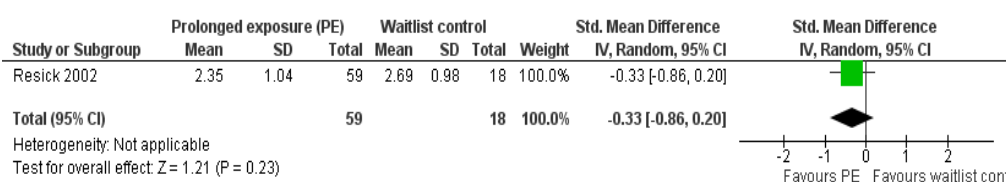
#### Analysis 3.8 (single study results)



OnOne study (n = 76) compared PE versus WLC (Resick 2002) for the outcome of guilt/ wrongdoing (TGRI: subscale). Results are not significant (SMD -0.34, 95% CI -0.88 to 0.19).

### 3.9 Guilt (TRGI : lack of justification subscale)

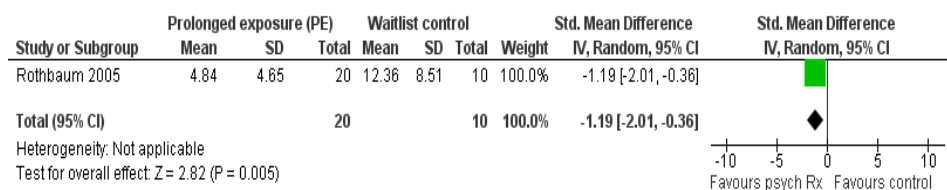
#### Analysis 3.9 (single study results)



One study (n = 77) compared PE versus WLC (Resick 2002) for the outcome of guilt/ lack of justification (TGRI: subscale). Results are not significant (SMD -0.33, 95% CI -0.86 to 0.20).

### 3.10 Dissociation symptoms (DES)

#### Analysis 3.10 (single study results)



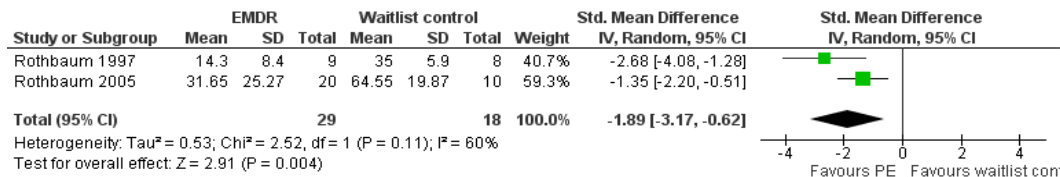


One study (n = 60) compared PE versus WLC (Rothbaum 2005) for the outcome of anxiety (trait). Results are significant (SMD -1.19, 95% CI -1.19 to -0.36).

#### 4. Eye movement reprocessing (EMDR) versus waitlist control (RCT data only)

##### 4.1. PTSD symptoms (clinician assessed)

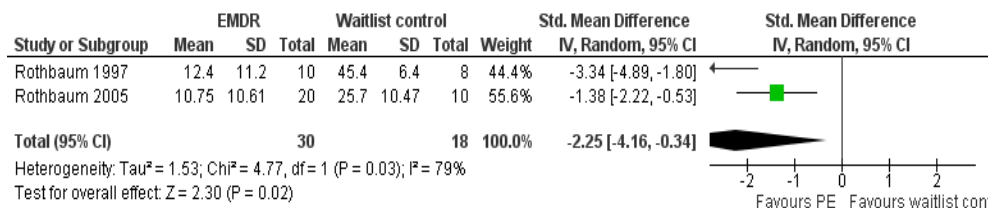
###### Analysis 4.1



Two studies conducted by the same group of researchers (n = 47) assessed the effects of EMDR versus waitlist control. Studies found highly significant effects for PTSD as measured by clinicians for EMDR versus control (SMD -1.89, 95% CI -3.17 to -0.62) Heterogeneity as assessed by the I<sup>2</sup> statistic is substantial (I<sup>2</sup> = 60%).

##### 4.2 PTSD symptoms (self-report measures, totals)

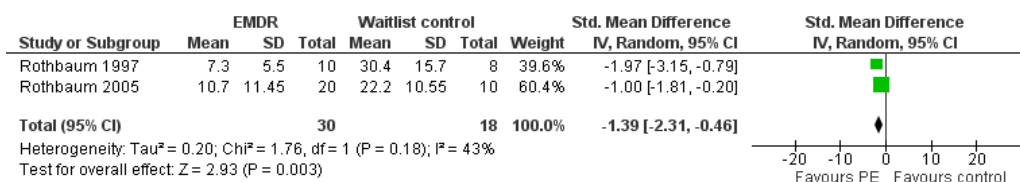
###### Analysis 4.2



As above — two studies including data from 48 participants found highly significant results for EMDR versus control for the outcome of PTSD as measured by self-report (SMD -2.25, 95% CI -4.16 to -0.34). Heterogeneity as assessed by the I<sup>2</sup> statistic is considerable (I<sup>2</sup> = 79%).

### 4.3 Depression symptoms (BDI)

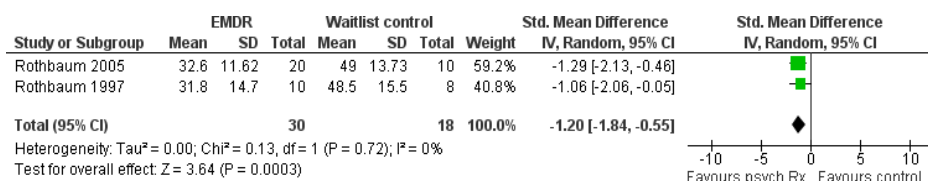
#### Analysis 4.3



As above — two studies including data from 48 participants found significant results for EMDR versus control for depression as measured by the BDI (SMD -1.39, 95% CI -2.31 to -0.46). Heterogeneity as assessed by the I<sup>2</sup> statistic is moderate (I<sup>2</sup> = 43%).

### 4.4 Anxiety (state) symptoms

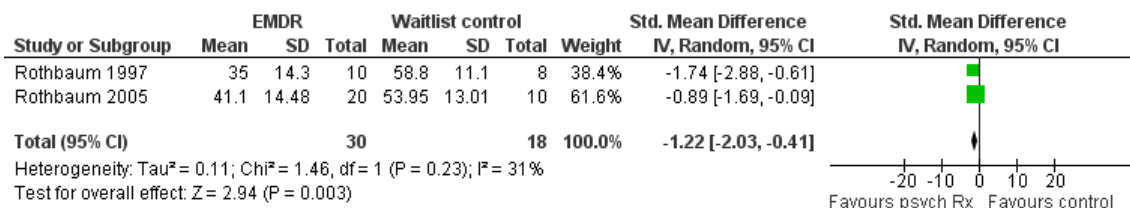
#### Analysis 4.4



As above — two studies including data from 48 participants found significant results for EMDR versus control for anxiety (state) (SMD -1.20, 95% CI -1.84 to -0.55). Heterogeneity as assessed by the I<sup>2</sup> statistic is negligible.

### 4.5 Anxiety (trait) symptoms

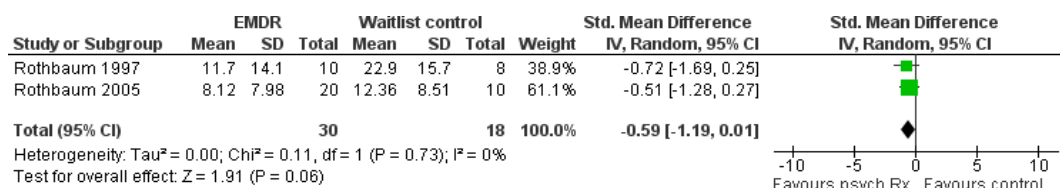
#### Analysis 4.5



Two studies including data from 48 participants found significant results for EMDR versus control for anxiety (trait) (SMD -1.22, 95% CI -2.03 to -0.42). Heterogeneity as assessed by the I<sup>2</sup> statistic is relatively low (I<sup>2</sup> = 31%).

## 4.6 Dissociation symptoms (DES)

### Analysis 4.6

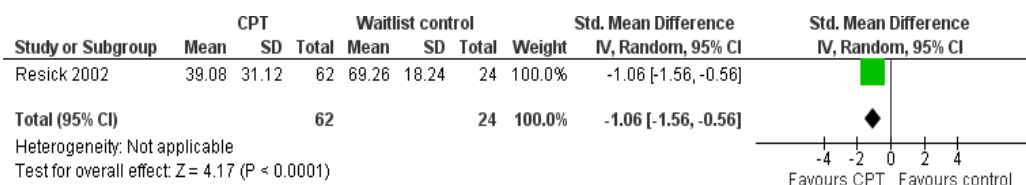


Two studies including data from 48 participants found significant results for EMDR versus control for dissociation as measured by the DES (SMD -0.59, 95% CI -1.19 to -0.01) with no apparent heterogeneity (I<sup>2</sup> = 0%).

## 5. Cognitive processing therapy (CPT) versus waitlist control (RCT data only)

### 5.1. PTSD symptoms (clinician assessed, PSS) (single study results)

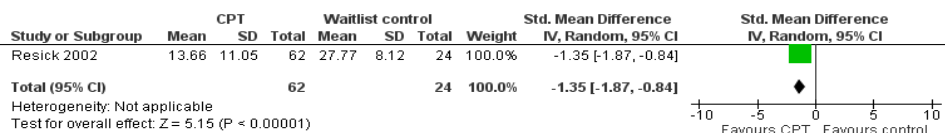
#### Analysis 5.1



One study (n = 86) compared CPT versus WLC (Resick 2002) for the outcome of PTSD as measured by the PSS (clinician form). Results are significant (SMD -1.06, 95% CI -1.56 to 0.56).

### 5.2 PTSD symptoms (self-report measures, PSS) (single study results)

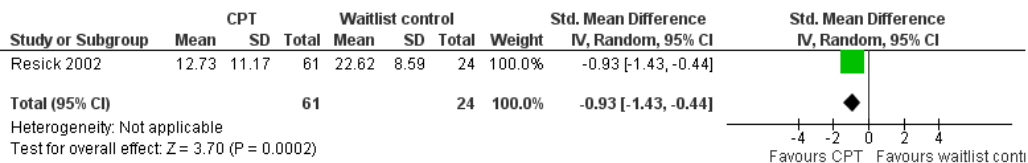
#### Analysis 5.2



One study (n = 86) compared CPT versus WLC (Resick 2002) for the outcome of PTSD as measured by the PSS (self-report). Results are significant (SMD -1.35, 95% CI -1.87 to 0.84).

### 5.3 Depression symptoms (BDI) (single study results)

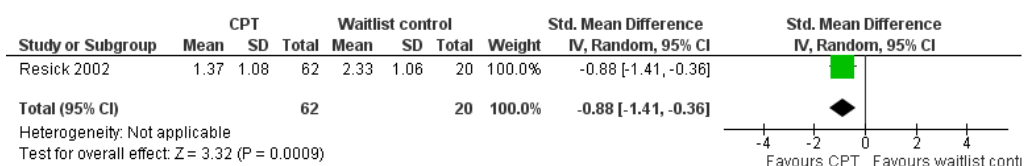
#### Analysis 5.3



One study (n = 85) compared CPT versus WLC (Resick 2002) for the outcome of depression as measured by the BDI. Results are significant (SMD -0.93, 95% CI -1.43 to 0.44).

### 5.4 Guilt (TRGI: total) (single study results)

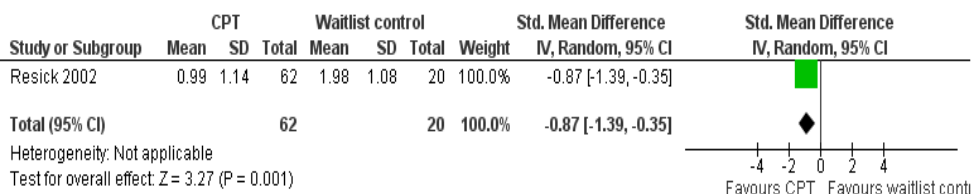
#### Analysis 5.4



One study (n = 82) compared CPT versus WLC (Resick 2002) for the outcome of guilt as measured by the TGRI (total). Results are significant (SMD -0.88, 95% CI -1.41 to 0.36).

### 5.5 Guilt (TRGI: hindsight bias subscale) (single study results)

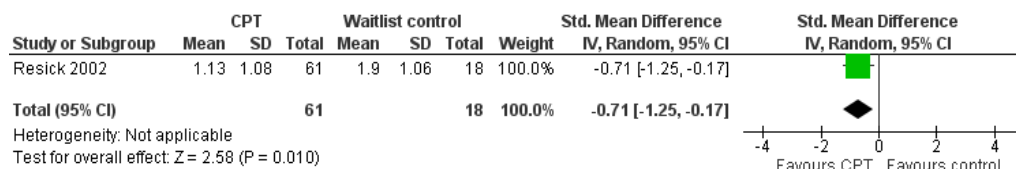
#### Analysis 5.5



One study (n = 82) compared CPT versus WLC (Resick 2002) for the outcome of guilt as measured by the TGRI (hindsight bias subscale). Results are significant (SMD -0.87, 95% CI -1.31 to 0.35).

## 5.6 Guilt (TGI: wrongdoing subscale)

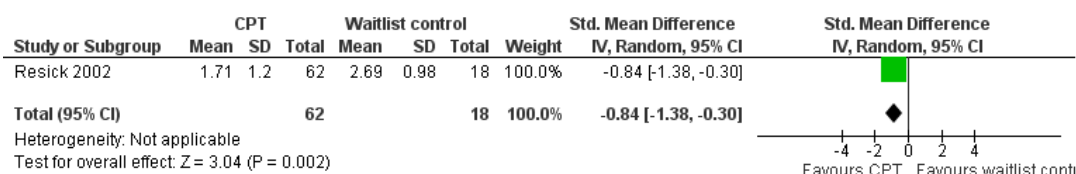
### Analysis 5.6 (single study results)



One study ( $n = 79$ ) compared CPT versus WLC (Resick 2002) for the outcome of guilt as measured by the TGRI (wrongdoing subscale). Results are significant (SMD -0.71, 95% CI -1.25 to 0.17).

## 5.7 Guilt (TRGI : lack of justification subscale)

### Analysis 5.7 (single study results)



One study ( $n = 80$ ) compared CPT versus WLC (Resick 2002) for the outcome of guilt as measured by the TGRI (lack of justification subscale). Results are significant (SMD -0.84, 95% CI -1.38 to 0.30).

## 6. Stress Inoculation Therapy (SIT) versus waitlist control

It was not feasible to pool data from the two small studies which assessed the effects of stress inoculation therapy (Resick 1988 and Foa 1991) as they were of different design. In addition, the intervention is currently less clinically relevant than others examined in this review. We restrict ourselves therefore to a brief narrative account of results.

Resick et al reported that participants ( $n = 12$ ) who received SIT benefitted significantly. SIT was (in common with the other active treatment groups within the review) “effective in producing lasting improvement, particularly with fear and anxiety, in only six therapy sessions” in contrast with a waitlist control condition ( $n = 13$ ) for whose participants “no improvement” was found. None of the three active treatment groups in this small ( $n = 43$ ) quasi-randomised study, was found to be clearly superior to the others (Resick 1988, p. 395).

Foa 1991 found SIT ( $n = 9$ ) to be superior to other treatments, notably PE ( $n = 9$ ), as well as waitlist control, but this effect seemed only to last a short time (until post-treatment). At long-term follow-up, participants who had engaged in PE treatment appeared to have better outcomes (Foa 1991, p. 721).

## **7. Relative effectiveness of the most clinically relevant psychological treatments**

Aware that data for a formal network analysis are not yet sufficient, we present (with great caution) indirect comparisons of the three most clinically relevant interventions assessed by studies included within this review (PE, CPT and EMDR). To calculate indirect comparisons we have taken the difference in pooled SMDs and added their variances (see Figure 2).

Results suggest (for the primary outcome, PTSD) that the difference between effect sizes for CPT and PE overall is slight (SMD -0.04 (-0.95 to 0.87),  $p = 0.93$ ). EMDR appears superior to both CPT (SMD -0.83 (-2.20 to 0.54),  $p = 0.23$ ) and to PE (SMD -0.87 (-2.36 to 0.62)  $p = 0.25$ ). None of these comparisons are significant, and formal network analysis in future will be required using data from newer, larger studies. Important considerations about whether the indirect evidence is clinically comparable and statistically similar to the direct evidence will be taken into account before such analysis is attempted.

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## 5 Discussion

Sexual violence and rape are extremely distressing events experienced by a sizable minority of women across the world (Krug, et al, 2002; Lundgren, 2002; Painter, 1991; Tjaden & Thoennes, 2006). The psychological and social aftermath of sexual violence on individual women includes such pervasive and long lasting effects such as depression, post-traumatic stress and anxiety; social and work adjustment problems; and sexual dysfunction (Burgess and Holstrum, 1974; Resick, 1983; Feeny, Foa, Treadwell and March, 2004). The professional and scholarly literature is replete with interventions aimed at reducing the traumatic aftermath of rape. However, most of this literature focuses on case reflections, descriptive analyses, and uncontrolled studies. Based on this review, it is clear that very few reported studies use rigorous controlled randomized methods to evaluate efficacy of treatments. Yet, given the fact that a proportion of trauma symptoms spontaneously remit in the early stages post-assault (Rothbaum, et al., 1992), controlled studies are required to determine the effectiveness of interventions.

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### 5.1 SUMMARY OF THE MAIN RESULTS

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Six studies, the most recent of which was conducted in 2005, met the inclusion criteria for this review. EMDR was examined in two small RCTs (Rothbaum 1997; Rothbaum 2005); CPT was assessed in two studies (Resick 1992; Resick 2002); PE in three studies (Foa 1991; Resick 2002; Rothbaum 2005; SIT in two studies (Foa 1991; Resick 1988); and Supportive Counselling, Supportive Psychotherapy, and Assertiveness Training were delivered in one study each (Resick 1988; Foa 1991). While this review also sought to investigate and compare the effectiveness of other forms of psychotherapy, in particular psychodynamic therapy, no published or unpublished such studies met the inclusion criteria.

In an analysis pooling the results of the various treatments (both for RCTs and quasi-randomized trials), all six studies demonstrated improvements in PTSD (self-administered (Tables 1.2, 2.1) and four studies clinician-assessed (Table 1.1); six studies demonstrated improvements in depression (Tables 1.3, 2.2); three studies demonstrated improvements in anxiety (Tables 1.4, 1.5); one in guilt (Table 1.6-1.9) and one in dissociation (Table 1.10) when compared with waitlist controls. Pooled analysis of RCTs for PE demonstrated improvements in PTSD (Tables 3.1, 3.2),

depression (Table 3.3), anxiety (Tables 3.4, 3.5), guilt (Tables 3.6-3.9) and dissociation (Table 3.10); EMDR demonstrated improvements in PTSD (Tables 4.1, 4.2), depression (Table 4.3), anxiety (Tables 4.4, 4.5) and dissociation (Table 4.6); CPT demonstrated improvements in PTSD (Tables 5.2, 5.2), depression (Table 5.3) and guilt (Table 5.4-5.7).

Dropout rates are an issue to be considered in the interpretation of results. Resick 1988 and Rothbaum 2005 reported dropout rates of 14% and 18% respectively, but evenly distributed between conditions. While Resick 1992 also reported a dropout rate of 14%, this occurred solely in the intervention arm. Most concerning was the 30% dropout rate reported by Resick 2002 for CPT, the intervention delivered with the greatest intensity and the longest duration of any included within the review.

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## **5.2 OVERALL COMPLETENESS AND APPLICABILITY OF EVIDENCE**

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This systematic review yielded only six studies of interventions with adult victims of rape or sexual assault. In part the scarcity of studies may be a result of the nature of sexual violence itself. Large national studies in the US suggest that only 19% - 39% of sexual assault crimes are reported to police (Tjaden & Thoennes, 2006; U.S. Department of Justice, 2002). A number of factors including guilt, fear of retribution, humiliation, lack of knowledge and trust in the legal and medical system contribute to underreporting and reluctance to seek medical or mental health treatment following rape and sexual assault (Burgess, Fehder, & Hartman, 1995; Burgess, Regehr & Roberts, 2012). For those individuals who seek treatment, services are often limited and waiting lists may deter many of those needing immediate help. Further challenges to conducting research in this field are that dropout rates from treatment tend to be high and that many of the services provided are through community-based agencies that do not attract research grant funding. There are also ethical concerns regarding excluding those in acute need from available interventions or deferring interventions in waitlist conditions.

Nevertheless, it is imperative that future effectiveness studies specifically include adult victims of sexual assault and rape, given the unique factors and considerations for this population that are differentiated from other forms of traumatic events. Once a sufficient number of studies are available, systematic reviews should include methodological and clinical exploration of heterogeneity among studies to explore variations associated with overall study design (experimental and quasi-experimental designs), participant recruitment (e.g., medical clinics, shelter homes, counselling agencies), baseline characteristics (e.g., age, gender, culture, education, SES), the nature of the sexual violence, intervention types, duration of intervention, setting, and duration of follow-up. Given the scarcity of included studies in this review, none of these tests were performed.



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### **5.3 QUALITY OF THE EVIDENCE**

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Only six studies were identified and included in the analysis. The sample size in the treatment and control groups were also small in some of the studies (e.g., Foa, Rothbaum, Riggs, & Murdock (1991) with only 10 – 14 participants per condition). Other factors that reduce the quality of the evidence include high drop-out rates (ranging from 14-30% in the treatment groups), use of stringent exclusion criteria, and high refusal rates for participation in treatment. All six studies had sample populations based in the United States which may limit generalizability. Finally, four of the studies included in the analysis were conducted by individuals who developed the treatment models. Thus, while the studies were rigorous, positive results need to be interpreted with caution until such time as they can be replicated independently.

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### **5.4 POTENTIAL BIASES IN THE REVIEW PROCESS**

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We believe that the search strategy was robust. It was further aided by the expert advice of trialists and statisticians. The review authors have no vested interests in the findings in favour of one treatment method over others.

Given that the purpose of this review was to isolate interventions specific for adult victims of sexual assault and rape, it may not be surprising that our searches identified only six studies, given that the majority of primary studies have not adequately differentiated this group from populations affected by other traumatic events.

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### **5.5 AGREEMENTS OR DISAGREEMENTS WITH OTHER STUDIES OR REVIEWS**

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Several literature reviews and meta-analyses have been conducted on treatment approaches for victim trauma and distress. These reviews include a wider range of studies than considered in this review as they are not limited to studies employing control groups and generally include a broader definition of the population served. Vickerman and Margolin (2009), for example, reviewed 32 papers reporting treatment outcomes for victims of rape. The majority were within-group designs or included adults who were victims of sexual abuse as children. The authors concluded that Cognitive Process and Prolonged Exposure garnered the most support with this population although Stress Inoculation Training and Eye Movement De-Sensitization and Reprocessing also showed some preliminary efficacy. Similarly, a meta-analysis conducted by Taylor and Harvey (2009) on 15 outcome studies of 25 treatment conditions for sexual assault (both during childhood and adulthood) reported considerably larger effect sizes with cognitive and behavioural approaches than with other forms of counseling. Finally, a Cochrane systematic review of studies

with survivors of other forms of trauma similarly reports the effectiveness of CBT methods for symptom relief (Bisson & Andrew, 2007).

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## 6 Authors' Conclusions

Results of this systematic review provide tentative evidence that cognitive and behavioural interventions, in particular Cognitive Processing Therapy, Prolonged Exposure Therapy, Stress Inoculation Therapy, and Eye Movement Desensitization Reprocessing can be associated with decreased symptoms of Post-Traumatic Stress Disorder (PTSD), depression and anxiety in victims of rape and sexual assault.

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### 6.1 IMPLICATIONS FOR PRACTICE

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A large minority of women report having been victims of rape and/or other forms of sexual violence in their adult lives. This victimization is associated with both acute and long-term symptoms of traumatic stress, anxiety and depression. Not surprisingly therefore, a vast array of treatment interventions have arisen with the intention of reducing the extreme distress experienced by victims. Research on trauma interventions with other populations has demonstrated that while some interventions may be useful with certain populations, they may in fact increase symptoms in some groups of victims (Bisson, Jenkins and Alexander, 1997; Mayou, Ehlers and Hobbs, 2000; Regehr, 2001). For instance, while psychological debriefing may be helpful or have no effect for those encountering traumatic events in the workplace, Bisson, Jenkins and Alexander (1997) demonstrated that the model in fact exacerbates symptoms in burn victims. It is therefore incumbent upon researchers and practitioners in mental health to ensure that treatment interventions provided are helpful and not iatrogenic.

Selection of treatment methods is always dependent on the particular characteristics of the client. One of the cautions that have been raised with respect to exposure methods for PTSD is that the re-experiencing of traumatic stimuli even in a controlled environment may contribute to an exacerbation of symptoms. Thus, the Practice Guidelines for the International Society for Traumatic Stress Studies recommend that exposure methods should be used only with individuals who have been assessed to have the capacity to tolerate high anxiety arousal, have no active suicidal ideation, and no current life crises (Foy et al., 2000). It is further suggested that models of treatment that involve exposure should be used only when a sound therapeutic alliance has been formed (Calhoun & Atkeson, 1991), that individuals embarking on this treatment should do so with full and informed consent, and

therapists should carefully monitor levels of distress during the treatment. Further issues to be considered are the time and resources required to engage in treatment. Given that shorter treatment approaches in this analysis yielded positive results and had lower rates of dropout, this should be a consideration in treatment recommendations.

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## **6.2 IMPLICATIONS FOR RESEARCH**

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Rape Trauma Syndrome was first identified as a distinct entity by Burgess and Holstrom in 1974. This ground-breaking article set the stage for subsequent changes in sexual assault law (Koss, 2000; Regehr et al, 2008), in societal views regarding sexual violence (Brownmiller, 1975), mental health diagnosis (APA, 1980) and treatment of victims. Treatment approaches reported in the scholarly and professional literature have flourished. Despite the widespread recognition of sexual violence and its aftermath for over four decades, there continues to be a surprising and discouraging paucity of rigorous evaluations of psychotherapeutic interventions specific to adult victims of sexual assault and rape. The results of this review point to the need for more and better quality randomized controlled studies that evaluate interventions that aim at relieving distress in adult victims in the form of PTSD, depression and anxiety.

It is important to note that the presented research has been conducted primarily in the USA. Evidence is lacking on the effectiveness of these therapeutic approaches for individuals from other cultures. The impact of the type of sexual assault is also unclear (e.g., single vs. repeated assaults, known vs. unknown perpetrators, assaults under “normal” living conditions vs. those that happen during other traumatic events such as war). Thus, the therapeutic approaches reviewed here may be less effective for certain types of adult sexual assault survivors. When exploring the effects of treatment with this population, researchers should be clear about the time elapsed since the index event, any history of childhood sexual abuse, and the nature of the assault. Intention to treat analyses and analysis of adverse events, such as an exacerbation of symptoms should also be reported.

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## 7 Acknowledgments

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## 8 References

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### 8.1 INCLUDED STUDIES

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#### **Foa 1991**

Foa, E., Rothbaum, B., Riggs, D., & Murdock, T. Treatment of posttraumatic stress disorder in rape victims: A comparison between cognitive-behavioral procedures and counseling. *Journal of Consulting and Clinical Psychology*, 1991;59(5) 715-723.

*Personal email correspondence between Edna Foa and J. Dennis, 15-16 April 2012; additional information on setting, design and nature of primary outcome measure*

#### **Resick 1988**

Resick, P. A., Jordan, C.G, Girelli, S.A., Hutter, C.K., Marhoefer-Dvorak, S. A comparative outcome study of behavioural group therapy for sexual assault victims. *Behavior Therapy*, 1988; 19: 385-401.

#### **Resick 1992**

Resick, P. & Schnicke, M. Cognitive processing therapy for sexual assault victims. *Journal of Consulting and Clinical Psychology*, 1992;60(5):748-756.

#### **Resick 2002**

Resick, P., Nishith, P., Weaver, T., Astin, M. & Feuer, C. A comparison of cognitive-processing therapy with prolonged exposure and a waiting condition for the treatment of chronic posttraumatic stress disorder in female rape victims. *Journal of Consulting and Clinical Psychology*, 2002;70(4):867-879.

Personal email correspondence between Patricia Resick and J. Dennis, 16 April 2012; additional information on setting, design and participant characteristics. Protocol available at: <http://www.controlledtrials.com/mrct/trial/432473/Resick>

### **Rothbaum 1997**

Rothbaum, B. A controlled study of eye movement desensitization and reprocessing in the treatment of posttraumatic stress disorder sexual assault victims. *Bulletin of the Menninger Clinic*, 1997;61(3):317-334.

Personal email correspondence between Barbara Rothbaum and J. Dennis, 14 June 2012; additional information on setting, design and participant characteristics.

### **Rothbaum 2005**

Rothbaum, B., Astin, M & Marsteller, F. Prolonged exposure versus eye movement desensitization and reprocessing (EMDR) for PTSD rape victims. *Journal of Traumatic Stress*, 2005;18(6):607-616.

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## **8.2 EXCLUDED STUDIES**

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### **Allen 1994**

Allen, S. & Bloom, S. Group and Family Treatment of Posttraumatic-Stress-Disorder. *Psychiatric Clinics of North America*, 1994; 17(2): 425-437.

### **Arntz 2007**

Arntz, A. Tiesema, M. & Kindt, M. Treatment of PTSD: a comparison of imaginal exposure with and without imagery rescripting. *Journal of Behavior Therapy & Experimental Psychiatry*, 2007; 38(4), 345-70.

### **Barker 1997**

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**Bornstein 2003**

Bornstein, H. A meta-analysis of group treatments for post-traumatic stress disorder: How treatment modality affects symptoms. *Dissertation Abstracts International*, 2003.

**Cantarella 2005**

Cantarella, G. Sexual Abuse in Families Today: Group Resonance as a Cure. *Group Analysis*, 2005; 38(2): 281-292.

**Carey 1996**

Carey, L. Effects of group treatment on rape victims. *Dissertation Abstracts International*, 1996.

**Castillo 2004**

Castillo, D. Systematic Outpatient Treatment of Sexual Trauma in Women: Application of Cognitive and Behavioral Protocols. *Cognitive and Behavioral Practice*, 2004; 11(4): 352-365.

**Clarke 2008**

Clarke, S. Rizvi, S. & Resick, P. Borderline personality characteristics and treatment outcome in cognitive-behavioral treatments for PTSD in female rape victims. *Behavior Therapy*, 2008; 39(1): 72-78.

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Cryer, L. & Beutler, L. Group therapy: an alternative treatment approach for rape victims. *Journal of Sex & Marital Therapy*, 1980; 6(1): 40-6.

**Echeburúa 1997**

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**Field 1997**

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Foa, E. Trauma and women: course, predictors, and treatment. *Journal of Clinical Psychiatry*, 1997; 58 (Suppl 9): 25-8.

**Foa 1999**

Foa E B; Dancu C V; Hembree E A; Jaycox L H; Meadows E A; Street G P. A comparison of exposure therapy, stress inoculation training, and their combination for reducing posttraumatic stress disorder in female assault victims. *Journal of Consulting and Clinical Psychology*, 1999; 67(2), 194-200

**Foa 1999**

Foa E. , Freund, B., Dancu, C., Franklin M., Perry, K., Riggs, D. & Molnar, C. A comparison of exposure therapy, stress inoculation training, and their combination for reducing posttraumatic stress disorder in female assault victims. *Journal of Consulting & Clinical Psychology*, 1999; 67(2): 194-200.

**Foa 1995**

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## **Weiss 1997**

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## 9 Characteristics of included studies with Risk of Bias tables

*Foa 1991*

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Methods	Design: quasi-experimental study.
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## Participants

Participants: survivors of rape or attempted rape (p. 716) meeting DSM-III-R criteria for PTSD.

Sex: all female.

Age: Mean 31.8 (SD 8.2) years.

Unit of allocation: individual participant.

Number allocated: 55 (66 met inclusion criteria but 11 "refused treatment").

Number completing: 45.

Setting: Referrals from local professionals, victim assistance agencies, recruitment via local newspaper advertisements or those previously involved "in a study of the response to rape [Rothbaum et al 1990]" (p. 716). Treatment setting was (implied, not stated) in a university clinic in Philadelphia, Pennsylvania, USA.

Inclusion criteria: Having been raped at least 3 months previously; meeting PTSD criteria under DSM-III-R (APA 1987).

Exclusion criteria: current or previous diagnosis of organic mental disorder, schizophrenia or paranoid disorders as defined by DSM-III R; depression severe enough to require immediate psychiatric treatment, bipolar depression, or depression accompanied by delusions; current alcohol or drug abuse; assault by spouse or other family member; illiteracy in English (p.716).

Ethnicity: 72.7% of total sample identified as white; 25% African-American; 2.3% Hispanic.

Other baseline characteristics: Mean length of time since assault: 6.2 years (SD = 6.7). Participants were screened by two interviews and an assessment of PTSD severity was made. Detailed demographic and assault characteristics given, by whole sample and by treatment group (pp. 716-7). 52.3% of women in the whole sample were single, 22.7% divorced or separated, 25% married or cohabiting. Income and occupation data reported. No significant differences found at baseline between the groups on these variables. Assault characteristics: 55.6% of women did not know their assailant; 86.7% were injured during the assaults; in 55.6% of cases a weapon was used. Most women reported a perception that their lives were at risk as "quite likely" or "convinced of it" (73.3%). Details on duration of attack given. No significant differences found between the four conditions except that fewer participants in the SIT group had been injured during their assaults. No data provided on previous psychological treatment or concurrent pharmacotherapy.

## Interventions

### Four conditions:

- **Stress inoculation training (SIT) (individual therapy)** (n = 17).
- **Prolonged exposure (PE) (individual therapy)** (n = 14).
- **Supportive counseling (SC) (individual therapy)** (n = 14).
- **Waitlist control** (n = 10) of women who were first (prior to randomization; unclear?) "entered into the waitlist condition" (p. 716; investigator has been asked for clarification but none has been received at time of manuscript submission).

**SIT** = (see Vernonen & Kilpatrick 1993). One session of information gathering followed by anxiety-lowering breathing exercises; second session devoted to explaining rationale and method of treatment and etiology of fear and anxiety; following seven sessions devoted to coping skills including deep muscle relaxation, controlled breathing, thought-stopping (Wolpe 1958); cognitive restructuring (Beck et al 1977); guided self-dialogue (Meichenbaum 1977). At the ninth session, role playing was introduced. "No instructions for exposure were included" (p. 717).

**PE** = Two sessions of information gathering, explaining rationale and method of treatment as well as treatment planning. Remaining sessions involved reliving the rape scene in imagination (imaginal exposure). Participants required vividly to "relive" the assault, in the present tense, repeating the scenario several times (60 mins per session). Narratives were recorded and participants instructed to listen to the tape at least once daily as homework. "Additional homework involved in vivo exposure to feared and avoided situations judged by the patient and the therapist to be safe" (p. 717).

**SC** = One session of information gathering; two sessions devoted to explaining rationale and method of treatment; remaining sessions involved the teaching of a "general problem solving technique" (p. 718). Therapists "played an indirect and unconditionally supportive role"; homework involved participant diaries documenting problems and problem-solving. Program contained no instructions for exposure and active instructions to focus on current problems if "discussions of the assault occurred" (p. 718).

**WLC** = waitlist control group participants were assessed at the same points as the treatment groups. Between assessments, participants were contacted by a therapist to ask whether "emergency services" were required. All were randomized to either SIT or PE after the study was complete.

Duration/intensity of intervention: 4½ weeks. All active treatments were delivered in 9 bi-weekly sessions of 90 minutes each, on an individual basis.

Therapists: six female therapists with masters or doctoral degrees in psychology or clinical social work...hired specifically for this project" (p. 716) Therapists were trained by two investigators (Foa and Rothbaum); latter were trained by program developers of SIT

	<p>(Kilpatrick et al); Foa is a “recognized expert” in PE and developer of manual for same (Foa 1993). Foa and Rothbaum were also trained in SC by a therapist “affiliated with the Philadelphia Chapter of Women Organized against Rape.” Therapists differed in theoretical orientation but were themselves allocated randomly to treatment delivery.</p>
	<p><u>Length of follow-up</u>: participants were followed up 3½ months after treatment concluded, but by this time the waitlist control was in treatment.</p> <p><u>Treatment fidelity</u>: “To ensure the integrity of the treatment procedures, therapists were supervised biweekly by Foa. Each therapy session was monitored during supervision to examine possible deviations from protocol. No gross deviations were detected; subtle deviations... noted ... suggestions for corrections provided...” (p. 717).</p>
<p><b>Outcomes</b></p>	<p><u>Primary outcome</u></p> <p><b>PTSD severity</b> measured “adding the interviewer’s severity rating of the following PTSD symptoms: reliving experiences, nightmares, flashbacks, avoidance of reminders and thoughts of the assault, impaired leisure activities... sense of detachment, blunted affect, disturbed sleep, memory and concentration difficulties, hyperalertness, increased startle response, feelings of guilt, and increased fearfulness (p. 716). We contacted the primary investigator who clarified that this as the study began in 1984 before the DSM-III-R, the PSS-I was developed to correspond to the DSM-III- R and ... later to the DSM IV. “We put together information we had from several measures to have a measure that would correspond to the DSMIII-R)” (Foa 2012). Completed by independent assessor.</p> <p>PTSD was also measured using three subscales of the PSS (re-experiencing, avoidance and arousal), clearly the scale later published as Foa 1993. Completed by independent assessor.</p> <p><u>Secondary outcomes</u></p> <p><b>Depression</b> (Beck Depression Inventory or BDI) (Beck 1961) (self-report) Anxiety-State subscale on the State-Trait (Spielberger 1970) (self-report).</p> <p><u>Other outcomes/ measures not reported in this review</u></p> <p>Assault reaction interview (117 questions selected from initial interview containing items not just about PTSD symptoms but about baseline characteristics and issues beyond the scope of this review (e.g. legal issues)).</p> <p>Rape Aftermath Symptom Test (RAST) (self-report) (Kilpatrick 1988).</p> <p>Expectancy of therapeutic outcome (on a Likert scale) (self-report).</p>



	Motivation for Behavior Change Scale (MBCS, Cautela 1977).
<b>Notes</b>	<p>Half the women “scheduled for initial evaluation” did not attend. Of these, treatment refusal was high (of 66 invited to be recruited after assessment, 19% declined).</p> <p>Investigators note that unlike other people with diagnoses of anxiety disorder, rape survivors are unwilling to see themselves as “patients” and are less likely to “comply with therapeutic demands”; that furthermore, rape is underreported, particularly amongst those of lower SES, and all these factors limit generalisability of findings.</p>

*Risk of bias table (Foa 1991)*

Bias	Authors' judgment	Support for Judgment
Random sequence generation (selection bias)	Unclear risk	Allocation to all groups was randomized (no method reported in paper) but the primary investigator clarified that this was via use of a random numbers table (Foa 2012). It would appear that due to concerns about slow recruitment, the waitlist group was capped at 10 participants ("When we realized that our recruitment was slower ... [than] expected, after we arrived at 10 patients in the WL, we change the randomization and thereafter, patients were randomized into the three active groups" (Foa 2012).
Allocation concealment (selection bias)	Low risk	Allocation concealment was not reported in the published paper but contact with the primary investigator clarified that this was achieved (the "IE was not aware of randomization [schedule]" nor of the "change" to randomization" (Foa 2012).
Blinding of participants and personnel (performance bias)	High risk	Participants and personnel were not blinded, nor could they be for these types of interventions.
Blinding of outcome assessment (detection bias)	Unclear risk	The primary outcome was assessed by independent assessors blinded to treatment condition (p. 716); other outcomes could not be considered blinded as they were by self-report.
Incomplete outcome data (attrition bias)	Unclear risk	Dropout was relatively high (18%) but difference in dropout is reported as not significant across groups (p. 718). No attempt at ITT analysis was conducted, but strenuous attempts to discover differences in baseline characteristics to account at least partially for dropout were made. Dropouts were found more likely to be of lower income and "blue collar" workers, and were somewhat more likely to score higher on the RAST. The implications of these findings are discussed when results are reported.
Selective reporting (reporting bias)	Low risk	Study protocol does not appear to be publicly available but it seems clear that the published report included all expected outcomes, including those that were pre-specified.

Other bias	Unclear risk	<p>Steps to ensure treatment fidelity were in place; furthermore, investigators tested for possible therapist effects and found they did not differ in percentage of improvement demonstrated by participants on any outcomes (p. 717). Some treatments under consideration in this review had yet to be manualised at the time this study took place. The programme developer of PE (Foa) was the main author of the subsequent manual and the primary investigator in this study). The involvement of the program developer must be considered at least a potential source of bias. The investigators themselves acknowledge that “experimental bias effects” may have occurred given “the principal authors provided training and supervision in all of the treatments”; likewise, as the investigators note themselves, “it is difficult to assess the impact of the fact that [some] therapists conducted therapies that may have been contrary to their preferences” (p. 722).</p>
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<b>Methods</b>	<u>Design</u> : quasi-experimental study.
<b>Participants</b>	<p><u>Participants</u>: rape survivors.</p> <p><u>Sex</u>: all female.</p> <p><u>Age</u>: mean 28.86 (SD 7.1) years.</p> <p><u>Unit of allocation</u>: individual participant.</p> <p><u>Number allocated</u>: 43 entered the study. A total of 59 were assessed; 8 did not meet criteria; 8 decided not to participate or had scheduling conflicts.</p> <p><u>Number completing</u>: 37. Participants who missed more than two sessions were dropped from analyses.</p> <p><u>Setting</u>: Participants either responded to media advertisements or were referred by victim assistance agencies. Treatment setting was (implied) in a university clinic, presumed to be St Louis, Missouri, USA.</p> <p><u>Inclusion criteria</u>: Having been raped at least 3 months previously; never been an incest victim; reporting "problems with rape-related fear and anxiety" (p. 387).</p> <p><u>Exclusion criteria</u>: No "severe competing psychopathology" (p. 387).</p> <p><u>Ethnicity</u>: 81% identified as white; 19% African-American.</p> <p><u>Baseline characteristics</u>: Mean length of time since "most recent rape" 5.2 years (SD = 7.7). It cannot be guaranteed that 100% of women were assaulted after the age of 18, but it is unlikely that the proportion of participants with a sole assault beneath the age of 18 would be substantive. Mean number of rapes was 1.30 (SD = .62). 78% of women in the whole sample were unmarried. Level of education and income reported. No significant differences reported at baseline between the groups on any of these variables. For the whole sample, 89% reported being raped by one assailant only; rape most often happened in the woman's residence (40%); assailant(s) was/were usually strangers (54%) who displayed a weapon (57%) and threatened to wound or kill (81%). Duration and nature of assaults were reported. 38% of participants had received therapy or counselling since the assault. 91% reported depression following the assault (47% reporting brief periods, 12% reporting chronic depression). No information provided on past or concurrent pharmacotherapy. Data on arrests of suspects and convictions reported (12% for whole sample).</p>
<b>Interventions</b>	<u>Four conditions.</u>

- **Stress inoculation therapy (SIT) (group therapy)** (n= 12, 2 groups were formed of 8 and 4 participants).
- **Assertion therapy (AT) (group therapy)** (n= 13, 2 groups were formed of 6 and 7 participants).
- **Supportive psychotherapy plus information (SPI) (group therapy)** (n= 12; 2 groups were formed of 7 and 5 participants).
- **Waitlist control** (n = 13) Each active treatment group began with an information session, “specifically a cognitive-behavioral explanation of the development of fear and anxiety following rape”... and including concepts of “classical conditioning, operant avoidance, and cognitive and social factors”.

**SIT** = (see also Kilpatrick et al 1982). After the session described above, group members were taught progressive relaxation and the quieting reflex (Stroebe 1982), thought-stopping (Wolpe 1958); covert rehearsal, guided self dialogue (Meichenbaum 1977) and later, practiced these fear management techniques in the presence of conditioned stimuli (p. 390) and to interrupt avoidance patterns. Problem-solving techniques were also taught. 30 mins of each session were “spent discussing rape-related issues” (exposure) (p. 390).

**AT** = The information session described above (common to all groups) for this group also involved an explanation of “how assertive responses can be used to counter fear and reduce avoidance”, issues of assertion and social support were discussed; techniques and exercises were adapted from a training book (Lange & Jakubowski 1976). Principles of Rational Emotive Therapy (RET) were discussed; use of “I” language in interactions, etc. Some sessions “focused on covert and behavioral rehearsal of assertive responses” using role play (p. 390).

**SPI** = After an information phase, participants selected topics for discussion, which included fear and anxiety, who they told about the rape, and “the reactions and continued support or lack of support by significant others” (p.390). The purpose of therapy was to “normalize reactions to sexual assault and have group members offer support and suggestions as to what they found... helpful. Although... co-therapists occasionally offered information, no specific training in behavioral techniques was provided.”

**WLC** = Women who remained on waiting list for at least 6 weeks and could thus be assessed over a similar period.

	<p><u>Duration/intensity of intervention:</u> 6 weeks. All groups featured 6 two-hour weekly treatment sessions.</p> <p><u>Therapists:</u> both female and male (the rationale for this was “to help participants overcome their avoidance of men and particularly to expose them to warm, empathetic male therapists who would be available for role-playing” (p. 389)). The “primary therapist” was a licensed clinical psychologist with experience with the population. The first two authors served as therapists for “five and four of the groups, respectively. The third author was a cotherapist for two groups of different types”. A male and a female postgraduate acted as cotherapists.</p> <p><u>Length of follow-up:</u> participants were followed up at 3 and 6 months after treatment concluded, but by this time the waitlist control was in treatment.</p> <p><u>Treatment fidelity:</u> All sessions were audiotaped, reviewed and supervised by the senior author in an attempt to ensure the integrity of different types of therapy (p. 389).</p>
<p><b>Outcomes</b></p>	<p><u>Primary outcome</u></p> <p><b>PTSD symptoms</b> (subjective) via the Impact of Event Scale (IES; Horowitz, Wilner &amp; Alvarez, 1979) (self-report) with different subscales for intrusion and avoidance.</p> <p><u>Secondary outcomes</u></p> <p><b>Depression</b> (subjective) via an adapted subscale of the (SCL-90-R; Derogatis, 1977, Saunders 1990) which measured depression (self-report).</p> <p><b>Anxiety</b> (subjective) via an adapted subscale of the (SCL-90-R; Derogatis, 1977, Saunders 1990) (self-report).</p> <p><b>Fear</b> (subjective) using the Vernonen-Kilpatrick Modified Fear Survey; Vernonen-Kilpatrick) (self-report).</p> <p><b>Self esteem/self concept</b> (subjective) using the Tennessee Self-Concept Scale (TSCS; Fitts, 1965) (self-report).</p> <p><b>Self efficacy/assertiveness</b> (subjective) using the Adult Self-Expression Scale (ASES; Gay, Hollandsworth &amp; Galassi, 1975) (self-report) (assertiveness; maps roughly on to protocol concept of self-efficacy).</p> <p><u>Other outcomes/outcome data not reported in this review</u></p> <p>“Emotion Thermometer” (Obanion and Veronen, 1978).</p>

	<p>Structured Interview (designed for study: chiefly captured baseline characteristics, demographics, characteristics of assault, legal status of case, trauma history etc).</p> <p><u>Time of assessments:</u> Assessments made at one week, 3 and 6 months (WLC disappeared however after intervention group completed treatment as participants moved into treatment).</p>
<p><b>Notes</b></p>	<p>Subsequent research in the area identified issues with the “overlap of potentially important procedures among the various treatment conditions (e.g. elements of exposure were included in two treatments)” (see pp. 715-6 Foa et al 1991).</p> <p>This study included male co-therapists (the only one of the six included studies).</p> <p>This is one of two studies in this review to make reference to power (p. 393) and calculations were made to estimate there would need to be 80 participants per condition (p. 394) to have sufficient power for testing between group effects.</p> <p>“Expectancy theory” (Reiss 1980; Reiss &amp; McNally, 1985) and “the fear of fear” Goldstein &amp; Chambless, 1978) (p.397) are used to explain why no differences between groups emerged concerning the outcome of fear.</p>

*Risk of bias table (Resick 1988)*

Bias	Authors' judgment	Support for judgment
Random sequence generation (selection bias)	High risk	This study was quasi-experimental. Allocation to groups was not randomized but alternate (quasi-randomised) for the three active interventions ("eligible participants were assigned to the next available group and were not given a choice of treatment modality to avoid any selection bias"); the waitlist control group, however, was "naturally occurring" and was not randomized in any way (p. 389).
Allocation concealment (selection bias)	High risk	Allocation concealment was not possible (see above).
Blinding of participants and personnel (performance bias)	High risk	Participants and personnel were not blinded, nor could they be for these types of interventions.
Blinding of outcome assessment (detection bias)	High risk	All outcomes were by self-report alone.
Incomplete outcome data (attrition bias)	Low risk	Of the 43 women initially allocated to CPT treatment, six from the active treatment arms of the study either dropped out entirely or were considered dropouts from an analysis point of view if they missed more than two sessions or missed a follow-up assessment. Dropouts comprised 14% of the total sample but were evenly distributed between groups, leading to a judgment of low risk of bias for this criterion.
Selective reporting (reporting bias)	Low risk	Study protocol does not appear to be publicly available but it seems likely that the published report included all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Efforts were made to assess adherence and therapist competence (p. 389).



Methods	<u>Design</u> : quasi-experimental study.
Participants	<p><u>Participants</u>: rape survivors.</p> <p><u>Sex</u>: all female.</p> <p><u>Age</u>: mean 30.6 (SD 7.3) years.</p> <p><u>Unit of allocation</u>: individual participant.</p> <p><u>Number allocated</u>: 28 assessed; four did not meet criteria. Three moved from the area or had scheduling conflicts. Of the remaining sample, 21 entered treatment and were randomized; 20 others from a waitlist of treatment seekers formed the control condition.</p> <p><u>Number completing</u>: N =19 for CPT intervention; n =20 for WLC.</p> <p><u>Setting</u>: Referrals from victim assistance agencies, mental health professionals or were self-referred. Treatment setting was (implied) in a university clinic, presumed to be St Louis, Missouri, USA.</p> <p><u>Inclusion criteria</u>: Having been raped at least 3 months previously; not an incest victim; reporting "significant PTSD symptomatology" (p.750).</p> <p><u>Exclusion criteria</u>: Any "severe competing psychopathology" (p. 750).</p> <p><u>Ethnicity</u>: 44/48 (92%) identified as white; 4/48 (8%) African-American.</p> <p><u>Baseline characteristics</u>: Mean length of time since "most recent rape" 6.4 years (SD 6.9). Most women had experienced 1 to 3 rapes (mean 1.32 (SD .58), an exception being one woman who had been repeatedly raped by her husband. 42% reported being raped by strangers only; in 58% of cases, at least one of the rapists was an acquaintance. 16/19 (84%) of completers in the CPT group had previously sought treatment for emotional problems since the rape; 11 of these from more than one source (mean no. sessions = 10; range 1-390 sessions). No data given on previous psychological treatment for the control group. No information provided on past or concurrent pharmacotherapy amongst the sample as a whole. Two women in the treatment group did not meet PTSD entry criteria but were permitted to carry on as other symptomatology was severe. 55.3% of women in the whole sample had never been married, 21% were divorced or separated, 23.7% were married or cohabiting. Level of education was reported. No significant differences were reported at baseline between the two groups.</p>

## Interventions

### Two conditions.

- **Cognitive-processing therapy (CPT)** (group therapy) (n= 21 allocated; groups were formed of 8, 5 and 6 participants).
- **Waitlist control** (n = 20) of women who remained on waiting list for at least 12 weeks.

CPT = At the first, an "information processing formulation of PTSD" is presented and participants "asked as homework to write about the meaning of the event for them". Session 2: participants "taught to differentiate feelings from thoughts"; sessions 3-4, participants were asked to write an account of the rape, with maximum detail on emotions and thoughts as well as sensory details. These two sessions "constituted the exposure part of CPT" as participants were asked to "experience their emotions fully while writing and reading over the account". Homework assignments were used to identify "stuck points", where conflict remained or processing was incomplete.

From session 5, participants were taught to "identify and challenge maladaptive beliefs", (self blame in particular); session 6 introduced participants to the "concept of faulty thinking patterns". Session 7 expanded on this with a worksheet and the "first of five areas of beliefs was introduced" (based on work by McCann et al., 1988). These included safety, trust, power, esteem and intimacy" and modules given to participants "described how prior positive beliefs could be disrupted, or prior negative beliefs confirmed, by rape." Themes were "presented sequentially and analyzed, one per week (sessions 7-11); homework was set and discussed. At the 11th session, participants "were asked to write again about the meaning of the event, without referring to their first assignment" (p. 752). The last session included an analysis of beliefs regarding intimacy and "to discuss the client's essay and goals for the future". The treatment manual was not complete during the conduct of the study (which from internal evidence seems to have extended over several years) and the manual was not published until a year after the publication of the study.

WLC = the waitlist control group was assessed at the same points as the treatment group and was offered treatment after the study was complete.

Duration/intensity of intervention: 12 weeks T CPT involved 12 sessions 90m in 1½ hour sessions.

Therapists: were the investigators/authors of the study, Resick and Schnicke, as well as three female clinical psychologists who served as co-therapists. The PI (also the programme developer) supervised all therapists.

Length of follow-up: participants were followed at 3 and 6 months after treatment concluded, but by this time the waitlist control was in treatment.

Treatment fidelity: The programme was being developed during the time this study was run (it is described as "developed in the context of an ongoing, evolving treatment program for rape victims") and as such could not easily be assessed for fidelity save by its developers, who either were the therapists in this review or supervised others.

## Outcomes

### Primary outcome

**PTSD symptoms** (subjective) measured on a subscale adapted by Saunders et al, 1990, from the Symptom Checklist 90 Revised (SCL-90-R; Derogatis, 1977).

### Secondary outcomes

#### **Depression** (BDI-I).

**Depression** measured on a subscale adapted by Saunders et al, 1990, from the Symptom Checklist 90 Revised (SCL-90-R; Derogatis, 1977).

### Other outcomes/measures/ outcome data not reported in this review

We would have reported at least some data from measures listed below, but due to circumstances not made entirely clear in the published paper, the measures listed below (see also pp 750-1) were used on some participants, but not all, in this study. So whilst data below were collected it is not clear for whom. See also Notes.

PTSD (objective) PTSD symptoms measured on three subscales (avoidance, intrusion, re-experiencing) of the PSS-SR (Foa et al, in press at time of publication of study), self-report version.

PTSD (subjective) measured by two subscales of the Impact of Event Scale (IES) (Intrusion and avoidance).

Structured Clinical Interview for DSM-III-R Non-patient version (SCID) (Spitzer et al 1987) containing modules for both PTSD module depressive disorders developed by Kulka et al (1988).

Social functioning, measured using the Social Adjustment Scale (SAS) (Weissman & Paykel, 1974).

Time of assessments: Assessments made at 1 week, post-treatment and at 3 and 6 months (WLC disappeared due to receipt of treatment after intervention group

	completed treatment).
<b>Notes</b>	Investigators report that “because the battery of instruments has changed over the past 5 years, the only measure that all of the comparison subjects and CPT subjects had in common was the SCL-90-R. Therefore the SCL-90-R was used to compare CPT and comparison subjects” (p. 751, repeated in both columns).

*Risk of bias table (Resick 1992)*

Bias	Authors' judgment	Support for judgment
Random sequence generation (selection bias)	High risk	This study was quasi-experimental. Allocation to groups was not randomized; the intervention and control groups were allocated by time of screening.
Allocation concealment (selection bias)	High risk	Allocation concealment was not feasible (see above).
Blinding of participants and personnel (performance bias)	High risk	Participants and personnel were not blinded, nor could they be for these types of intervention.
Blinding of outcome assessment (detection bias)	High risk	Even for those outcomes that were not by self-report alone, risk of bias is high. Outcome assessment was blinded for a minority (8 /19 CPT participants) of participants; one of the remaining participants was unavailable and the majority (10) were assessed by their own therapists.
Incomplete outcome data (attrition bias)	Unclear risk	Of the 21 women initially allocated to CPT treatment, two dropped out of the treatment group and one was unavailable for assessment. No women dropped out of the WLC condition but nor could they: data were only presented for those (non-contemporaneously) women who, for whatever reason, remained on a waiting list for 12 weeks. The unevenly distributed dropout rate (14% for the intervention arm only) leads to an assessment of unclear risk of bias.
Selective reporting (reporting bias)	Unclear risk	Results are reported for only two of many measures collected in the review. Investigators report that "because the battery of instruments has changed over the past 5 years, the only measure that all of the comparison subjects and CPT subjects had in common was the SCL-90-R. Therefore the SCL-90-R was used to compare CPT and comparison subjects" (p. 751, repeated in both columns).

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<b>Other bias</b>	<b>Unclear risk</b>	The treatment under consideration in this review (CPT) had yet to be manualised at the time this study took place. The programme developers (Resick & Schnicke) were the main authors of the manual and the primary investigators in this (non-randomized) study) and had been developing the program over 10 years. The involvement of the program developers, including in outcome assessment whilst the treatment was still in development, must be considered at least a potential source of bias.
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Methods	<u>Design</u> : parallel randomized controlled trial.
Participants	<p><u>Participants</u>: rape survivors.</p> <p><u>Sex</u>: all female.</p> <p><u>Age</u>: mean 32 (SD 9.9) years.</p> <p><u>Unit of allocation</u>: individual participant.</p> <p><u>Number allocated</u>: 181 randomized; 10 excluded before the study began (see below). Of the initial "ITT" sample (171), n = 62 for CPT intervention; n = 62 for PE condition; n = 47 for MA.</p> <p><u>Number completing</u>: 121 (n = 41 for CPT intervention; n = 40 for PE condition; n = 40 for no treatment).</p> <p><u>Setting</u>: Community. Missouri, USA.</p> <p><u>Inclusion criteria</u>: Having experienced a "discrete incident of completed rape" in childhood or adulthood; at least 3 months post-trauma (with no upper limit) (p. 868); evidence from trial protocol clarifies that no participant whose index rape or first rape occurred below the age of 14 was admitted. The exact number of those whose sole assault(s) took place within the age range 14 to 17 is unknown. The primary investigator expressed the opinion that these cases were likely to be uncommon amongst the sample, and more precise data are being sought from an analyst associated with long-term follow-up of the study (Michael Suvak, Resick et al 2011, Resick, 2012). The investigators were keen include a truly generalisable clinical sample (for example, there were no restrictions on personality disorders or trauma history, p.878). Women had to meet diagnostic criteria for PTSD (measured via the CAPS [Blake et al 1990]). A random selection of approximately a third of such assessments was double-assessed for inter-rater reliability [p. 869]). Two modules of the Structured Interview for DSM-IC-Patient Version (SCID) (First et al., 1996) were used to assess mood disorders including MDD (major depressive disorder), substance abuse or dependence (interrater reliability was also assessed). The Standardised Trauma Interview (Resick et al 1988) was used to gain information on demographics, the circumstances of the rape, etc.</p> <p>If on medication, medication had to be stabilized; if participants had substance abuse problems, they had to have been "off of the substance(s) for 6 months"; women with a history of substance abuse were permitted to participate "if they agreed and were deemed able to desist in usage during... treatment."</p>

	<p><u>Exclusion criteria:</u> current psychosis; developmental disabilities; suicidal intent; current parasuicidal behavior; current dependence on drugs or alcohol; illiteracy; currently being stalked; currently in an abusive relationship. Those who had experienced marital rape “must have been out of the relationship for at least 6 months. Those with a history of incest were not excluded as long as there was another index rape that met the primary inclusion criterion for PTSD” (p.868).</p> <p><u>Ethnicity:</u> 71% white; 25% African-American; 4% other racial backgrounds.</p>
	<p><u>Baseline characteristics:</u> Average length of time since rape 8.5 (SD 8.5) years. Majority of women had never been married or were divorced or separated (75.7%). 30.7% of the participants were on psychotropic medications. 85% had experienced traumas other than that for which they sought treatment (including the 48% who had experienced at least one other rape; 41% reported having been sexually abused as children). Other demographics were reported including education and other traumas (serious physical assaults; being victims of robbery or kidnapping or being the victim of attempted murder). No significant differences were reported at baseline between the three groups including crime history.</p>
<p><b>Interventions</b></p>	<p><u>Three conditions.</u></p> <ul style="list-style-type: none"> <li>• <b>Cognitive-processing therapy (CPT) (individual)</b> (n= 62 randomized).</li> <li>• <b>Prolonged exposure (PE) condition (individual)</b> (n = 62).</li> <li>• <b>Minimal attention (MA)</b> (n = 47).</li> </ul> <p>CPT = involved delivery in groups: an “initial” session, then 12 sessions (2x per week, 90 minutes in length). Each session featured “5 to 8 unique and essential items” (69 items in total). Treatment was manualised (Resick &amp; Schnicke 1993); details of each session provided (p. 870); general principles include deconstructing “dysfunctional beliefs”, generating and practicing “more balanced self-statements” (p. 867) and overcoming “stuck points” (i.e. “conflicts between prior schemata and this new information (the rape)” (Resick 1992, p. 750). See also description of sessions for Resick 1992, above. 1 hr was added to the CPT protocol “as a means of equating therapist contact time with PE” (p.870).</p> <p>PE = involved an “initial” session, then 12 sessions (2x per week, 90 minutes in length) “8 to 15 unique and essential items for each session (85 items in total)” (p. 870). Manualised intervention involves four ordered components, i.e.: education-rationale; breathing retraining; behavioral exposures and imaginal exposures (Foa et al, 1994); details given on p. 870.</p>



**MA** = involved “minimal attention” (wait-list control; women allocated to this condition “were told that therapy would be provided in 6 weeks and that an interviewer would call them every two weeks to ensure that they did not need emergency services” (p. 871)). Investigators ensured that any woman reporting suicidal ideation or who called more than 1x in the first 2 wks or > 4x in the 6 week period, “would have been terminated from participation... and treated immediately”..... However, this “never occurred” (p. 871).”

Duration/intensity of intervention: 6 weeks; 13 sessions in all (one introductory, then 2x per week, 90 minutes in length 13 sessions of 90 mins each). Both active treatment arms required daily homework assignments; authors report CPT group averaged 22.6 hrs (SD = 6.5) per week homework; PE averaged 44.8 hrs (SD= 33.5).

Therapists: were “eight women with doctorates in clinical or counseling psychology” and a background in CBT. Therapists read manuals and attended training (2 day workshop for each therapist). All treatment sessions were videotaped and the PI closely supervised all therapists.

Length of follow-up: participants were originally to be followed up for 3 months but this was extended to 9 months post-treatment. Data for all groups (bar the waitlist control participants, who have now received treatment) is now available at between 5 and 10 years follow-up (Resick 2011).

Treatment fidelity: Strenuous efforts were made to assess adherence and therapist competence. Assessments were made by raters independent of the project (p. 869).

## Outcomes

### Primary outcome

**PTSD symptoms** (objective) using the Clinician-Administered PTSD Scale (CAPS; Blake et al 1990).

**PTSD symptoms** (subjective) measured by the total frequency score of the PTSD Symptom Scale (PSS; Foa et al 1993) (self-report).

### Secondary outcomes

**Depression** (BDI); however, investigators state that these data were not available for true Intention to Treat (ITT) analysis; only the PSS data were available for ITT.

**Guilt** (global) using the Trauma-Related Guilt Inventory (TRGI; Kubany et al 1996) as well as three separate scales for “guilt cognitions” (“hindsight bias”, “wrongdoing” and “lack of justification”).

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Other outcomes/measures not reported in this review

Expectancy of therapeutic outcome via a questionnaire (Foa et al 1991). Two interviews used chiefly to gather baseline characteristics (e.g. trauma history, depression and substance abuse, treatment history, etc). These included the Structured Interview for the DSM-IV Patient Version (SCID) (First et al 1996) and an adapted version of Resick et al's "Standardised trauma interview" (p. 869).

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**Notes**

The PSS scale was administered throughout the study so values for women who dropped out partway through are more likely to be informative than values for the CAPS or BDI where only baseline could be used in the LOCF (last observation carried forward) analysis (p. 871).

Investigators report that participants in the MA group had "significantly higher symptom scores than either the CPT or PE group" (pp 871-2).

This is one of two studies in this review to make reference to power (p. 868).

Because a secondary purpose of the study was to "examine the effects of both therapies on dysfunctional cognitions, specifically blame and guilt" (p. 868) and that cognitive therapy is "specifically tailored to challenge dysfunctional cognitions" it was thought likely CPT would alter guilt cognitions more than PE would and that indeed "procedures effective for fear may be ineffective, or even harmful, for guilt and other negative emotions" (Foa & McNally 1996). Therefore "there was an effort not to introduce "casual cognitive therapy" in the PE protocol or to conduct prolonged imaginal or behavioral exposures in the CPT protocol" (p. 867).

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*Risk of bias table (Resick 2002)*

Bias	Authors' judgment	Support for judgment
Random sequence generation (selection bias)	Low risk	No information was reported on method of sequence generation; correspondence with the primary investigator established that a "random number generator" was used (Resick 2012).
Allocation concealment (selection bias)	Low risk	No information was reported on method of allocation concealment; however, personal contact with the primary investigator established that allocation was concealed (Resick 2012) from treatment staff by use of numbered packets.
Blinding of participants and personnel (performance bias)	High risk	Participants and personnel were not blinded, nor could they be for these types of interventions.
Blinding of outcome assessment (detection bias)	Unclear risk	Outcome assessment was blinded for the objective measurement of the primary outcome (PTSD via the CAPs) and participants were asked not to discuss their therapy with other participants or to refer to it when speaking with assessors. All other outcomes however, were by self-report.

<b>Incomplete outcome data (attrition bias)</b>	<b>Low risk</b>	<p>Of the 181 women initially randomized, 10 were “terminated from the study as a result of meeting exclusion criteria subsequent to new violence... changes in medication or substance dependence relapse” (p. 868). 171 women were therefore considered the “ITT sample”. Of these, 13 (7.5%) did not attend more than one session. 37 (21.7%) dropped out of treatment. 121 women completed treatment.</p> <p>Although the overall dropout rate was high, it was evenly distributed between treatment groups. As investigators report all reasons for dropouts and also made assessments to confirm that there were “no significant differences between women who dropped out of therapy and those who completed therapy with regard to their initial PTSD or depression scores” (p.868) and conducted ITT analysis according to a LOCF model, we judge this criterion to be at low risk of bias for the one scale (the PSS) where measurements were taken throughout the study (see p. 871) and also at low risk for other outcomes (e.g. the CAPS and the BDI for which only pretreatment data were available), as attrition will lead, at worse, to a conservative estimate of treatment.</p>
<b>Selective reporting (reporting bias)</b>	<b>Low risk</b>	<p>Study protocol is publically available (<a href="http://www.controlled-trials.com/mrct/trial/432473/Resick">http://www.controlled-trials.com/mrct/trial/432473/Resick</a>) but details of outcomes apart from PTSD and guilt are vague. It seems clear however that the published report included all expected outcomes, including those that were pre-specified, as well as depression.</p>
<b>Other bias</b>	<b>Low risk</b>	<p>Strenuous efforts were made to assess adherence, and therapist competence and ratings were excellent (92 to 100% between the two treatments [p. 870]). These tended to be slightly better for the CPT than the PE condition. Assessments were made by raters independent of the project (p. 869). In addition, participants’ “expectancy of therapeutic outcome” was measured (using a questionnaire by Foa et al, 1991) (p. 869).</p>

<b>Methods</b>	<p><u>Design</u>: parallel randomized controlled trial.</p>
<b>Participants</b>	<p><u>Participants</u>: rape survivors.</p> <p><u>Sex</u>: all female.</p> <p><u>Age</u>: Means given for intervention group = 31.6 (SD 9.8) years; for WLC, mean 37.5 (SD =11.1) years.</p> <p><u>Unit of allocation</u>: individual participant.</p> <p><u>Number allocated</u>: 21 recruited; 3 dropped out after completing pre-treatment assessment before randomisation. Of those entering the trial, (18), n = 10 for EMDR intervention; n = 8 for WLC.</p> <p><u>Number completing</u>: 18.</p> <p><u>Setting</u>: Participants referred by local rape crisis centers, other professionals, and self-referred through local media efforts (p. 322). Setting not stated; contact with investigator confirmed participants were seen at an outpatient clinic at a university medical school, Atlanta, Georgia, USA.</p> <p><u>Inclusion criteria</u>: "Rape must have occurred at least 3 months prior to allow for the natural decline in PTSD symptoms... All participants met DSM-III-R criteria for PTSD..." (p. 322). All participants screened on the PTSD Symptom Scale (PSS; Foa et al 1993); Assault Information Interview (AII); the Treatment, Legal and Drug Update Interview (UPDATE); the Trauma History Checklist (THC); the Impact of Event Scales (IES; Horowitz et al 1979); the Rape Aftermath Symptom Test (RAST; Kilpatrick 1988); the State-Trait Anxiety Inventory (STAI; Spielberger et al 1970); the Beck Depression Inventory (BDI; Beck et al 1961); the Dissociative Experiences Scale (DES; Bernstein et al 1986).</p> <p><u>Exclusion criteria</u>: alcohol or drug dependence; having used cocaine in the past 60 days (p. 322).</p> <p><u>Ethnicity</u>: No data reported.</p> <p><u>Baseline characteristics</u>: Mean length of time since rape 5.2 (SD 4.45) years (intervention group) and (13 (SD 8.9) years (control group). Other demographics reported including marital status (5/18 married; 6/18 single; 2/18 divorced; 1/18 "other"), education, income and employment status. 3/18 in the EMDR group were engaged in concurrent therapy compared with 2/18 in the control group. No data</p>

	<p>provided on concurrent psychotropic medications. Investigators report no significant differences at baseline between the two groups, although the WLC group was clearly older on average and there was a longer time between their index assault and treatment (p. 326 and p. 330).</p>
<p><b>Interventions</b></p>	<p><u>Two conditions.</u></p> <ul style="list-style-type: none"> <li>• <b>EMDR (individual therapy)</b> (n = 10)</li> <li>• <b>Waitlist control (WLC)</b> (n = 8)</li> </ul> <p><b>EMDR</b> = After initial session of “information gathering”, 3 sessions were delivered as recommended by Dr Shapiro and adapted from manual (Pitman et al 1993), once weekly. “In simplified terms, EMDR involves having the patient imagine a scene that represents the entire trauma, focusing on the sensations of anxiety in her body and rehearsing words that match the picture. The patient simultaneously follows the therapist’s finger moving back and forth approximately 18 inches in front of her, a minimum of 24 times each repetition. Anxiety ratings are gathered at various points in the session using a 0-10 Subjective Units of Discomfort (SUDs) scale (Wolpe, 1982). ... Once the anxiety drops to 0 or 1, the patient is asked to track the therapist’s finger while rehearsing a new, preferred belief (e.g., “It’s over”), repeating this sequence until the new statement feels true to the patient. ... EMDR... is... more complicated than this, and includes cognitive techniques...” (pp. 325-6).</p> <p><b>WLC</b> = “WAIT participants were provided with treatment free of charge after the post-treatment assessment.”</p> <p><u>Duration/intensity of intervention:</u> 4 weeks including 4 weekly sessions of 90 minutes, delivered on an individual basis</p> <p><u>Therapists:</u> The therapist for the EMDR group was the primary investigator/author of the study (Barbara Rothbaum) who had been trained by Francine Shapiro (developer of EMDR) to “Levels I and II” (p. 326).</p> <p><u>Length of follow-up:</u> participants were followed up for 3 months but by this time the WLC group had also received treatment.</p> <p><u>Treatment fidelity:</u> Efforts were made to assess “treatment integrity”, with 10 ratings averaging 3.9 (SD=1.5), range 2-6, indicating “treatment delivered was deemed acceptable by an EMDR expert” (p. 324 and p.326).</p>

<p><b>Outcomes</b></p>	<p><u>Primary outcome</u></p> <p><b>PTSD symptoms</b> (objective) using three subscales of the PSS (re-experiencing, avoidance and arousal), and also with the “total” for that instrument, completed by independent assessors (Foa 1993).</p> <p><b>PTSD symptoms</b> (subjective) using two subscales of the Impact of Event Scale (IES) (Intrusion and avoidance) and also the total for that scale.</p> <p><u>Secondary outcomes</u></p> <p>Depression using the BDI (Beck 1961).</p> <p>Anxiety using the State and Trait sub-scales on the State-Trait Anxiety Inventory (Spielberger 1993).</p> <p>Dissociation using the Dissociative Experiences Scale (DES; Bernstein &amp; Putnam 1986).</p> <p><u>Other outcomes/measures not reported in this review</u></p> <p>Rape Aftermath Symptom Test (RAST; Kilpatrick 1988).</p> <p>The Treatment, Legal and Drug Update Interview (UPDATE; no reference provided; used to collect baseline data).</p> <p>Trauma History Checklist (THC; no reference provided; used to collect baseline data).</p> <p>Assault Information Interview (All; appears similar to that used in Foa 1991 and is not used in this review for the same reasons).</p>
<p><b>Notes</b></p>	<p>None.</p>

*Risk of bias table (Rothbaum 1997)*

Bias	Authors' judgment	Support for judgment
Random sequence generation (selection bias)	Low risk	No information was reported on method of sequence generation in published paper. Contact with investigator (Rothbaum 2012) confirmed that method used was a random numbers table.
Allocation concealment (selection bias)	Unclear risk	No information was reported on method of allocation concealment. Contact with investigator (Rothbaum 2012) confirmed that no method was used to conceal allocation in this pilot study; however, she retained the only allocation list.
Blinding of participants and personnel (performance bias)	High risk	Participants and personnel were not blinded, nor could they be for these types of interventions.
Blinding of outcome assessment (detection bias)	Unclear risk	Most outcomes were by self-report (e.g. depression and the IES); the PSS was, however, scored by an independent assessor.
Incomplete outcome data (attrition bias)	Low risk	Of the 21 women initially recruited 3 dropped out after the pretreatment assessment (one due to pregnancy; one assigned to WLC decided to pursue private therapy; one dropped out for unknown reasons). As dropout occurred before randomization and reasons are given, risk of bias to results is assessed as low. Data for all participants for all outcomes except one (PSS where 1 participant is missing) are complete.
Selective reporting (reporting bias)	Low risk	Study protocol does not appear to be publicly available but it seems likely that the published report included all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Efforts were made to assess adherence and therapist competence and ratings were good.



<b>Methods</b>	<u>Design</u> : parallel randomized controlled trial.
<b>Participants</b>	<p><u>Participants</u>: female rape survivors.</p> <p><u>Sex</u>: all female.</p> <p><u>Age</u>: mean 33.8 years (SD 11.0) for the completer sample (n = 60).</p> <p><u>Unit of allocation</u>: individual participant.</p> <p><u>Number allocated</u>: 74 enrolled; 1 dropped out during assessment, 1 terminated and referred elsewhere during treatment for not meeting criteria. Number at randomization not stated in paper but calculating from rates of dropout allocation numbers would appear to be n = 25 for EMDR intervention; n = 23 for P.E intervention; n = 24 for WLC.</p> <p><u>Number completing</u>: 60 (EMDR, n = 20; P.E, n = 20; WLC, n = 20).</p> <p><u>Recruitment and setting</u>: Recruitment method not stated. Phone screening was conducted by study coordinator; an independent assessor later evaluated those deemed appropriate by coordinator; those who met criteria and gave consent were then randomized (p. 609). Setting not stated; contact with investigator confirmed participants were seen at an outpatient clinic at a university medical school, Atlanta, Georgia, USA.</p> <p><u>Inclusion</u>: Rape must have occurred at least 3 months prior to evaluation (p. 609); "no maximum time since the index rape was imposed" in order to "obtain a diverse sample of rape victims with chronic PTSD".... All participants were screened on the CAPS (Blake et al 1990, etc.); the Assault Information Interview (AII, Rothbaum et al 1992); the Treatment, Legal and Drug Update Interview (UPDATE) (Rothbaum 1997); the Stressful Life Events Screening Questionnaire (SLESQ) Goodman et al 1998) the SCID (First et al 1996); the PSS-SR (Foa et al 1993); the revised Impact of Event Scales (IES; Weiss &amp; Marmar 1997); the State-Trait Anxiety Inventory (STAI; Spielberger et al 1970); the Beck Depression Inventory (BDI; Beck et al 1961) and the Dissociative Experiences Scale (DES; Bernstein et al 1986).</p> <p><u>Exclusion criteria</u>: history of schizophrenia or other psychoses; current suicidal risk</p>

	<p>or "practiced self-mutilation"; illiteracy; current alcohol or drug dependence as set by SCID; blind or having a history of serious eye disease "... that would cause risk with rapid eye movement"; use of cocaine within 60 days of treatment administration; in an ongoing threatening situation (e.g. domestic violence)(p.609).</p> <p><u>Ethnicity</u>: Completer sample (n = 60): 41 (68.3%) Caucasian; 29 (31.7%) of other ethnicity.</p>
	<p><u>Baseline characteristics</u>: Mean length of time since rape was (for the EMDR group) 145.9 months, (SD 146.8); for the PE group, 120.9 months (SD 94.1); and for the WLC group, 162.9 months (SD 136.9). One quarter of completers (n = 15) had two or more psychiatric diagnoses in addition to PTSD; 40% (n = 24) had one comorbid diagnosis and 35% (n=21) had a diagnosis of PTSD only. Details were given of assault characteristics for the completer group as a whole. Average length of assault was 88 minutes and 90% of assaults were perpetrated by one assailant. In 67% percent of cases the assailant was known to the survivor; other details (setting of assault and number of traumas) provided. Data on marital status (73.3% were never married, or divorced); percentage of those with children (31.7%); as well as education, income and employment status of sample were provided. Investigators reported that no significant differences existed at baseline between the three groups on any demographic or assault variable; nevertheless groups differed <i>significantly</i> on some baseline measures. The EMDR group had significantly higher overall PTSD symptoms on the CAPS (in terms of avoidance in particular) than did the PE group (p &lt;.01); EMDR group also had higher levels of one subscale of the PSS than the PE group (intrusive symptoms, p &lt; .05) , as well as greater depression, dissociation, and trait anxiety (p. 612).</p>
<p><b>Interventions</b></p>	<p><u>Three conditions.</u></p> <ul style="list-style-type: none"> <li>• <b>EMDR</b> (n = 25; 30 completed).</li> <li>• <b>P.E intervention</b> (n = 23, 20 completed).</li> <li>• <b>Waitlist control (WLC)</b> (n = 24, 20 completed).</li> </ul> <p><b>EMDR</b> = modified "to match the standard nine-session PE protocol used in previous studies" (and was thus delivered in 9 sessions rather than four). After initial sessions (two) of "information gathering, education about trauma effects, a rationale for the particular treatment, and treatment preparation"; sessions "3 to 9 consisted of administration of PE or EMDR" (p. 610). EMDR was described similarly to Rothbaum 1997, but not identically; as "having the patient imagine a scene that represents the worst part of the trauma, focusing on the sensations of</p>

	<p>distress in her body, and rehearsing negative thoughts that match the picture. The patient simultaneously follows the therapist's finger moving back and forth approximately 18 inches in front of her, a minimum of 20 times each repetition. Distress ratings are gathered using a 0-10 Subjective Units of Discomfort (SUDs) scale ... Once the distress about this scene from the memory drops to 0 or 1, the patient is asked to track the therapist's finger while rehearsing a new, preferred belief, repeating this sequence until the new statement feels true to the patient. Cognitive work is accomplished through the use of cognitive interweaves" (p. 610).</p> <p>PE = "A hierarchy of avoided situations is constructed for in vivo exposure homework. The next seven sessions are devoted to reliving the rape scene in imagination. Patients are instructed to try to imagine the assault scene as vividly as possible and describe it aloud in the present tense. Anxiety levels (SUDs = 0-100) are monitored every 5 minutes... Patients are encouraged to describe the rape in its entirety repeating it several times for 45 to 60 minutes per session. ... the patient's reaction to the exposure [is then discussed] and a homework assignment... is assigned. The patient's narratives are tape-recorded, and they are instructed to listen to the tapes at home at least once daily" ([. 610)</p> <p>WLC = WAIT participants were provided with treatment free of charge after the post-treatment assessments of those in the active intervention groups.</p>
	<p><u>Duration/intensity of intervention:</u> 4½ weeks, including 9 twice-weekly sessions of 90 minutes, delivered on an individual basis.</p> <p><u>Therapists:</u> "three doctoral-level psychologists who were trained in both therapies (p. 610).</p> <p><u>Length of follow-up:</u> participants were followed up for 6 months but by this time the WLC group had also received treatment.</p> <p><u>Treatment fidelity:</u> Efforts were made to assess "treatment adherence and competence" with 25% of session tapes overall (two from each participant within the active intervention groups) independently rated by experts chosen by programme developers Shapiro and Foa. EMDR sessions were rated as 92.09% adherent and PE ones, 90.46% adherent. Both mean scores for EMDR and PE therapist skill were "very good" for essential and unique items.</p>
<p><b>Outcomes</b></p>	<p><u>Primary outcomes</u></p> <p><b>PTSD symptoms</b> (objective) using the CAPS (Blake et al 1990; Blake et al 1995;</p>

	<p>Weathers et al 1992) via subscales assessing intrusion, avoidance and hyperarousal, and also with the “total” for that instrument, completed by independent assessors (Foa 1993).</p> <p><b>PTSD symptoms</b> (subjective) measured in two ways:</p> <ul style="list-style-type: none"> <li>• with the PSS-SR (Foa et al 1993) with sub-scores available for re-experiencing, avoidance and arousal;</li> <li>• with a revised version of the IES (the IES-R, Weiss &amp; Marmar, 1997) with sub-scores available for intrusion and avoidance/numbing as before, but now with hyperarousal as well.</li> </ul> <p><u>Secondary outcomes</u></p> <p>Depression using the BDI (Beck 1961).</p> <p>Anxiety using both State and Trait sub-scales on the State-Trait Anxiety Inventory (STAI; Spielberger 1993).</p> <p>Dissociation using the Dissociative Experiences Scale (DES; Bernstein &amp; Putnam 1986).</p>
<p><b>Notes</b></p>	<p>Investigators hypothesized that EMDR participants would improve faster than PE ones (p. 608).</p> <p>Investigators define an assault in adulthood as one when the girl is aged 12 or older.</p>

*Risk of bias table (Rothbaum 2005)*

Bias	Authors' judgment	Support for judgment
Random sequence generation (selection bias)	Low risk	No information was reported on method of sequence generation in published paper. Contact with investigator (Rothbaum 2012b) confirmed that method used was a random numbers table.
Allocation concealment (selection bias)	Unclear risk	No information was reported on method of allocation concealment. Contact with investigator (Rothbaum 2012b) confirmed that no method was used to conceal allocation in this pilot study; however, she retained the only allocation list.
Blinding of participants and personnel (performance bias)	High risk	Participants and personnel were not blinded, nor could they be for these types of intervention.
Blinding of outcome assessment (detection bias)	Unclear risk	Most outcomes were by self-report (with the exception of the CAPS); judgment: unclear risk of bias.
Incomplete outcome data (attrition bias)	Low risk	Of the 74 women initially recruited 74 enrolled; 1 dropped out during assessment, 1 terminated and referred elsewhere during treatment for not meeting criteria. 12 dropped out (no reasons given). Overall dropout was 19%. As dropout was similar across all treatment arms and investigators report that "intent to treat analyses provide no consequentially different results" (p. 611) the risk of bias for this criterion is assessed as low
Selective reporting (reporting bias)	Low risk	Study protocol does not appear to be publicly available but it seems likely that the published report included all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Efforts were made to assess treatment adherence and therapist competence and ratings were good (p. 610).

## 9.1 CHARACTERISTICS OF EXCLUDED STUDIES

Source Excluded	Reason for Exclusion
1. Allen, S.N. Bloom, S.L. (1994)	2. Not a study, a review
3. Arntz, A., Tiesema, M., Kindt, M. (2007)	4. Sample included both female victims of sexual assault and non-sexual assault
5. Barker J. (1997)	6. Sample included youth under the age of 18
7. Barker-Collo, S., Melnyk, W., McDonald-Miszczak, L. (2000)	8. 9. Sample included youth under the age of 18
10. Barnett, V. (2001)	11. Single system design n=1
12. Cantrella, G. (2005)	13. Within group design, no comparison group
14. Carey, L. (1996)	15. Qualitative study
16. Castillo, D. (2004)	17. Within group design, no comparison group
18. Clarke, S.B., Rizvi, S.L. Resick, P.A. (2008)	19. 20. Focus on borderline personalities
21. Cryer, L. Beutler, L. (1980)	22. Within group design, no comparison group
23. Echeburua, E., de Corral, P., Zubizarreta, I., Sarasua, B. (1997)	24. 25. Sample included youth under the age of 18
26. Echeburua, E., de Corral, P., Sarasua, B., Zubizarreta, I. (1996)	27. 28. Sample included youth under the age of 18
29. Field, T., Hernandez-Reif, M., Hart, S., Quintino, O., Drose, L., Field, T., Kuhn, C., Schanberg, S. (1997)	30. 31. 32. Did not include trauma outcome
33. Foa, E. (1997)	34. Not a study, a review
35. Foa E, Freund B, Dancu C: Franklin M, Perry K, Riggs D, Molnar C. (1999)	36. Sample mixed sexual assault and non- sexual assault
37. Foa, E., Dancu, C., Hembree, E. A., Jaycox, L.H., Meadows, E. A., Street, G.P. (1999)	38. Includes 27 non-sexual assault victims (e.g. aggravated assault or assault with a weapon)
39. Foa, E. Hearsti-Ikeda, D.; Perry, K. J. (1995)	40. Sample included both female victims of sexual assault and non-sexual assault
41. Foa, E., Hembree, E., Cahill, S., Rauch, S., Riggs, S., Feeny, N. (2005)	42. Sample included both female victims of sexual assault and non-sexual assault

43. Foa, E.B., Molnar, C., Cashman, L. (1995)	44. 45. Within group design, no comparison group
46. Frank, E., Anderson, B., Duffy Stewart, B., Dancu, C., Hughes, C., West, D. (1988)	47. Non-equivalent groups: analysis of immediate treatment seekers to late treatment seekers
48. Hébert, M. & Bergeron, M. (2007)	49. Sample was survivors of sexual abuse
50. Howard, A., Riger, S. Campbell, R. Wasco, (2003)	51. Compared victims of sexual assault to victims of physical assault
52. Ironson, G., Freud, B., Strauss, J. L., Williams, J. (2002)	53. Various conditions: spousal abuse, rape, child abuse, single trauma
54. Koss, M., Figueredo, A. (2004)	55. Longitudinal design
56. Krakow, B., Hollifield, B., Johnston, L., Koss, M., Schrader, R., Warner, T., et al. (2001)	57. Sample includes multiple traumatised women diagnosed with PTSD (non-specific to adult victims of sexual assault and rape). Contact with investigators was unsuccessful (disaggregated data could not be obtained)
58. Lindsay, J (1995).	59. Within group design, no comparison group
60. Longo, J. (2004)	61. Includes adulthood and childhood
62. Lubin, H., Loris, M., Burt, J., Johnson, D.R. (1998)	63. Sample includes multiple traumatised women diagnosed with PTSD (non-specific to adult victims of sexual assault and rape) 64.
65. MacIntosh, H. (2006)	66. Conceptual article
67. Mezey, G. (1997)	68. Not a study, a review
69. McFarlane, A. (2000)	70. Not a study, a review
71. Nishith, P., Duntley, S., Domitrovich, P., Uhles, M., Cook, B., Stein, P. (2003)	72. Within group design, no comparison group
73. Nishith, P., Nixon, R., Resick, P. (2005)	74. Sample includes multiple traumatised women diagnosed with PTSD (non-specific to adult victims of sexual assault and rape) 75.
76. Obinna, J. L. (2001)	77. Did not include trauma-based outcomes
78. Reed, H. (2002)	79. Within group design, no comparison group

80. Resick, H., Acierno, R, Holmes, M., Kilpatrick, D.G., Jager, N. (1999)	81. Study included victims within 72 hours post sexual
82. Resick, H., Acierno, R, Waldrop, A. E, King, L., King, D., Danielson, C., Ruggiero, K J., Kilpatrick, D.(2007)	83. Study included ages 15 and older within 72 hours post
84. Resick,P., Schnicke, M. (1990)	85. Not a study, a review
86. Roth, S., Dye, E., Lebowitz, L. (1988)	87. Within group design, no comparison group
88. Rothbaum, B. O.; Schwartz, A.C. (2002)	89. Not a study, a review
90. Scheck, M., Schaeffer, J., Gilette, C. (1998)	91. Sample included youth under the age of 18
92. Taylor, S. (2003)	93. Sample included non-sexual victims (e.g. traffic accident)
94. Vaa, G., Egner, H., Sexton, H. (2002)	95. Within group design, no comparison group
96. Welch, J., Mason, F. (2007)	97. Not a study, a review
98. Zeper, R., Schlaffman (1997)	99. Multiple baseline study
100.Zoellner, L., Feeny, N. , Fitzgibbons, L Foa, E. (2003)	101. Includes sexual and nonsexual assault



## 9.2 ONGOING STUDIES

<p>Suris, A, VA North Texas Health Care System, Dallas Treatment for Veterans with Military Sexual Trauma</p>	
Intervention	Cognitive Processing Therapy Present-Centered Therapy
Design	Randomized allocation, parallel assignment, single blind
Sample	Veterans with PTSD due to military sexual trauma
Outcomes	CAPS
Notes	Unpublished, last updated Nov 17 2011
<p>Galovski, T. Center for Trauma Recovery St. Louis Sleep-directed Hypnosis as a Complement to CPT in Treating PTSD</p>	
Intervention	Cognitive Processing Therapy with Hypnosis
Design	Randomized allocation, parallel assignment, single blind
Sample	Female victims of physical or sexual assault
Outcomes	BDI, PSS
Notes	Unpublished, last updated April 2011 May be useful if the sexual assault population can be extracted
<p>Galovski, T. Center for Trauma Recovery St. Louis Improving Effectiveness: Treatment Outcome Research</p>	
Intervention	Cognitive Processing Therapy
Sample	Female victims of interpersonal assault
Outcomes	BDI, PSS

Notes	Unpublished, last updated April 2011
May be useful if the sexual assault population can be extracted	
<p>Smith, T.  Wm S. Middleton Memorial Veterans Hospital, Wisconsin  Comparison of videoconference and face-to-face delivery of cognitive processing therapy for PTSD</p>	
Intervention	<b>Cognitive Processing Therapy</b>
Design	Randomized allocation, parallel assignment, single blind
Sample	<b>Adults with PTSD, index event involves military service</b>
Outcomes	<b>CAPS</b>
Notes	Unpublished, last updated July 2010 May be useful if the sexual assault population can be extracted

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# 10 Appendices

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## 10.1 DATA EXTRACTION CODING LOG

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### *Study Level*

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#### Administration

---

Reference Number (Study identifier):

*If multiple documents were used to code this study, indicate the supplemental study ID numbers*

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Cross reference document identifier:

---

Reviewer:

---

Date(s) of the Review:

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#### Source

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Author(s):

---

Year of Publication:

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Title:

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Source:

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Number of different "modules included in the report \_\_\_\_\_

Is the same control/comparison group used in different modules (1 = Yes; 0 = No)

---

## ***Treatment – Comparison Contrast Level***

### **Intervention Description**

**Intervention Description:** \_\_\_\_\_

**Intervention Type:**

- Behavioural Techniques
  - Flooding
  - Systematic Desensitization
  - Eye Movement Desensitization (EMDR);
- 2) Cognitive Behavioural Therapy
- 3) Cognitive Therapy
- 4) Relaxation
- 5) Rational-Emotive Therapy
- 6) Group Therapy
- 7) Hypnosis
- 8) Family/Couple Therapy
- 9) Existential Therapy
- 10) Humanistic Approach
- 11) Psychodynamic Therapy
- 12) Other: \_\_\_\_\_
- 13) Other: \_\_\_\_\_
- 14) Other: \_\_\_\_\_

**In what format or social setting is the treatment delivered:**

1. One-on-one
2. Group setting
3. Family setting
4. Internet-based
5. Mixed (any combination of the above)
6. Unclear

**Who delivers the treatment?**

1. Mental health professional
2. Academic Educator
3. Nonprofessional
4. Other

**Length of treatment type in months:**

- a. Minimum [ ]
- b. Maximum [ ]
- c. Mean [ ]
- d. Fixed (same for all subjects [ ])

**Length of follow-up program component (in weeks) [ ]**

**Details of the intended treatment type included:**

1 = Yes; 0= No

**Details on the implementation of the treatment type included:**

1 = Yes; 0= No

**Manuals used for implementation of the treatment type:**

1 = Yes; 0= No

**Fidelity checklist used for the implementation of the treatment type:**

1 = Yes; 0= No

---

Describe the program for the comparison group if other than no treatment or treatment as usual: \_\_\_\_\_

**What happens to the comparison group?**

- No treatment
- Waiting list (treatment begins at post)
- Waiting list (treatment begins at follow-up)
- Waiting list (treatment begins after study)
- Minimal treatment
- Alternate treatment

Where is the comparison drawn from:

**Methodological Rigor**

Use of control variables in statistical analyses to account for initial group differences (1 = Yes; 0= No)

Use of random assignment to conditions (1= Yes; 0= No)

If not random assignment, use of subject level matching (1= Yes; 0= No)

Matching variable(s) appropriate (1=Yes; 0=No)

Measurement of distress (1= Yes; 0= No)

Rating of initial group similarity (7 = highly similar; 1= dissimilar)

- Anchors:
- 7     Randomized design or matching
  - 5     Nonrandomized design with strong evidence of initial equivalence
  - 1     Nonrandomized design, comparison group highly likely to be different or known different that are related to distress.

Was attrition discussed in the study reported? (1= Yes; 0= No)

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**Quality Assessment**

a) Concealment of allocation

- ADEQUATE: indicates adequate concealment of the allocation (for example, by telephone randomisation, or use of consecutively numbered, sealed, opaque envelopes)
- UNCLEAR: indicates uncertainty about whether the allocation was adequately concealed (for example, where the method of concealment is not known);
- INADEQUATE: indicates that the allocation was definitely not adequately concealed (for example, open random number lists or quasi-randomization such as alternate days, odd/even date of birth, or hospital number).

b) Outcome assessment

- MET: assessor unaware of the assigned treatment when collecting outcome measures
- UNCLEAR: blinding of assessor not reported and cannot be verified by contacting investigators
- NOT MET: assessor aware of the assigned treatment when collecting outcome measures.

c) Co-intervention

- MET: interventions other than exercise avoided, controlled or used similarly across comparison groups.
  - UNCLEAR: use of interventions other than exercise not reported and cannot be verified by
-

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contacting the investigators

- NOT MET: dissimilar use of interventions other than exercise across comparison groups, i. e. differences in the care provided to the participants in the comparison groups other than the intervention under investigation.

d) Losses to follow-up

- MET: losses to follow up less than 20% and equally distributed between comparison groups  
 UNCLEAR: losses to follow up not reported  
 NOT MET: losses to follow up greater than 20%.

e) Intention-to-treat

- MET: intention to treat analysis performed or possible with data provided  
 UNCLEAR: intention to treat not reported, and cannot be verified by contacting the investigators  
 NOT MET: intention to treat analyses not done and not possible for reviewers to calculate independently.

(Adapted from Ekeland, Heian, Hagen, Abbott, & Nordheim 2004)

Note: Studies will be categorized in one of three groups: 1) low risk of bias (all criteria MET); 2) moderate risk of bias (3-4 criteria MET); 3) and high risk of bias (less than 3 criteria MET) .

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### ***Sample Level Coding Sheet***

#### **Characteristics of Setting and Participants**

Sample Description:

Sample description treatment group:

Sample description comparison group

---

Explanation of recruitment procedures:

---

Are the subjects included in the study clearly defined in terms of demographic features (age, sex, ethnicity, presence/absence of condition for eligibility criteria)?

Yes  No  Not Clear

---

Population Characteristics:

---

#### **Sampling**

Total number of individuals at beginning of the study:

Treatment Group N=

Control Group N=

---

---

Use of power analysis to determine sample size:

Yes  No  Not Clear

---

***Outcome Level Code Sheet***

Outcome Data
--------------

Outcome indicator of distress:

- 1 Trauma
- 2 PTSD
- 3 Depression
- 4. Anxiety

Outcome measures relevant to goals of intervention

Yes  No  Not Clear

Explanation of measurement instrument and information regarding reliability and validity

Yes  No  Not Clear

---

**Outcomes**

Outcome: \_\_\_\_\_

Instrument: \_\_\_\_\_

Type of measurement scale []

(1=Dichotomy; 2= Tricotomy; 3= 4-9 discrete ordinal categories; 4= >9 discrete ordinal categories or continuous

Source of data []

(1=self-report; 2= other report (teacher, parent), 3= official report, 4= other, 5=unclear

Is this a valid and reasonable measure of distress? (1 = questionable; 2= acceptable)

---

## *Effect Size Level Code Sheet*

### Data Reported

#### Identifying Information

Study identifier [ ]

Module identifier [ ]

Sample identifier [ ]

Outcome identifier [ ]

Effect size identifier (number each effect size within a study sequentially) [ ]

Pages where data are found [ ]

---

#### **Effect Size Information**

Effect size type

1. Baseline (pretest; prior to start of intervention)
2. Post-test (first measurement point post intervention)
3. Follow-up (all subsequent measurement points, post intervention)

Time frame in months captured by measure

a. Minimum [ ]

b. Maximum [ ]

c. Mean [ ]

d. Fixed [ ]

#### **Effect Size Data**

Treatment group sample size for this effect size [ ]

Comparison group sample size for this effect size [ ]

Treatment group mean (indicate decimal points [ ]

Comparison group mean (indicate decimal points [ ]

Are the above means adjusted? (1=Yes; 0=No)

Treatment group standard deviation [ ]

Comparison group standard deviation [ ]

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t-value from an independent t-test or square root of F-value from a one-way analysis of variance with one df in the numerator (only two groups) [ ]

Exact probability for a t-value from an independent t-test or square root of F-value from a one-way analysis of variance with one df in the numerator (only two groups) [ ]

Chi-square value with df = 1 (2 by 2 contingency table) [ ]

Correlation coefficient (point biserial) [ ]

Correlation coefficient (phi) [ ]

Computer Calculated ES [ ]

Hand Calculated ES [ ]

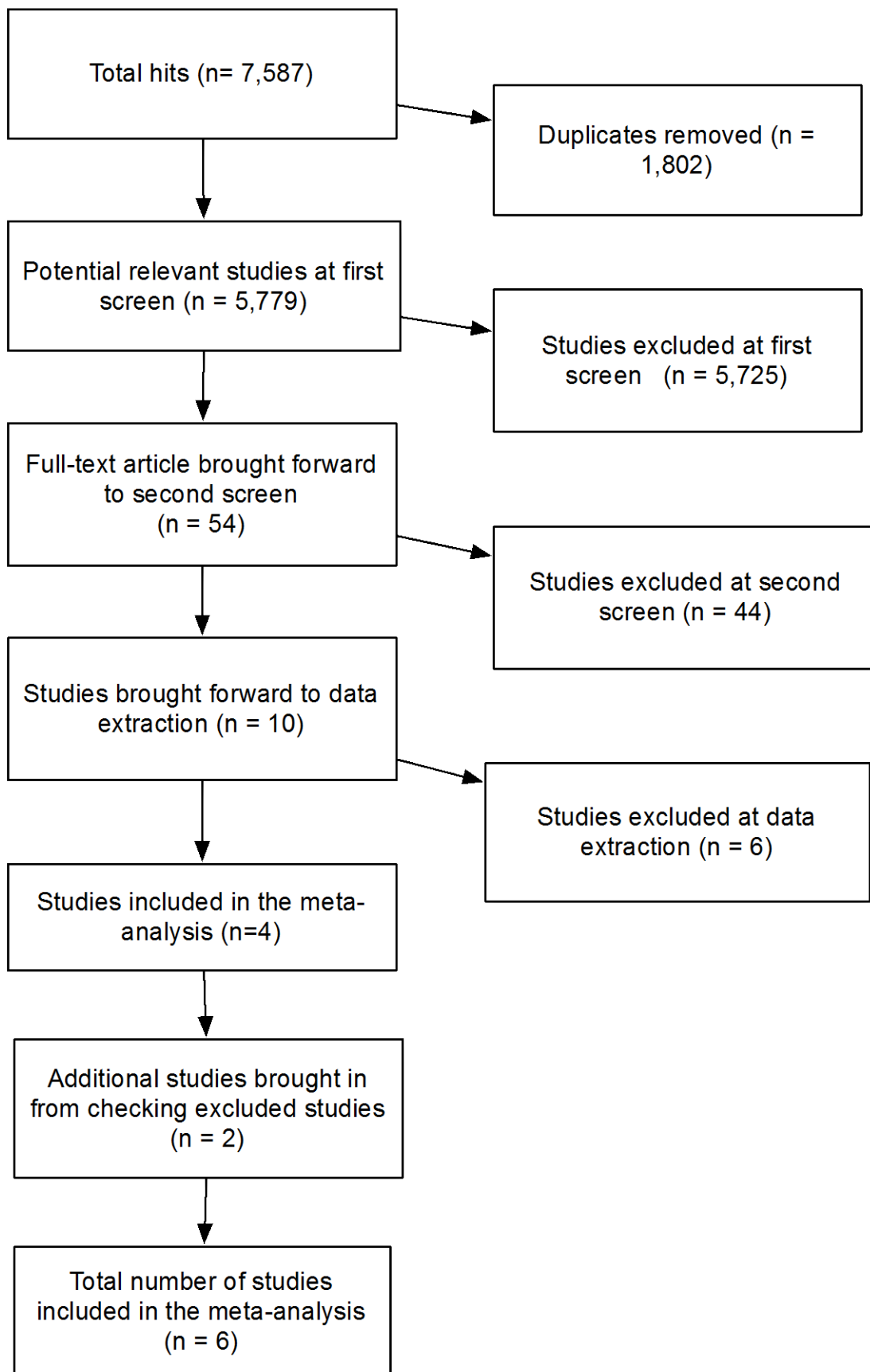
Hand Calculated SE of ES [ ]

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# 11 Figures

*Figure 1: Screening Process for Included Studies*



**Figure 2: Calculations for relative effectiveness of treatments for PTSD (objective)**

EMDR vs WTC					
SMD	SMDlow	SMDup	seSMD	Z	P
-1.89	-3.17	-0.62	0.65051	2.905412	0.003668

CPT vs WTC					
SMD	SMDlow	SMDup	seSMD	Z	P
-1.06	-1.56	-0.56	0.255102	4.1552	3.25E-05

EMDR vs CPT INDIRECT					
SMD	SMDlow	SMDup	seSMD	Z	P
-0.83	-2.19953	0.539535	0.698742	1.187849	0.234893

EMDR vs WTC					
SMD	SMDlow	SMDup	seSMD	Z	P
-1.89	-3.17	-0.62	0.65051	2.905412	0.003668

PE vs WTC					
SMD	SMDlow	SMDup	seSMD	Z	P
-1.02	-1.78	-0.25	0.390306	2.613333	0.008966

EMDR vs PE INDIRECT					
SMD	SMDlow	SMDup	seSMD	Z	P
-0.87	-2.35689	0.616893	0.758619	1.146821	0.251456

CPT vs WTC					
SMD	SMDlow	SMDup	seSMD	Z	P
-1.06	-1.56	-0.56	0.255102	4.1552	3.25E-05

PE vs WTC					
SMD	SMDlow	SMDup	seSMD	Z	P
-1.02	-1.78	-0.25	0.390306	2.613333	0.008966

CPT vs PE INDIRECT					
SMD	SMDlow	SMDup	seSMD	Z	P
-0.04	-0.95391	0.873906	0.466279	0.085786	0.931637

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## 12 Contribution of authors

**Cheryl Regehr:** Conceiving the review, securing funding, providing content expertise, writing the protocol and review

**Ramona Alaggia:** Conceiving the review, providing content expertise, writing the review.

**Jane Dennis:** Extracting data, constructing tables, writing up results

**Annabel Pitts:** Conducting the review

**Michael Saini:** Writing, designing and overseeing the protocol, conducting the analyses, writing the review.

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## 13 Declarations of interest

Although the authors of the review have contributed to research on the topic, they have no vested interest in the treatments that are the subject of this review or in the outcome of the review. The authors also do not have any incentives to represent findings in a biased manner.

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## 14 Sources of support

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### 14.1 INTERNAL SOURCES

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Canadian Partner of the Campbell Collaboration, Factor-Inwentash Faculty of Social Work, University of Toronto.

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### 14.2 EXTERNAL SOURCES

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