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Psychosocial interventions for survivors of rape and sexual assault experienced during adulthood (Review)

O'Doherty L, Whelan M, Carter GJ, Brown K, Tarzia L, Hegarty K, Feder G, Brown SJ

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[Intervention Review]

Psychosocial interventions for survivors of rape and sexual assault experienced during adulthood

Lorna O'Doherty^{1,2}, Maxine Whelan¹, Grace J Carter¹, Katherine Brown³, Laura Tarzia^{2,4}, Kelsey Hegarty^{2,4}, Gene Feder⁵, Sarah J Brown^{6,7}

¹Institute for Health and Wellbeing, Coventry University, Coventry, UK. ²Department of General Practice, The University of Melbourne, Melbourne, Australia. ³Department of Psychology and Sports Science, University of Hertfordshire, Hatfield, UK. ⁴The Royal Women's Hospital, Victoria, Australia. ⁵Centre for Academic Primary Care, Population Health Sciences, Bristol Medical School, University of Bristol, Bristol, UK. ⁶Faculty of Arts, Business and Law, Law School, USC: University of the Sunshine Coast, Sippy Downs, Australia. ⁷Faculty of Health and Applied Sciences, University of the West of England, Bristol, UK

Contact: Lorna O'Doherty, lorna.odoherty@coventry.ac.uk.

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ABSTRACT

Background

Exposure to rape, sexual assault and sexual abuse has lifelong impacts for mental health and well-being. Prolonged Exposure (PE), Cognitive Processing Therapy (CPT) and Eye Movement Desensitisation and Reprocessing (EMDR) are among the most common interventions offered to survivors to alleviate post-traumatic stress disorder (PTSD) and other psychological impacts. Beyond such trauma-focused cognitive and behavioural approaches, there is a range of low-intensity interventions along with new and emerging non-exposure based approaches (trauma-sensitive yoga, Reconsolidation of Traumatic Memories and Lifespan Integration). This review presents a timely assessment of international evidence on any type of psychosocial intervention offered to individuals who experienced rape, sexual assault or sexual abuse as adults.

Objectives

To assess the effects of psychosocial interventions on mental health and well-being for survivors of rape, sexual assault or sexual abuse experienced during adulthood.

Search methods

In January 2022, we searched CENTRAL, MEDLINE, Embase, 12 other databases and three trials registers. We also checked reference lists of included studies, contacted authors and experts, and ran forward citation searches.

Selection criteria

Any study that allocated individuals or clusters of individuals by a random or quasi-random method to a psychosocial intervention that promoted recovery and healing following exposure to rape, sexual assault or sexual abuse in those aged 18 years and above compared with no or minimal intervention, usual care, wait-list, pharmacological only or active comparison(s). We classified psychosocial interventions according to Cochrane Common Mental Disorders Group's psychological therapies list.

Data collection and analysis

We used the standard methodological procedures expected by Cochrane.

Main results

We included 36 studies (1991 to 2021) with 3992 participants randomly assigned to 60 experimental groups (3014; 76%) and 23 inactive comparator conditions (978, 24%).

The experimental groups consisted of: 32 Cognitive Behavioural Therapy (CBT); 10 behavioural interventions; three integrative therapies; three humanist; five other psychologically oriented interventions; and seven other psychosocial interventions. Delivery involved 1 to 20 (median 11) sessions of traditional face-to-face (41) or other individual formats (four); groups (nine); or involved computer-only interaction (six). Most studies were conducted in the USA ($n = 26$); two were from South Africa; two from the Democratic Republic of the Congo; with single studies from Australia, Canada, the Netherlands, Spain, Sweden and the UK. Five studies did not disclose a funding source, and all disclosed sources were public funding.

Participants were invited from a range of settings: from the community, through the media, from universities and in places where people might seek help for their mental health (e.g. war veterans), in the aftermath of sexual trauma (sexual assault centres and emergency departments) or for problems that accompany the experience of sexual violence (e.g. sexual health/primary care clinics). Participants randomised were 99% women (3965 participants) with just 27 men. Half were Black, African or African-American (1889 participants); 40% White/Caucasian (1530 participants); and 10% represented a range of other ethnic backgrounds (396 participants). The weighted mean age was 35.9 years (standard deviation (SD) 9.6). Eighty-two per cent had experienced rape or sexual assault in adulthood (3260/3992). Twenty-two studies (61%) required fulfilling a measured PTSD diagnostic threshold for inclusion; however, 94% of participants (2239/2370) were reported as having clinically relevant PTSD symptoms at entry.

The comparison of psychosocial interventions with inactive controls detected that there may be a beneficial effect at post-treatment favouring psychosocial interventions in reducing PTSD (standardised mean difference (SMD) -0.83, 95% confidence interval (CI) -1.22 to -0.44; 16 studies, 1130 participants; low-certainty evidence; large effect size based on Cohen's D); and depression (SMD -0.82, 95% CI -1.17 to -0.48; 12 studies, 901 participants; low-certainty evidence; large effect size). Psychosocial interventions, however, may not increase the risk of dropout from treatment compared to controls, with a risk ratio of 0.85 (95% CI 0.51 to 1.44; 5 studies, 242 participants; low-certainty evidence). Seven of the 23 studies (with 801 participants) comparing a psychosocial intervention to an inactive control reported on adverse events, with 21 events indicated. Psychosocial interventions may not increase the risk of adverse events compared to controls, with a risk ratio of 1.92 (95% CI 0.30 to 12.41; 6 studies; 622 participants; very low-certainty evidence).

We conducted an assessment of risk of bias using the RoB 2 tool on a total of 49 reported results. A high risk of bias affected 43% of PTSD results; 59% for depression symptoms; 40% for treatment dropout; and one-third for adverse events. The greatest sources of bias were problems with randomisation and missing outcome data. Heterogeneity was also high, ranging from $I^2 = 30%$ (adverse events) to $I^2 = 87%$ (PTSD).

Authors' conclusions

Our review suggests that survivors of rape, sexual violence and sexual abuse during adulthood may experience a large reduction in post-treatment PTSD symptoms and depressive symptoms after experiencing a psychosocial intervention, relative to comparison groups. Psychosocial interventions do not seem to increase dropout from treatment or adverse events/effects compared to controls. However, the number of dropouts and study attrition were generally high, potentially missing harms of exposure to interventions and/or research participation. Also, the differential effects of specific intervention types needs further investigation.

We conclude that a range of behavioural and CBT-based interventions may improve the mental health of survivors of rape, sexual assault and sexual abuse in the short term. Therefore, the needs and preferences of individuals must be considered in selecting suitable approaches to therapy and support. The primary outcome in this review focused on the post-treatment period and the question about whether benefits are sustained over time persists. However, attaining such evidence from studies that lack an active comparison may be impractical and even unethical. Thus, we suggest that studies undertake head-to-head comparisons of different intervention types; in particular, of novel, emerging therapies, with one-year plus follow-up periods. Additionally, researchers should focus on the therapeutic benefits and costs for subpopulations such as male survivors and those living with complex PTSD.

PLAIN LANGUAGE SUMMARY

How helpful to recovery and healing are support and psychological interventions after exposure to sexual violence and abuse?

Key messages

- We found evidence that psychological or social (collectively known as 'psychosocial') interventions may reduce symptoms of post-traumatic stress disorder (PTSD) and depression in survivors of rape, sexual assault and abuse experienced during adulthood.

- Our review suggests that interventions did not worsen symptoms or lead to unwanted effects. However, as large numbers of participants dropped out of treatments or did not complete studies' assessments, these findings are unclear. More recent studies were better at reporting information about participant safety, and reasons why survivors did not complete treatments or health and wellbeing assessments after the interventions.
- As the studies brought diverse groups of participants together, future research is needed to improve understanding about which interventions are most suited to particular groups of survivors, including those with long-term or complex trauma, as well as men and gender minorities. 'Emerging' interventions, which have potential to expand treatment choices for survivors, also warrant more evaluation.

What is 'sexual violence and abuse'?

'Sexual violence and abuse' means any sexual activity or act that happened without consent. It includes rape, sexual assault, sexual abuse and sexual harassment. It causes emotional and physical health problems that can be long-lasting. The effects are often made worse by fear, shame, feelings of self-blame and the negative responses of others.

How is sexual violence and abuse treated?

Survivors have a range of physical, sexual health and forensic care needs in the aftermath of rape, sexual assault or abuse. Psychosocial interventions may be offered in response to these needs at different stages in survivors' recovery journeys. Some interventions aim to assist survivors by carefully re-exposing them to aspects of the original trauma to 'process' what happened (e.g. Trauma-focused Cognitive Behavioural Therapy (CBT)). Other treatments focus less on the traumatic memories, instead helping survivors cope with life after abuse (e.g. different forms of counselling; education about mental health; and support for a range of needs).

What did we want to find out?

We wanted to know whether psychosocial interventions help to relieve the mental health impact experienced by survivors as a result of rape, sexual assault or sexual abuse in adulthood. We also wanted to know if some types of interventions were more helpful than others.

What did we do?

We searched for studies comparing the effects of psychosocial interventions for individuals who had been subjected to rape, sexual assault or sexual abuse from the age of 18 years, with a control group (a group of participants who did not receive the intervention but instead were given their usual care, were placed on a waiting-list for treatment, or received very minimal assistance, such as leaflets). We looked for differences between groups on trauma and depression symptoms after receiving the intervention; dropout from interventions (non-completion); and any unwanted effects related to the intervention or research.

About the studies and their participants

We found 36 studies that placed consenting adult participants by chance into an intervention or a control group. Participants were invited from a range of settings: community; universities; places where people seek help for their mental health, sexual trauma (e.g. specialist sexual assault centres and emergency departments) or for problems that occur alongside the experience of sexual violence (e.g. primary care clinics); and via media requests. The studies included 3992 survivors; only 27 were men. Sixty per cent of participants were Black or from a minority ethnic or cultural background. The average age was 36 years, and nearly all had symptoms of PTSD.

Most studies were done in the USA (26); there were two from South Africa; two from the Democratic Republic of the Congo; and single studies from Australia, Canada, the Netherlands, Spain, Sweden and the UK. Five studies did not disclose a funding source; those that did reported public funding.

Over half the interventions were CBT-based. Support was mostly delivered one-to-one by trained mental health professionals and varied between 1 and 20 sessions.

What did we find?

Survivors who participate in a psychosocial intervention may experience a large reduction in PTSD and depression symptoms soon after the intervention is completed. Non-completion was not more common among survivors who experienced interventions compared to control groups, but this was based on a small number of studies. Psychosocial interventions may not increase the risk of unwanted effects. Only seven studies reported 21 unwanted effects, suggesting most researchers may not have actively monitored the negative impacts of interventions or participation in the studies.

What are the limitations of the evidence?

We have little confidence in the results because of concerns about the level of variation across the studies (e.g. types of survivor experiences, wide range of interventions and study sizes). It is possible that the allocation of survivors to one group or another may not have been entirely random. Furthermore, survivors who did not complete interventions or study assessments may have differed in important ways from survivors who did (e.g. had better/worse health problems).

How up-to-date is the evidence?

The evidence is up-to-date to January 2022.

SUMMARY OF FINDINGS

Summary of findings 1. Summary of findings table - Psychosocial interventions compared to inactive control for survivors of sexual violence and abuse

Psychosocial interventions compared to inactive control for survivors of sexual violence and abuse

Patient or population: survivors of sexual violence and abuse

Setting: mental health clinics; veterans affairs medical centres; sexual assault and abuse services in acute, primary care and community; and academic/experimental settings

Intervention: psychosocial interventions

Comparison: inactive control

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with inactive control	Risk with psychosocial interventions				
PTSD symptoms, post-treatment (self-reported or clinician-rated)	-	SMD 0.83 lower (1.22 lower to 0.44 lower)	-	1130 (16 RCTs)	⊕⊕⊕⊕ Low ^{a,b}	Lower score means fewer PTSD symptoms. An SMD of -0.83 is a large effect (Cohen's D). Sub-group analyses indicate there may be evidence of a group difference for CBT (SMD -0.77) and Behavioural Therapy (SMD -1.85), but no evidence of a difference for low-intensity interventions (P = 0.09).
Depressive symptoms, post-treatment (self-reported or clinician-rated)	-	SMD 0.82 lower (1.17 lower to 0.48 lower)	-	901 (12 RCTs)	⊕⊕⊕⊕ Low ^{a,c,d}	Lower score means fewer depressive symptoms. An SMD of -0.82 is a large effect (Cohen's D). Sub-group analyses indicate there may be evidence of a group difference for CBT (SMD -0.73) and Behavioural Therapy (SMD -1.51), but no evidence of a difference for low-intensity interventions (P = 0.39).
Dropout from treatment (a count of participants not meeting study-defined completion threshold)	336 per 1000	286 per 1000 (171 to 484)	RR 0.85 (0.51 to 1.44)	242 (5 RCTs)	⊕⊕⊕⊕ Low ^{e,f}	
Adverse events (a count of reported harms or adverse	7 per 1000	13 per 1000 (2 to 82)	RR 1.92 (0.30 to 12.41)	622 (6 RCTs)	⊕⊕⊕⊕ Very low ^{g,h,i}	There were 21 adverse events reported in just 7 studies, suggesting many studies may not have

actively monitored negative impacts of the treatments or being in the research.

events/experiences over life of study/follow-up)

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

CI: confidence interval; **RR:** risk ratio; **SMD:** standardised mean difference

GRADE Working Group grades of evidence

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

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

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

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

See interactive version of this table: https://gdt.gradepr.org/presentations/#/isof/isof_question_revman_web_429039861582912181.

^a Sensitivity analyses removing studies at high risk of bias reduced the effect size to moderate based on Cohen's D.

^b Downgraded 1 level due to heterogeneity I² = 87%, P < 0.001.

^c Downgraded 1 level due to 50% or more of the results receiving an overall high risk of bias judgement.

^d Downgraded 1 level due to heterogeneity I² = 78%, P < 0.001.

^e Only includes the 5 studies that reported dropout from a psychosocial intervention vs minimal intervention; this analysis may not directly address the question about treatment completion as this requires comparing 2 active interventions.

^f The confidence interval includes appreciable benefit or harm.

^g Only 6 of 23 studies in the main comparison reported on adverse events by group, raising concerns about selective reporting bias.

^h Adverse events were not reported using consistent methods.

ⁱ Imprecision due to too few events.

BACKGROUND

Description of the condition

Rape, sexual assault and sexual abuse are serious public health and human rights problems (WHO 2013a). For the purpose of the review, we will use the overarching term 'sexual assault', which refers to any act of physical, psychological and emotional violation in the form of a sexual act, inflicted on someone without their consent (see review protocol for overview of definitions; Brown 2019). Sexual assault disproportionately affects the lives of women (Walby 2016). Research into men's experiences of sexual assault has been scant by comparison, and the prevalence of sexual assault perpetrated against men is largely unknown. In England and Wales, it is estimated that 4% of adults aged 16 to 74 years (1.6 million people) have experienced sexual assault by rape or penetration (including attempts) since the age of 16 years (7% for women and 0.5% for men) (ONS 2021). Social and legal marginalisation, exacerbated by gender-defined services, stigma and discrimination, all mean that sexual assault experienced by gender and sexual minorities is hidden and poorly understood (e.g. see Wirtz 2018). There are extensive immediate and long-term physical and mental health consequences for survivors (Jina 2013). The consequences for adult and child victims include injuries, substance misuse, eating disorders, post-traumatic stress disorder (PTSD), anxiety, depression, self-harm and suicidality (Oram 2017; WHO 2013a). Sexual and reproductive health implications include condom non-use, unwanted pregnancy (Decker 2014), sexually transmitted infections (WHO 2013a), urinary tract infections, painful sex, chronic pelvic pain and vaginal bleeding (Campbell 2002), fistula (Dossa 2014) and increased risk of sexual dysfunction such as low sexual desire and difficulty with physiological and psychological sexual arousal, and low sexual satisfaction (Pulverman 2018; Pulverman 2021). For male victims, physical health consequences include genital and rectal injuries and erectile dysfunction (Tewkesbury 2007; Weare 2021). The negative effects of rape and sexual assault ripple across generations, having social and economic costs in addition to impacts on physical and mental health by affecting individuals' capacities to work and to participate in family and community life.

The mental health burden is substantial and similar across male and female victims (Coxell 2010; Tewkesbury 2007; Walker 2005; WHO 2013a). Sexual assault was ranked among the top three most traumatic life events in the US National Epidemiologic study (Pietrzak 2011). Those with a psychiatric diagnosis of PTSD were four times more likely to report exposure to sexual assault than those that did not have a diagnosis, and 13% of women with PTSD had lifetime experience of sexual assault. PTSD is a psychiatric disorder that can follow exposure to psychological trauma and is associated with intrusive memories, nightmares, avoidance, and problems with sleep and concentration (Lerman 2019). Guina and colleagues reported no difference in PTSD symptoms and severity among men and women who had experienced sexual trauma (Guina 2016). Indirect pathways to poor long-term health outcomes are also of concern; for example, taking lifetime PTSD as a proxy, PTSD is associated with increased risk of hypertension, cardiovascular disease (Jakubowski 2018) and gastrointestinal problems (Pietrzak 2011). Thus, the immense physical and psychological impacts of sexual violence exposure can lead to long-term disability.

Considering what is known about the prevalence of sexual assault, the risk for developing PTSD and poor mental health after exposure to sexual violence and abuse, and the risk for re-victimisation and further traumatisation (Finkelhor 2007; Möller 2017), identifying accessible and cost-effective treatments for this population is of great importance.

A large body of work exists to establish the most effective psychological treatments for PTSD in mixed trauma populations such as among those affected by disasters; migration/refugee trauma; active duty and ex-serving military service; physical abuse; medical trauma; traumatic grief; intimate partner violence; child sexual abuse; sexual assault and rape; and military sexual trauma. This work has led to trauma-focused therapies being recommended as frontline interventions for PTSD (e.g. Centre for Posttraumatic Mental Health 2013; NICE 2018; VA/DoD 2017). Trauma-focused therapies include behaviour-based approaches such as Eye Movement Desensitisation Reprocessing (EMDR), and Cognitive Behavioural Therapy with a trauma focus (TF-CBT), of which Cognitive Processing Therapy (CPT) and Prolonged Exposure (PE) have received the most attention.

Our work aims to extend this body of research by synthesising evidence focused specifically on survivors of rape, sexual assault and abuse during adulthood. Given the wide range of contexts in which survivors of sexual assault are located, and the variable needs of individuals depending on their stage of recovery and resources available, we aimed for broad scope around the nature of the interventions we included. We refer to 'psychosocial' interventions as encompassing support and advocacy interventions for survivors as well as psychological or psychotherapeutic treatments.

Description of the intervention

Psychosocial interventions are those that involve "interpersonal or informational activities, techniques, or strategies that target biological, behavioural, cognitive, emotional, interpersonal, social, or environmental factors with the aim of improving health functioning and well-being" (IOM 2015 p.5). For the purposes of this review, we organised psychosocial interventions according to the list of psychological therapies of the former Cochrane Depression, Anxiety and Neurosis (CCDAN) and Cochrane Common Mental Disorders (CCMD) Groups. These include the following types of interventions:

a) Cognitive Behavioural Therapy (CBT) including trauma-focused CBT (TF-CBT) and other CBT-based techniques are promoted for the treatment of PTSD in best practice guidelines (Centre for Posttraumatic Mental Health 2013; Foa 2009; IOM 2008; NICE 2018; VA/DoD 2017). Cognitive-behavioural processes can be sub-classified into three major classes (Dobson 2009): 1) cognitive re-structuring, which focuses on internal underlying beliefs and thoughts with the aim of challenging maladaptive thought patterns; 2) coping skills therapy, which targets the identification and alteration of cognitions and behaviours that may increase the impact of negative external events; and 3) problem-solving therapies, which combine cognitive re-structuring and coping skills therapy to change internal thought patterns and optimise responses to external negative events. Each of these three classes have a slightly different target for change, demonstrating the wide range of psychological interventions based upon cognitive-behavioural principles (Dobson 2009). Cognitive

Processing Therapy (CPT; [Resnick 1997](#)) and Prolonged Exposure Therapy (PET; [Foa 1986](#)) are the most common cognitive-behavioural approaches evaluated in studies of interventions for people affected by PTSD and for those who have been subjected to sexual assault. Cognitive Processing Therapy and Prolonged Exposure are considered trauma-focused CBT and they are also 'exposure'-based therapies. This means they use the concept of emotional processing theory ([Foa 1986](#)), that is, they use interventions for activation of fear structure, habituation and disconfirmation of erroneous cognitions and beliefs to treat PTSD ([Foa 2016](#)). Other CBTs used with sexual assault survivors such as Stress Inoculation Therapy (SIT; [Meichenbaum 1977](#)) do not encourage imaginal exposure.

b) Behaviour therapies include relaxation techniques and Eye Movement Desensitisation and Reprocessing (EMDR; [Shapiro 1995](#)). NICE guidance recommends EMDR for adults with a diagnosis of PTSD (or clinically important symptoms of PTSD) who have presented after a (non-combat related) trauma if the person has a preference for EMDR ([NICE 2018](#)). As with TF-CBT, EMDR sits within a trauma-response theoretical model ([Goodman 1993](#); [Herman 1992](#)).

c) Third-Wave CBT, such as Acceptance and Commitment Therapy and mindfulness, prioritises the holistic promotion of psychological and behavioural processes associated with well-being over the reduction of psychological and emotional symptoms. It focuses on context, processes and functions of how a person relates to internal experiences over the content of the thoughts themselves.

d) Integrative Therapies include such approaches as interpersonal therapy and blend elements of different traditions or approaches.

e) Humanistic Therapies include Gestalt and experiential approaches, as well as supportive and non-directive therapy following the work of Rogers among others. Person-Centred Therapy focuses on providing support, and discussing and understanding in the present problems that are generated by the client.

f) Other psychologically orientated interventions such as art therapy; meditation; and hypnotherapy. A good example is Present-Centred Therapy, initially developed as a control group for other therapies and recommended as a second-line treatment in its own right ([Hamblen 2019](#)). The theoretical basis for Present-Centred Therapy arises from the large literature on 'common factors' used in psychotherapy like the supportive therapeutic relationship, a rationale that explains the person's symptoms and the steps for relieving them, the experience of talking about problems in a safe environment, and creating positive expectations and hope.

g) Support and services delivered by mentors, support workers, advisors or advocates (for example, independent sexual assault advisors (ISVAs), in the UK), and support groups.

To emphasise the evidence of benefits (and harms) of psychosocial interventions across diverse adult survivor communities, we set out to include studies of sexual assault-only samples, as well as studies where sexual assault survivors were a subset of a wider trauma sample. Despite the focus on sexual assault alone, we anticipated a high degree of heterogeneity across study populations due to the different settings in which people get help and due to the

widespread contexts of abuse. Studies evaluating treatments for exposure to sexual assault involve university students ([Anderson 2010](#)); veterans and active service personnel subjected to military sexual trauma ([Acierno 2021](#); [Katz 2014](#); [Suris 2008](#)); acute settings such as emergency departments ([Walsh 2017](#)); survivors seeking counselling and specialist support for sexual assault ([Nixon 2016](#); [Rajan 2020](#)) and other forms of support in the community ([Bass 2013](#); [Bass 2016](#)); and clinical samples and mental health outpatients ([Falsetti 2008](#); [Foa 2006](#)). Such features are important; for example, the military environment may serve to intensify trauma and impact a person's capacity to cope following a military sexual trauma, if they have limited options for escaping the perpetrator in such a closed environment ([Suris 2013](#)). In this sense, Katz and colleagues liken it to child sexual abuse, feeling betrayed by those who are supposed to be protective, and not being able to report or get help without incurring devastating consequences ([Katz 2014](#)). The experience of intimate partner sexual violence may also produce these adverse effects. Aside from the nature and context of the assault, studies may also focus on how effectively interventions serve survivors with certain characteristics such as age ([Bowland 2012](#)); cultural and ethnicity heritage ([Feske 2008](#)); and gender ([Echeburua 1996](#); [Gray 2020](#)).

Thus, in order to respond to the needs and circumstances of these varied samples of survivors, studies test not only different intervention types but also different modalities for delivering them. These include group ([Bass 2013](#); [Bass 2016](#)) and individual ([Foa 1991](#); [Foa 1999](#); [Foa 2005](#); [Foa 2006](#)) formats and delivery via computer ([Bomyea 2015](#)), online, by telephone ([Anderson 2010](#)), video ([Miller 2015](#)), using telemedicine or in person ([Acierno 2021](#)). A large proportion of the work has emerged from expert treatment centres and/or with clinicians highly proficient in and with strong allegiance to trauma-focused CBT approaches used for sexual assault survivors ([Nixon 2016](#)) and interventions might involve single sessions ([Rajan 2020](#)) or a small number of sessions ([Gray 2020](#)) or multiple sessions ([Belleville 2018](#); [Falsetti 2008](#)). It is important, therefore, to compare the effects of interventions of different intensity and duration to identify cost-effective ways of supporting survivors. Thus, the review will extend beyond this to include non-specialist settings and will examine these many different aspects of interventions and populations.

See [Appendix 1](#).

How the intervention might work

See [Appendix 1](#).

Why it is important to do this review

Clinical and policy guidelines inform responses to rape and sexual assault (e.g. [NICE 2018](#); [WHO 2013b](#)), but gaps remain in our knowledge of the most effective ways of intervening to improve health outcomes and prevent further victimisation. While there is moderate evidence on the consequences of sexual trauma ([Description of the condition](#)), it is less clear what happens to people's health and well-being over time, including in response to different interventions. Whilst TF-CBT and EMDR are recommended for PTSD, none has been fully effective in its treatment ([Kitchiner 2019](#)), with most studies reporting that between 60% and 72% of participants retain diagnosis ([Steenkamp 2015](#)). Dropout is also a concern in studies of interventions that involve in vivo or imaginal exposure, or both. In response, there have been calls for new and

more effective approaches to the treatment of PTSD (Gray 2020; Kitchiner 2019; Steenkamp 2015).

There is good evidence for the effects of psychological treatments in reducing mental health issues in children who have experienced sexual trauma (Gillies 2016), with CBT for sexually abused children with symptoms of post-traumatic stress showing the best evidence for reduction in mental health conditions (MacDonald 2012; MacMillan 2009). However, these conclusions cannot be extrapolated to adults who have experienced sexual trauma, and there has been no recent systematic review or meta-analysis examining the effects of intervention on this population.

Relative to intimate partner violence (IPV), sexual violence has received less attention in the research literature, and several reviews focus on psychological interventions for IPV (Arroyo 2017; Hameed 2020; Trabold 2018). While there is certainly overlap in the populations of interest, in that many sexual assaults and rapes occur within IPV, rape and sexual assault is not exclusive to IPV and many who experience sexual trauma as adults outside a domestic abuse context require support or interventions. Those reviews that have looked at rape and sexual assault have tended to focus on women (Parcesepe 2015) and children (Gillies 2016; MacDonald 2012), indicating that the experiences of men and transgender survivors are less represented in the literature. Similarly, the representation of sexual minorities and ethnic minorities is typically minimal in intervention studies (IOM 2008), with studies rarely sufficiently powered to detect benefits and costs for specific user groups or subgroups of survivors.

Other reviews have focused on psychological therapies for PTSD in any population (Bisson 2013); in specific populations such as military personnel with PTSD (Kitchiner 2019) or those with comorbid substance misuse problems (Roberts 2015; Roberts 2016); or examined combined pharmacotherapy and psychological therapies for PTSD (Hetrick 2010). In these reviews, sexual assault and rape survivors are a subset of the population. While these reviews are helpful in understanding appropriate therapies to combat PTSD specifically, not all sexual assault or rape victims experience PTSD, and the impacts of sexual trauma are broader than PTSD. Campbell and colleagues published a review in 2009 (Campbell 2009) and Regehr and colleagues a systematic review in 2013 (Regehr 2013) on interventions to reduce distress in adult victims of sexual assault and rape. These reviews are relevant; however, they are now a decade out of date, and there have been many developments in terms of novel interventions since these publications. Contemporary approaches have been tested in several recent studies, including Reconsolidation of Traumatic Memories (Gray 2020), Lifespan Integration (Rajan 2020); trauma-sensitive yoga (Kelly 2021); and neurofeedback and biofeedback (Bell 2019).

We believe it is important to examine the interventions that go beyond psychotherapeutic approaches. Survivors may not be able to access psychotherapy (e.g. due to long waiting lists or lack of available services) or they may not be at the appropriate stage in their recovery to discuss the traumatic experience. Among those involved in criminal justice proceedings, there may be concerns about material generated as a result of therapy being obtained by police on the basis that it represents a reasonable line of enquiry (CPS 2021). For these reasons, psychosocial interventions that avoid discussion of the trauma can be a vital source of support to rape and sexual assault victims. Although many psychosocial

interventions have demonstrated effectiveness, the findings have not been synthesised well, and it can be difficult to know what treatments are effective (IOM 2015).

The current review also examines the broader range of impacts of sexual trauma for all victims who experience rape and sexual assault as adults. Hence, this review is feasible and timely and addresses an important gap in the current literature.

OBJECTIVES

To assess the effects of psychosocial interventions on mental health and well-being for survivors of rape and sexual assault experienced during adulthood.

METHODS

Criteria for considering studies for this review

Types of studies

Any study that allocated individuals or clusters of individuals by a random or quasi-random method (whereby the method of allocation was not truly random such as alternate allocation, allocation by birth date, day shift etc.) to a psychosocial intervention for adult victims of rape or sexual assault compared with no intervention, usual care, wait-list, or minimal or active comparison (see 'Comparator intervention' under [Types of interventions](#)).

Studies were eligible for inclusion in the review if they used random assignment to treatment and comparison groups or employed one of the following designs: quasi-randomised controlled trial (RCT) (non-randomised experimental design trials); cluster-randomised trials (instead of individuals, groups will be randomised) or cross-over trial (longitudinal studies where the participant receives a sequence of different treatments).

Types of participants

Adults aged 18 years and older, of any gender, who had experienced rape or sexual assault as an adult (i.e. aged 18 years and older), irrespective of a mental health diagnosis. Types of sexual assault included rape, attempted rape, forced oral sex, anal sex, penetration with objects, touching of intimate parts and any sexual contact where consent was not given, as well as forcing or manipulating someone to witness sexual acts. We included studies of participants who screened positive for exposure to sexual violence, even if they did not report what those behaviours were. We included studies involving subsets of eligible participants provided that the subset included at least 50% of those randomised and could be analysed separately. We included studies of participants recruited in any setting (e.g. community, forensic, criminal justice and health).

We excluded samples made up entirely of individuals (adult or child) who were victims of rape, sexual assault or sexual abuse during their childhood (aged 17 years and under), as well as samples of children (i.e. those younger than 18 years of age).

Types of interventions

Experimental intervention

The experimental intervention consisted of any type of psychosocial and psychological intervention that targeted recovery from sexual assault or rape, including the following.

1. Formal CBT, TF-CBT and CBT-based techniques
2. Integrative therapies (e.g. interpersonal therapy)
3. Behaviour therapies (e.g. EMDR and relaxation techniques)
4. Third-wave CBT (e.g. Acceptance and Commitment Therapy, mindfulness)
5. Humanistic therapies (e.g. supportive and non-directive therapy)
6. Other psychologically orientated interventions (e.g. art therapy, meditation, trauma-informed body-based practices (such as embodied relational therapy, yoga and Tai Chi), narrative therapy)
7. Other psychosocial interventions, including support services delivered by mentors, support workers, advisors or advocates (such as independent sexual assault advisors (ISVAs) in the UK), support groups and coping interventions.

We included interventions of any duration or frequency of treatment so long as the treatment met the criteria stated above.

For all interventions, mode of intervention delivery included one or more of the following: face-to-face; telephone; or computer-based delivery. We included both individual and group delivery of the intervention.

Comparator intervention

Comparator interventions consisted of inactive controls, such as usual care, no treatment, delayed provision of psychological interventions (or wait-list conditions), or pharmacological treatment only, and minimal interventions such as information provision. However, we did not exclude studies on the grounds that an active control group had been used (e.g. where an intervention from one category (CBT) was compared to an intervention from another category (psychosocial intervention), or different intensities or dosages of an intervention were compared). We recognised that there will be instances where researchers employ an active comparison condition for pragmatic or ethical reasons (e.g. the importance of offering some care or treatment to a survivor and that research studies may replicate this when designing or delivering an evaluation). In our analyses, we strived to pool studies that conducted similar types of comparisons (i.e. active versus inactive or active versus active).

Types of outcome measures

We did not select studies based on the nature of the outcomes assessed. The review was designed to measure the effects of psychological therapies and psychosocial interventions for survivors of rape and sexual assault experienced during adulthood, based on a wide range of indicators of a person's health and well-being, particularly mental health and well-being. We were also mindful about evaluating harm and adverse consequences from therapies and other interventions.

Where studies used multiple measures of the same outcome within the same study (e.g. PTSD symptoms collected using an interview-

based assessment *and* a self-report measure), we extracted all data. However, we prioritised the interview-generated data in meta-analyses on the basis that such assessments of symptoms are likely to be more reliable.

We extracted data arising at four time points (post-treatment, three months, six months and 12 months). The primary time point for treatment efficacy was post-treatment ([Differences between protocol and review](#)), encompassing an assessment period extending from immediately after the intervention up to one month; we frequently refer to post-treatment as 'the days and weeks after intervention'.

For the purpose of interpreting the time between intervention and outcome assessments, we classified time points up to six months as short term; up to 12 months as medium-term; and long-term as 12 months or longer.

Primary outcomes

1. Treatment efficacy, PTSD symptoms: response to treatment, determined by differences in scores for PTSD symptoms, assessed by independent observer or self-report. Validated observer-rated instruments include the Clinician-Administered PTSD Symptom Scale ([Kulka 1988](#)), Clinician-Administered PTSD Scale (CAPS; [Blake 1990](#); [Blake 1995](#)), and the PTSD Symptom Scale - Interview (PSS-I; [Foa 1993](#)). Validated self-report measures include the PTSD Symptom Scale - Self-Report (PSS-SR; [Foa 1993](#)), Impact of Event Scale (IES; [Horowitz 1979](#)), Impact of Event Scale - Revised (IES-R; [Weiss 1997](#)), and PCL-5 ([Bovin 2016](#)), which is the self-reported PTSD Checklist for the *Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders* (DSM-5; [APA 2013](#)).
2. Treatment efficacy, depressive symptoms: response to treatment, determined by differences in scores for depressive symptoms, assessed by independent observer or self-report measures, including the Hospital Anxiety and Depression Scale (HADS; [Zigmond 1983](#)), Beck Depression Inventory (BDI; [Beck 1961](#)), Center for Epidemiologic Studies Depression Scale (CES-D; [Radloff 1977](#)), Patient Health Questionnaire (PHQ; [Spitzer 1999](#)), and Hamilton Depression Rating Scale (HAM-D; [Hamilton 1960](#)).
3. Treatment acceptability: the number of participants who dropped out of the intervention (as distinct from attrition), including in studies of two intervention types and other assessments of acceptability (e.g. measures of patient/client satisfaction).
4. Adverse effects, such as counts of mortality, completed suicides and attempted suicides, or worsening of symptoms (specifically, group differences on PTSD, depression, self-harm and suicidality - see below for tools), including those summarised in narrative form, or using a tool such as the Negative Effects Questionnaire ([Rozenal 2018](#)). We recorded whether or not studies made reference to this outcome.

Secondary outcomes

1. Anxiety symptoms, assessed with self-report scales such as the Beck Anxiety Inventory (BAI; [Beck 1988](#)), State-Trait Anxiety Inventory (STAI; [Spielberger 1970](#)), or Generalised Anxiety Disorder - Seven-item Scale (GAD-7; [Kertz 2013](#); [Spitzer 2006](#)).
2. Dissociation symptoms, measured using instruments such as the Dissociative Experiences Scale (DES; [Bernstein 1986](#)), or

- the Dissociative Experiences Scale-II (DES-II; [Bernstein 1986](#); [Carlson 1993](#)).
3. Global mental health functioning/distress, which is frequently measured by either the Global Severity Index (GSI), Positive Symptom Distress Index (PSDI) and Positive Symptom Total (PST) of the SCL-90-R ([Derogatis 1983](#)), or by the Behavior And Symptom Identification Scale (BASIS-32; [Eisen 1999](#)).
 4. Feelings of guilt or self-blame (or both; hereon described as trauma-related beliefs) experienced by survivors, measured by self-report tools such as the Trauma-Related Guilt Inventory (TRGI; [Kubany 1996](#)), Rape Attribution Questionnaire (RAQ; [Frazier 2003](#)), South African Stigma Scale ([Singh 2011](#)), Social Support Appraisal (SSA) scale ([Vaux 1986](#)), Rape Aftermath Symptom Test (RAST; [Kilpatrick 1988](#)), or Inventory of Interpersonal Problems (IPP; [Horowitz 1988](#)).
 5. Substance use, measured by a number of established scales, including the Michigan Alcoholism Screening Test (MAST; [Selzer 1971](#)), Drug Abuse Screening Test (DAST; [Skinner 1982](#)), Addiction Severity Index (ASI; [McLellan 1980](#); [McLellan 1992](#)), Alcohol Use Inventory (AUI; [Chang 2001](#)), Drug Use Disorders Identification Test (DUDIT; [Berman 2005](#)), or the Alcohol Use Disorders Identification Test (AUDIT; [Pradhan 2012](#)).
 6. Quality of life, which is commonly measured by self-report measures such as the WHO Quality of Life scale - Abbreviated Version (WHOQOL-BREF; [Skevington 2004](#)) and EuroQol-5 Dimensions (EQ-5D; [Brooks 1996](#)).
 7. Self-harming or suicidality often measured by the Deliberate Self-Harm Inventory (DSHI; [Gratz 2001](#)), Self-Harm Behaviour Questionnaire (SHBQ; [Gutierrez 2001](#)), or the Self-Injury Questionnaire (SIQ; [Santa Mina 2006](#)).
 8. Sexual violence assessment, measured by instruments such as the Sexual Experiences Survey (SES; [Koss 1987b](#)) and the Abuse Assessment Screen (AAS) ([Basile 2007](#); [NSVRC 2011](#)). These tools differ in terms of their method of delivery; their appropriateness for screening for females, males, or both; the setting in which screening is to occur; the total number of questions they contain; and the number of questions that are specific to sexual violence ([Basile 2007](#); [NSVRC 2011](#)).
1. Cochrane Central Register of Controlled Trials (CENTRAL 2021, Issue 12) in the Cochrane Library. Searched 10 January 2022.
 2. Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR; current to June 2016). Searched 2 July 2019. No new content added after this date. See [Appendix 3](#) for one of the core strategies (MEDLINE) used to populate CCMDCTR.
 3. MEDLINE Ovid (1946 to December Week 5 2021).
 4. MEDLINE In-Process & Non-Indexed Citations Ovid (7 January 2022).
 5. MEDLINE Epub Ahead of Print Ovid (7 January 2022).
 6. Embase Ovid (1974 to 7 January 2022).
 7. CINAHL Plus EBSCOhost (Cumulative Index to Nursing and Allied Health Literature; 1937 to 11 January 2022).
 8. PsycINFO Ovid (1806 to January Week 1 2022).
 9. ERIC EBSCOhost (Education Resources Information Center; 1966 to 11 January 2022).
 10. Social Policy and Practice Ovid (last updated 202110). Searched 11 January 2022.
 11. PTSDpubs Proquest (previously known as PILOTS; 1871 to 11 January 2022).
 12. *Cochrane Database of Systematic Reviews* (CDSR 2022, Issue 1), in the Cochrane Library. Searched 10 January 2022.
 13. Web of Science Core Collection: Citation Indexes Clarivate (Science Citation Index, Social Sciences Citation Index, Conference Proceedings Citation Index - Science and Conference Proceedings Citation Index - Social Science & Humanities; 1970 to 11 January 2022).
 14. Epistemonikos (www.epistemonikos.org; searched 12 January 2022).
 15. ClinicalTrials.gov (www.ClinicalTrials.gov; searched 12 January 2022).
 16. WHO International Clinical Trials Registry Platform (ICTRP; apps.who.int/trialsearch; searched 12 January 2022).
 17. Be Part of Research (replaced UK Clinical Trials Gateway; www.bepartofresearch.nihr.ac.uk; searched 12 January 2022).

Searching other resources

Personal communication

We contacted a wide range of triallists and experts in the field regarding published, unpublished and ongoing research and to ask for further trial data where applicable.

Reference lists

We examined the reference lists of all included studies and relevant systematic reviews to identify additional studies from the electronic searches (for example, unpublished or in-press citations).

Supplementary searches

Supplementary searches were conducted through to February 2022. We conducted a forward citation search of included studies using Web of Science.

Search methods for identification of studies

We identified RCTs of psychological interventions for survivors of rape and sexual assault experienced during adulthood from key bibliographic databases listed in [Electronic searches](#). We ran the first searches in July 2019, and updated them in March 2021 and again in January 2022.

Electronic searches

We searched the databases and trials registers listed below for published and unpublished studies. We adapted the MEDLINE strategy in [Appendix 2](#) for the other sources using appropriate indexing terms and syntax. We did not apply any limitations on publication date, place or language of any research; we did not exclude any potentially relevant studies and we included research from different backgrounds and disciplines. The Information Specialist for Cochrane Developmental Psychosocial and Learning Problems searched all of the databases listed below, with the exception of the Common Mental Disorders Controlled Trials Register, which was searched by the Information Specialist for Cochrane Common Mental Disorders.

Data collection and analysis

Selection of studies

Titles and abstracts of all records identified through the searches were each assessed against the inclusion criteria ([Criteria for considering studies for this review](#)) by two of five authors/researchers (NK, KB, SB, GC, LOD) working independently, and were coded as 'yes' (eligible), 'no' (not eligible) or 'maybe' (potentially eligible or unclear).

We retrieved full-text reports for those titles and abstracts identified as eligible or potentially eligible and two review authors (SB and LOD) independently assessed each report against the inclusion criteria ([Criteria for considering studies for this review](#)). Studies were identified for either inclusion or exclusion. We contacted study authors, as required, to decide whether the inclusion criteria were met. We recorded reasons for excluding studies. In the event of disagreements, the authors discussed the papers and reasons for the decisions, with final decisions being made by consensus and with input from a third author when needed (GF, KH, KB, MW).

We identified and excluded duplicate records and collated multiple reports that related to the same study, so that each study, rather than each report, is the unit of interest in the review. We recorded the selection process in sufficient detail to complete a four-phase (identification, screening, eligibility and included) PRISMA flow diagram for study collection ([Moher 2009](#)).

Data extraction and management

We used Covidence as a platform to upload the included studies and extract data ([Covidence 2018](#)), and export data into Review Manager 5 (RevMan 5) ([Review Manager 2014](#)). After the review was checked into RevMan 5, Review Manager Web (RevMan Web) allowed us to analyse the data and build the text, tables and figures for presenting the review ([Review Manager Web 2019](#)). We generated a PRISMA diagram report.

We piloted and refined the data collection form using the first five studies included in the review. Two authors (LOD with KB, SB, GC), working independently, extracted all data on key characteristics, methods and outcomes from each included study, and compared their results to identify differences. Where differences were identified, we resolved them by consensus or by referral to another member of the review team (KB, SB, GC). When further clarification or missing data were needed from study authors, we made all reasonable attempts to contact the study authors and obtain the relevant information.

Specifically, we extracted data on the following characteristics from each included study.

1. Methods: brief description of study design and randomisation method; dates or total duration of study; location of study.
2. Participants: baseline characteristics, including gender, age, ethnicity, disability, markers of opportunity/deprivation; recruitment setting; inclusion and exclusion criteria; group differences; number of eligible people recruited and assigned; attrition; numbers analysed.
3. Interventions: number of intervention groups and sessions; type of psychosocial intervention; mode of delivery; frequency and duration of delivery; format (i.e. group, individual or a blend); level of training of person delivering the intervention; relevant

comparator intervention characteristics; treatment completion rates.

4. Outcomes: primary and secondary outcomes; outcome measures used; timing of outcome measurement (i.e. post-treatment, 3 months, 6 months or 12 months); mean, standard deviation, number of events and sample size.
5. Notes: funding for trial; notable conflicts of interest of trial authors.

One review author (MW) transferred the data into RevMan 5 ([Review Manager 2014](#)). Another review author (LOD) independently checked the data extraction forms for accuracy and completeness.

Assessment of risk of bias in included studies

Randomised parallel-group trials

We undertook our risk of bias assessment using RevMan Web ([Review Manager Web 2019](#)) and according to Cochrane's revised risk of bias tool for randomised trials (RoB 2) ([Higgins 2021a](#); [Sterne 2019](#)) and using the suite of templates and tools available online ([Higgins 2019](#)). The review aimed to assess the effect of assignment to intervention - the 'intention-to-treat' effect. We assessed the risk of bias for each result arising from studies that reported our primary outcomes (i.e. treatment efficacy based on PTSD and depression, treatment acceptability and adverse effects). We applied RoB 2 to any result involving our primary outcome at post-treatment. Three review authors (LOD with LT and MW) independently undertook these assessments. Any disagreement was resolved by discussion and involving a third review author (LT and MW).

For a single trial result, we responded to a series of 'signalling' questions covering five domains.

1. Risk of bias arising from the randomisation process.
2. Risk of bias due to deviations from the intended interventions (effect of assignment to intervention).
3. Risk of bias due to missing outcome data.
4. Risk of bias in measurement of the outcome.
5. Risk of bias in the selection of the reported result.

We selected one of the five response options to each question ('yes', 'probably yes', 'probably no', 'no' and 'no information'). We used these responses to reach a judgement of low, some or high concerns. The final step was to combine these responses for the five domains to reach an overall rating of low risk of bias, some or high risk of bias for the result. When considering treatment effects, we took into account the risks of bias of the results contributing to that effect.

Cluster-randomised parallel-group trials

We assessed the risk of bias of cluster-randomised trials in line with Section 23.1.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2021b](#)), assessing each study for risk of bias across the five domains listed below.

1. Bias arising from the randomisation process.
2. Bias due to deviation arising from intended interventions.
3. Bias due to missing outcome data.
4. Bias in the measurement of outcome.
5. Bias in the selection of the reported outcome.

We also examined bias arising from identification or recruitment of individual participants within clusters.

Quasi-experimental

In assessing the risk of bias in quasi-randomised studies, we applied the same methods as those recommended for randomised trials, in line with Cochrane guidance (Reeves 2021) and new guidance from Sterne and colleagues (Sterne 2019). Generally, we judged such studies to be at high risk of bias arising from the randomisation process.

Measures of treatment effect

We imported the data for each study and outcome entered into Covidence (Covidence 2018) into RevMan 5 (Review Manager 2014). We used RevMan Web to perform meta-analyses and present results in graph form (Review Manager Web 2019).

Dichotomous data

While primary and secondary outcomes are usually assessed with continuous measures, we expected that some investigators would have presented dichotomous data on these outcomes. We required counts and percentages by trial arm for each study that reported dichotomous outcomes (e.g. dropout or adverse events). Using the summary data, we calculated the pooled risk ratio (RR) and 95% confidence intervals (CI) across the studies for each outcome.

Continuous data

We required means and standard deviations by study arm for studies that reported continuous outcomes. When studies used different outcome measures to assess the same construct, we calculated standardised mean differences (SMD) and 95% CI as the measure of effect (Schünemann 2011). We expected outcomes to be measured with a range of tools (see Types of outcome measures) across studies, and that we would largely be calculating SMD. We used Cohen's general rule of thumb to interpret effect sizes computed using the SMD, where 0.2 represents a small effect, 0.5 represents a medium effect, and 0.8 or larger represents a large effect (Cohen 1988).

Unit of analysis issues

Studies with multiple treatment groups

When studies compared multiple eligible experimental interventions with a single control group, we split the control group to enable pairwise comparisons. This led to having more comparisons than studies. For continuous outcomes, we split the sample size by the number of eligible experimental conditions but kept the mean and standard deviation consistent. For dichotomous outcomes, we split the sample size and the number of events by the number of eligible experimental conditions. If studies used multiple control groups, we combined the control groups to compare them to the experimental intervention group.

Dealing with missing data

Where data were missing, we followed the recommendations outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021b). We classified data as either 'missing at random' or 'not missing at random'. Where we considered data to be missing at random, we analysed the available data. For data that we considered not missing at random, we made every effort

to contact study authors to gather the missing information. We asked questions in an open-ended manner to prevent the skewing of responses (Higgins 2021b). We documented all correspondence with study authors. It was not possible to use analytical methods to handle missing data as we only collected summary data from the studies; we did not source individual level data from the study authors (Egger 2001). We highlighted any suppositions that we made during our analysis when data were unavailable.

Assessment of heterogeneity

Clinical heterogeneity refers to variability in the participants, setting, interventions and outcomes studied; methodological heterogeneity refers to variability in study design and risk of bias; and statistical heterogeneity refers to variability in the effects reported in the different studies. Statistical heterogeneity is a consequence of clinical or methodological heterogeneity, or both, among the studies and manifests in the observed intervention effects being more different from each other than one would expect due to random error (chance) alone.

We identified sources of clinical heterogeneity by constructing tables to summarise studies in terms of participants, setting, type of intervention, intervention delivery (e.g. group or individual, number of sessions) and outcomes examined. Where studies were similar, we conducted further analyses, initially by reviewing the consistency of the results across studies using graphical representations (Egger 1997). To initially identify the heterogeneity/inconsistency of the whole network, we used the Q statistic, separating the studies based on whether they shared the same design or not. We assessed statistical heterogeneity with the Chi² test, which provided us with evidence of variation in effects, disregarding the effect of chance. The Chi² test is ineffective for analysing heterogeneity in studies with only a small number of participants or trials, so we set our P value at 0.10 (Deeks 2021), and assessed heterogeneity using the I² statistic, which found the percentage of variability due to heterogeneity outside of the effect of chance (Higgins 2003).

We interpreted the observed value of I² using the guide given in Section 10.10.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2021), where 0% to 40% might not be important, 30% to 60% may represent moderate heterogeneity, 50% to 90% may represent substantial heterogeneity, and 75% to 100% shows considerable heterogeneity. We took into consideration the size and direction of effects and the strength of evidence for heterogeneity using the Chi² test and the 95% CI for I². With a small number of studies (< 20), both the I² confidence interval and the Q test should be interpreted very cautiously (Huedo-Medina 2006).

Where there was evidence for statistical heterogeneity, we used the strategies outlined in Section 10.10.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2021), to identify potential sources of heterogeneity among the results of the studies. In particular, we explored differences in the characteristics of the studies or other factors as possible explanations for heterogeneity in the results. We summarised any differences identified in the narrative summary. The significance of the I² statistics observed will rely upon the effects of treatment and the quality of evidence suggesting heterogeneity.

We used RevMan 5 ([Review Manager 2014](#)) to produce forest plots and calculate Tau², the between-study variance in a random-effects meta-analysis ([Deeks 2021](#); [Review Manager 2014](#)). To understand the intervention effects, we used Tau² to identify a range for the primary outcome. We used the *Cochrane Handbook for Systematic Reviews of Interventions* as a guideline throughout this process ([Deeks 2021](#)).

Assessment of reporting biases

We attempted to locate the protocols or study records (or both) in trial registries of the RCTs included in the review. Where the protocol was available, we compared its outcomes against the published report; and where the protocol could not be found, we compared the outcomes included in the methods section of the trial report to the reported results. We identified outcome reporting bias where outcomes were included in the methods but not reported ([Pocock 1987](#); [Tannock 1996](#)).

If there were 10 or more studies, we constructed funnel plots to investigate associations between effect size and study precision (which is closely related to sample size) ([Egger 1997](#)). We also applied Egger's regression asymmetry test to funnel plots to test for funnel plot asymmetry ([Egger 1997](#)). Such an association could be due to publication or related biases, or due to systematic differences between small and large studies. If we identified an association, we examined the clinical diversity of the studies as a possible explanation. If appropriate, we also conducted a sensitivity analysis to determine whether assumptions about the effect of the bias impact the estimated treatment effect and the conclusions of the review.

Data synthesis

We performed a meta-analysis if there were sufficient data (three or more studies was selected as a threshold given the potential for a very large number of analyses if we pooled two or more studies and issues relating to statistical power when examining an outcome with a small number of studies) ([Borenstein 2011](#)). It also had to be meaningful to pool the data across studies; for instance, the treatments, comparisons, participants and the underlying measures needed to be similar enough for pooling to be appropriate. Our decision to perform a meta-analysis was determined by the comparability of populations, denominators and interventions (clinical heterogeneity); the comparability of the duration of follow-up (methodological heterogeneity); and the comparability of outcomes. We used a random-effects model to analyse the data across the studies. The Mantel-Haenszel method, a default program in RevMan 5 ([Review Manager 2014](#)), can take account of few events or small study sizes and can be used with random-effects models. Studies were excluded from the meta-analysis for the dichotomous outcomes when no events were reported in either arm of a trial as per Cochrane guidance Chapter 10.4.4.1 ([Deeks 2021](#)). We used the inverse-variance method, another default program in RevMan 5 ([Review Manager 2014](#)), for continuous outcomes. This approach assumes that the different studies were estimating different, yet related, intervention effects.

We stratified results for the main comparison (psychosocial interventions versus inactive controls) by type of therapy (see [Subgroup analysis and investigation of heterogeneity](#) and [Types of interventions](#)), where there were sufficient numbers of studies of the same intervention type, comparison arm and reporting

the same outcome. For other comparisons, comparing two experimental interventions (i.e. an intervention from one category against an intervention from another category), we required three or more studies comparing similar experimental interventions using similar outcomes.

Subgroup analysis and investigation of heterogeneity

We were keen to investigate intervention effects for subsets of interventions. To do this, we performed subgroup analyses on the category of intervention (i.e. Cognitive Behavioural Therapies, Behavioural Therapies and low-intensity psychosocial interventions). We used a simple approach, described in Chapter 9.6.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* ([Deeks 2021](#)), to investigate whether there was a difference in the intervention effect between the subgroups.

If we identified a considerable degree of heterogeneity (75% to 100%), we first checked the data for errors. If the data were correct, we conducted a sensitivity analysis by excluding certain studies from the existing meta-analysis, assessing the influence of the studies on the degree of heterogeneity (see [Sensitivity analysis](#)).

Sensitivity analysis

We based our primary analyses on available data from all included studies relevant to the comparison of interest. In order to examine any effects of methodological decisions on the overall outcome, we performed the following sensitivity analyses, provided there were sufficient numbers of studies.

1. Re-analysis of the data excluding studies with results at high risk of bias.
2. Re-analysis of the data excluding studies with a high degree of heterogeneity.

Summary of findings and assessment of the certainty of the evidence

We created our summary of findings table(s) using GRADEpro GDT ([GRADEpro GDT 2015](#)) in RevMan Web ([Review Manager Web 2019](#)), and followed standard methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Schünemann 2017](#)). The table provides key information concerning the quality of evidence, the magnitude of effect of the interventions examined, and the sum of available data on primary outcomes. The table includes details relating to the participants, interventions, comparisons, outcomes, settings, length of the follow-up and outcome measurement.

The key comparison for the summary of findings table is impact of psychosocial interventions versus inactive controls on treatment efficacy. For each outcome, we presented standardised effect size estimates and 95% CI. The primary outcomes for the review were: treatment efficacy measured by group differences on PTSD symptoms and on depressive symptoms, treatment acceptability (dropout from treatment) and adverse effects. We have reported treatment efficacy at post-treatment, which constitutes a change in time point from the original protocol ([Differences between protocol and review](#)).

It was recognised that the main comparison combined all intervention types in one, which may lead to high levels of heterogeneity, and also that it may be more useful to stakeholders

to understand effects by type. Thus, we conducted subgroup analyses to accompany Comparison 1 and added the result as a comment in the summary of findings table.

Two authors (LOD, KB) independently assessed the certainty of the evidence using the GRADE approach and included the results of this assessment in the summary of findings table. The level of certainty was defined by five factors: risk of bias; indirectness of factors (such as evidence, population, control, intervention and outcomes); inconsistency of results; imprecision of results (and large CI); and a high likelihood of publication bias. We downgraded all evidence by one level for a single factor up to a maximum of three levels for all factors. The final grade was determined by how likely the effect can be predicted. We assessed the certainty of the evidence on a four-point scale, ranging from high (the real effect is close to what will be predicted) to very low (what actually happens is significantly varied from the predicted effect) (Schünemann 2017). Differences of opinion between the two authors were resolved through discussion and consulting a third author (SB).

We created the summary of findings table after data entry into RevMan 5 (Review Manager 2014), writing up our results and conducting the risk of bias assessment, but before writing our abstract, discussion and conclusions, to allow the opportunity to consider the impact of risk of bias in the studies contributing to

each outcome on the mean treatment effect and our confidence in these findings.

RESULTS

Description of studies

See: [Included studies](#); [Excluded studies](#); [Studies awaiting classification](#); [Ongoing studies](#).

Results of the search

Our electronic searches retrieved a total of 22,162 records. We found an additional 35 records from other sources. Once we had identified and deleted duplicate citations, the searches identified 15,250 records that were potentially relevant to the review. After screening title and abstracts, we retrieved the full texts for 243 records for further investigation. A total of 149 reports were excluded (See section on [Excluded studies](#)). In total, 36 studies (from 83 reports) met the inclusion criteria for the current review, and nine (from 10 reports) were categorised as ongoing studies that had not yet published outcomes (See [Ongoing studies](#) table), and one study was categorised as awaiting classification (See [Studies awaiting classification](#) table), see [Figure 1](#). All were available in English and published in peer-reviewed journals.

Figure 1. PRISMA flow diagram for selection of studies

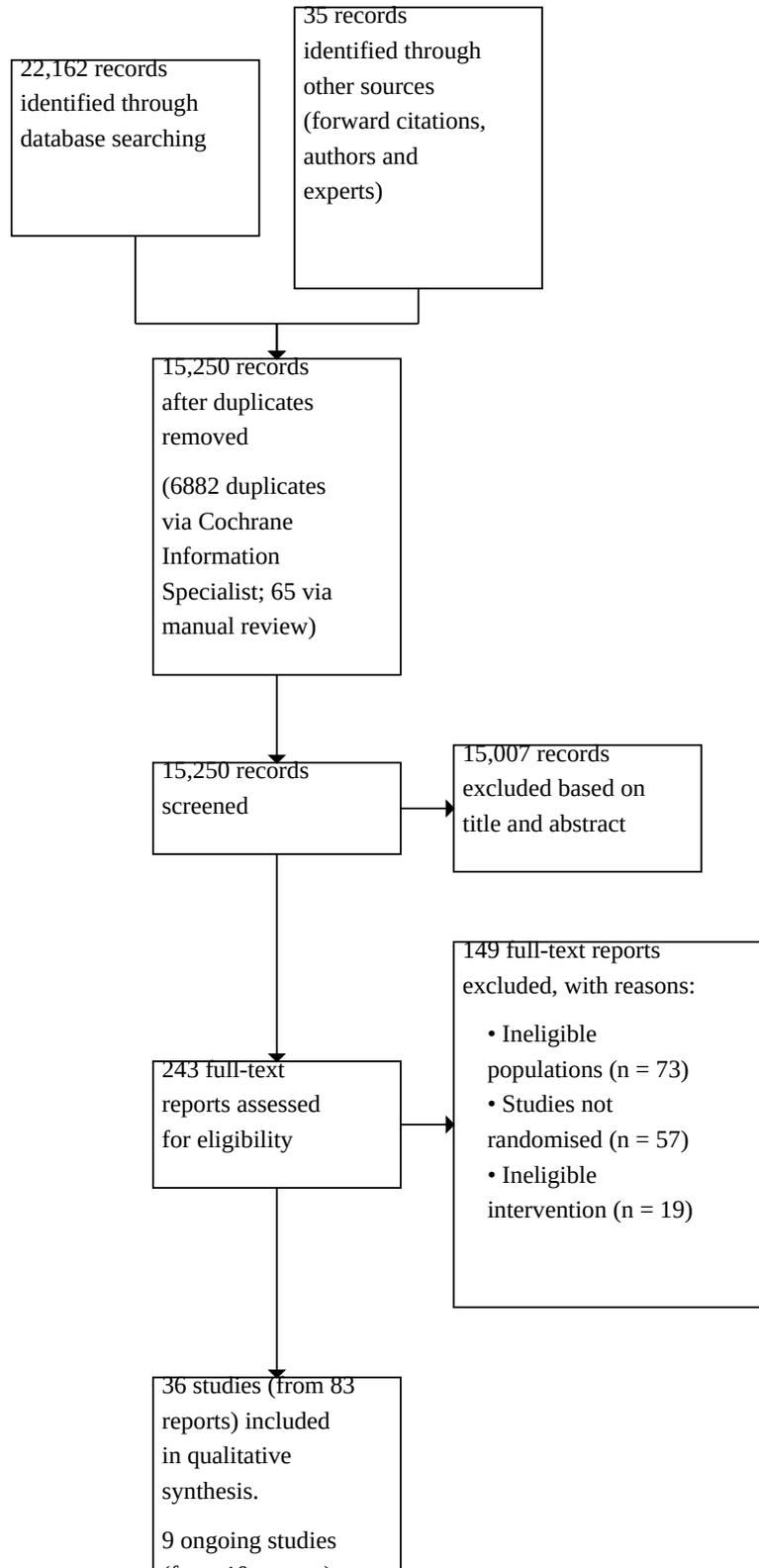
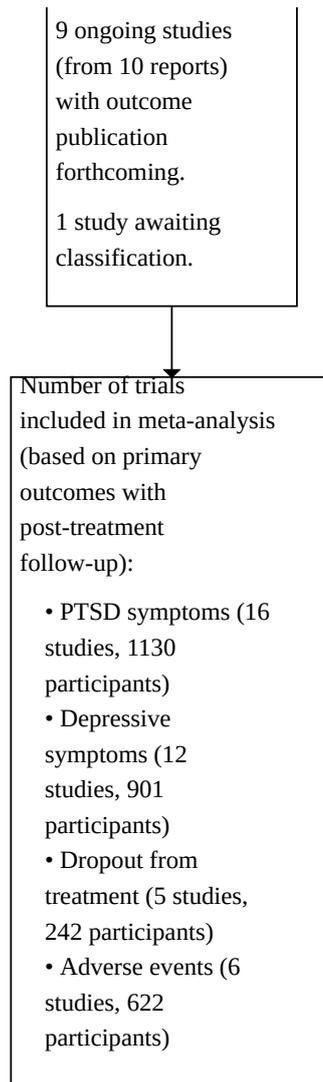


Figure 1. (Continued)



Included studies

We included 36 studies in this review. Below, we summarise the key characteristics of the included studies.

Study design

Thirty-five studies used a randomised controlled trial and one employed a cluster-randomised controlled trial design (Bass 2013). The 36 studies included a range of active and comparative groups (Table 1).

Sample sizes

The included studies randomised a total of 3992 individuals. The number of individuals randomised within the included studies ranged from 16 (Belleville 2018) to 405 (Bass 2013). Fifteen studies randomised more than 100 participants (Abrahams 2010; Acierno 2021; Bass 2013; Bass 2016; Creech 2021; Foa 2005; Galovski 2016; Kelly 2021; Krakow 2001; Miller 2015; Resick 2002; Resick 2008a; Schnurr 2007; Surís 2013; Walsh 2017). The number of individuals

approached and randomised in each of the studies is described in the Included studies table.

Setting

Most studies (n = 26, 76%) were conducted in the USA; two were from South Africa (Abrahams 2010; Sikkema 2018), two were conducted in the Democratic Republic of the Congo (Bass 2013; Bass 2016) and there were single studies in Australia (Nixon 2016), Canada (Belleville 2018), the Netherlands (Covers 2021), Spain (Echeburua 1996), Sweden (Rajan 2020), and the UK (Brady 2021). Studies were published over a 30-year period (1991 to 2021).

Characteristics of participants

Participants’ experience of violence

All 36 studies included participants who had experienced rape and sexual assault in adulthood. All but seven (Bell 2019; Bowland 2012; Brady 2021; Falsetti 2008; Feske 2008; Gray 2020; Schnurr 2007) had exposure to rape or sexual assault as an eligibility criterion.

Overall, 82% of the participants counted in this review reported an experience of rape or sexual assault in adulthood (3260/3992). Seven studies with 887 participants included survivors of military sexual trauma (MST; 22% of all those randomised) (Acierno 2021; Creech 2021; Gray 2020; Katz 2014; Kelly 2021; Schnurr 2007; Surís 2013). The time since the index trauma ranged from < 72 hours (Miller 2015) to a mean of 16 years (SD 14 years) for a range of index traumas, which included sexual assault in adulthood (Galovski 2016).

Participants' experience of PTSD

A diagnosis of PTSD was specifically indicated as an inclusion criterion in 21 studies. In the 26 studies that reported on proportions of the sample with probable PTSD at baseline, 94% of participants (2239/2370) had a clinician-derived PTSD diagnosis or clinically relevant symptoms based on cut-off for the Clinician-Administered PTSD Scale (CAPS; Blake 1990) (10 studies); the PTSD Symptom Scale-Interview (PSS-I; Foa 1993) (six studies); the PCL-5 (Blevins 2015) (four studies); or other assessments (six studies).

Participant socio-demographic characteristics

Whilst 13 studies specified female gender in their inclusion criteria (Abrahams 2010; Bass 2013; Bass 2016; Bomyea 2015; Creech 2021; Feske 2008; Foa 2005; Galovski 2016; Krakow 2001; Rothbaum 1997; Schnurr 2007; Sikkema 2018; Walsh 2017), 99% (3965) of all participants were female. Just 27 male survivors, derived from four studies, were included (Brady 2021; Covers 2021; Nixon 2016; Surís 2013).

The average age of participants across all those randomised was 35.9 years (SD 9.6) (based on the data of 3467 participants). Overall, participant mean age ranged from 19.3 years (Anderson 2010) to 61.3 years old (Bowland 2012).

Half the randomised participants in studies furnishing data on cultural or ethnic background were Black, African or African-American (1889/3815). Several studies had a majority of African-American participants (Acierno 2021; Creech 2021; Feske 2008; Foa 2006; Kelly 2021) or were studies located in African countries (Abrahams 2010; Bass 2013; Bass 2016). Forty per cent of participants had White or Caucasian ethnicity (1530/3815) and 10% (396/3815) were from mixed backgrounds or other ethnicities. The one UK study included only migrant or asylum-seeking people, representing nine nations (Brady 2021).

Five studies explicitly reported on disability. The way in which disability was reported varied across these five studies, and there was little detail about the nature of the disability. One study reported that one-third of participants received disability payments (33% in Feske 2008). Two studies reported the proportion of participants who were disabled in the context of reporting about employment status (i.e. those that were unemployed and unable to work or find work (7.5% in Foa 2005; 53% in Katz 2014)). Two studies reported on approved disability status in the context of Veterans Affairs (21.8% 'PTSD disability' status approved in Schnurr 2007; 62% 'disability' status approved, 21% 'PTSD disability' status approved in Surís 2013). Based on these indicators alone, 180 individuals were reported to have a disability. It should be noted that 34 studies reported that they excluded participants from participating in the study if they had cognitive impairments, severe medical conditions or mental health difficulties that would prevent individuals from providing informed consent to take part. Thus,

opportunities for diversity (including those affected by disabilities) may have been lost on account of rigorous inclusion criteria.

The socioeconomic status of participants was mixed. Several studies reported a high proportion of participants on low incomes (e.g. Bomyea 2015; Feske 2008; Foa 2005; Galovski 2016; Walsh 2017). Others reported attainment of college education (e.g. Creech 2021; Foa 1999; Foa 2005; Foa 2006; Gray 2020; Krakow 2001; Littleton 2016; Resick 2008a; Rothbaum 1997; Rothbaum 2005; Surís 2013). Two studies reported 100% of participants currently engaged in university education (Anderson 2010; Littleton 2016). In the 12 studies reporting employment status, between 9.6% and 77% of participants self-reported being employed at study entry (Falsetti 2008; Feske 2008; Foa 1991; Foa 1999; Foa 2005; Gray 2020; Rothbaum 1997; Rothbaum 2005; Schnurr 2007; Sikkema 2018; Surís 2013; Walsh 2017).

Many of the participants were not partnered at study entry. Of the 22 studies reporting partner status, 21 reported 13.6% to 87.5% of participants having a partner (three exceeded 50%: Bass 2016; Bowland 2012; Sikkema 2018) and one reported that 4.8% of participants were married (Feske 2008). Studies did not address participants' sexual identities except for one reporting that 14% of the women in the study were bisexual, lesbian or other minority sexual orientation (Creech 2021).

The number of participants reporting comorbid conditions ranged from 52.4% (Bomyea 2015) to 95.2% (Feske 2008). Some studies reported specific prevalence of major depressive disorder (e.g. Bomyea 2015; Feske 2008; Foa 2005; Resick 2008a), anxiety disorders (e.g. Bomyea 2015; Falsetti 2008) and hazardous drinking (Creech 2021; Sikkema 2018).

Participant recruitment settings

Settings for recruitment of participants and delivery of the intervention were not always the same.

Recruitment settings were diverse: for 15 studies, this was mainly community settings (Bass 2013; Bass 2016; Bell 2019; Belleville 2018; Bomyea 2015; Bowland 2012; Echeburua 1996; Falsetti 2008; Foa 1991; Foa 2005; Foa 2006; Galovski 2016; Krakow 2001; Rajan 2020; Resick 2008a); five recruited through health and forensic sexual assault services or medico-legal environments (Abrahams 2010; Covers 2021; Miller 2015; Nixon 2016; Walsh 2017); seven were clinics for veterans and active service people in the USA (Acierno 2021; Creech 2021; Gray 2020; Katz 2014; Kelly 2021; Schnurr 2007; Surís 2013); two were purely university student samples (Anderson 2010; Littleton 2016); two were outpatients/clinical settings (Feske 2008; Rothbaum 1997); one was a clinic for delivery of HIV medicine and primary care (Sikkema 2018) and one was a charity providing support for survivors of human rights abuses (Brady 2021). Three were unclear in terms of how or where participants were invited (Foa 1999; Resick 2002; Rothbaum 2005).

It was not uncommon for studies to utilise multiple recruitment strategies that included police (Foa 2006); victim agencies (Belleville 2018; Foa 1991; Foa 2006; Krakow 2001; Resick 2008a); counselling centres (Schnurr 2007); community therapists (Resick 2008a) and other professionals (Brady 2021); media (Foa 1991; Foa 2006); healthcare settings such as hospitals (Bowland 2012; Miller 2015; Schnurr 2007) and emergency departments (Foa 2006; Walsh 2017); mental health clinics (Gray 2020; Krakow 2001); and outpatient clinics (Feske 2008; Surís 2013).

Interventions

Types of interventions

We classified the experimental interventions according to the list of psychological therapies of the former Cochrane Depression, Anxiety and Neurosis (CCDAN) Group.

Across the 36 studies, there were a total of 60 active experimental conditions (3014 participants; 76%) and 23 inactive or minimally active comparator conditions (978 participants; 24%). The 60 experimental groups consisted of: 32 cognitive behavioural therapy (CBT); 10 behavioural interventions; three integrative therapies; three humanist; five other psychologically oriented interventions; and seven other psychosocial interventions.

See [Table 1](#) for a list of studies according to the number of active and comparative trial arms. Sixteen studies consisted of a traditional two-arm trial of an active intervention versus a control group. In relation to the active arm of these studies, four were CBT interventions ([Anderson 2010](#); [Falsetti 2008](#); [Krakow 2001](#); [Littleton 2016](#)); and six were behavioural interventions - EMDR ([Rothbaum 1997](#)); High Interference Control ([Bomyea 2015](#)); Narrative Exposure Therapy ([Brady 2021](#)); Reconciliation of Traumatic Memories study ([Gray 2020](#)); Lifespan Integration ([Rajan 2020](#)); biofeedback ([Bell 2019](#)). The remaining six were classified as 'other psychosocial interventions' or 'other psychologically oriented interventions': telephonic psychosocial support ([Abrahams 2010](#)); village savings and loans association ([Bass 2016](#)); spiritually focused group therapy ([Bowland 2012](#)); psychoeducation and coping video ([Miller 2015](#)); a brief motivational interviewing and psychoeducation-based computerised intervention ([Creech 2021](#)) and an intervention to improve AIDS care after trauma ([Sikkema 2018](#)).

Seven studies compared either two ([Foa 2005](#); [Foa 2006](#); [Resick 2002](#); [Rothbaum 2005](#); [Walsh 2017](#)) or three ([Foa 1991](#); [Foa 1999](#)) active interventions and included a control group. These included 16 active intervention groups, of which 11 were CBT; two were behavioural interventions - EMDR ([Rothbaum 2005](#)) and pleasant imagery/relaxation video ([Walsh 2017](#)); two were humanist (supportive counselling) ([Foa 1991](#); [Foa 2006](#)); and one was grouped as 'other psychosocial interventions' - a prevention of post-rape stress video ([Walsh 2017](#)).

The remaining 13 studies did not have a control condition; rather, they compared two ([Acierno 2021](#); [Bass 2013](#); [Belleville 2018](#); [Covers 2021](#); [Echeburua 1996](#); [Feske 2008](#); [Galovski 2016](#); [Kelly 2021](#); [Nixon 2016](#); [Schnurr 2007](#); [Surís 2013](#)) or three ([Katz 2014](#); [Resick 2008a](#)) active conditions.

Comparisons

Of the 23 studies that included a control group, two used a no-treatment control ([Anderson 2010](#); [Bowland 2012](#)); two used an assessment condition ([Creech 2021](#); [Foa 2006](#)); four compared usual or standard care ([Abrahams 2010](#); [Miller 2015](#); [Sikkema 2018](#); [Walsh 2017](#)); four compared the active intervention(s) to a minimal intervention ([Bell 2019](#); [Bomyea 2015](#); [Brady 2021](#); [Littleton 2016](#)) and the remaining 11 used wait-list controls.

Occasionally, a study indicated 'usual care' or 'standard care' typical of the delivery setting, which we classified as sufficiently active to warrant placing it in an active category for analysis. For example, [Nixon 2016](#) compared Cognitive

Processing Therapy to treatment as usual in a sexual assault services setting; since the latter encompassed a range of methods, including psychoeducation, supportive counselling, problem-solving, interpersonal therapy, elements of mindfulness, acceptance and value-based techniques, and discussion of thoughts and feelings, we believed it was better analysed as active and classified it as 'integrative' (where therapists select models and methods from across orientations to best suit a particular client and context). Another study, also located in a sexual assault services setting, compared the experimental group to treatment-as-usual (TAU) at participating sexual assault centres ([Covers 2021](#)). This TAU consisted of two telephone contacts of approximately 30 minutes with a case manager, who provided psychoeducation and emotional support in accordance with a watchful waiting protocol ([NICE 2018](#)); thus, we defined the comparison as 'Other psychosocial intervention'. Lastly, we classified the treatment as usual condition in [Feske 2008](#) as integrative therapy; it consisted of 9 to 12 sessions of the standard treatment provided at the clinic and included one weekly, hour-long individual counselling session and a weekly, 90-minute group treatment session (e.g. anger management).

Inactive controls

Twenty-three studies had an inactive group.

- [Abrahams 2010](#): usual care
- [Anderson 2010](#): no treatment control
- [Bass 2016](#): wait-list
- [Bell 2019](#): minimal intervention
- [Bomyea 2015](#): minimal intervention
- [Bowland 2012](#): no treatment control
- [Brady 2021](#): minimal intervention
- [Creech 2021](#): assessment control
- [Falsetti 2008](#): wait-list
- [Foa 1991](#): wait-list
- [Foa 1999](#): wait-list
- [Foa 2005](#): wait-list
- [Foa 2006](#): assessment condition
- [Gray 2020](#): wait-list
- [Krakow 2001](#): wait-list
- [Littleton 2016](#): minimal intervention
- [Miller 2015](#): usual care
- [Rajan 2020](#): wait-list
- [Resick 2002](#): wait-list
- [Rothbaum 1997](#): wait-list
- [Rothbaum 2005](#): wait-list
- [Sikkema 2018](#): usual care
- [Walsh 2017](#): usual care

Active treatment

For the 13 studies that tested the performance of different interventions against one another, these involved a total of 28 different intervention groups.

- [Acierno 2021](#): CBT (Prolonged Exposure via home-based telemedicine) versus CBT (Prolonged Exposure via in-person)

- [Bass 2013](#) CBT (Cognitive Processing Therapy contained no in vivo exposure) versus other psychosocial interventions (individual support)
- [Belleville 2018](#): CBT (Image Rehearsal Therapy + Prolonged Exposure) versus CBT (Prolonged Exposure only)
- [Covers 2021](#): Behavioural (Eye Movement Desensitisation and Reprocessing) versus other psychosocial interventions (Telephonic psychosocial support)
- [Echeburua 1996](#): CBT (Cognitive Restructuring + Coping Skills) versus behavioural (Progressive Relaxation)
- [Feske 2008](#): CBT (Cognitive Processing Therapy) versus Integrative Therapy
- [Galovski 2016](#): CBT (Cognitive Processing Therapy + Hypnosis) versus CBT (Cognitive Processing Therapy)
- [Katz 2014](#): CBT (Prolonged Exposure) versus humanist (Person-centred Therapy) versus Integrative Therapy (Holographic Reprocessing)
- [Kelly 2021](#): Other psychologically oriented interventions (Trauma-sensitive Yoga) versus CBT (Cognitive Processing Therapy)
- [Nixon 2016](#): CBT (Cognitive Processing Therapy) versus Integrative Therapy
- [Resick 2008a](#): CBT (Cognitive Processing Therapy) versus CBT (Cognitive Therapy) versus CBT (Written Exposure)
- [Schnurr 2007](#): CBT (Prolonged Exposure) versus other psychologically oriented interventions (Present-centred Therapy)
- [Surís 2013](#): CBT (Cognitive Processing Therapy) versus other psychologically oriented interventions (Present-centred Therapy)

Formats of interventions

For the 60 active intervention groups, 41 interventions used individual and face-to-face delivery; nine used a group and face-to-face approach (in [Bass 2013](#); [Bass 2016](#); [Bowland 2012](#); [Falsetti 2008](#); [Feske 2008](#); the two groups in [Kelly 2021](#); [Krakow 2001](#); [Sikkema 2018](#)); six involved computer use and no interpersonal element (in [Bell 2019](#); [Bomyea 2015](#); [Creech 2021](#); [Miller 2015](#); two in [Walsh 2017](#)); and the final four were individual and used telephone ([Abrahams 2010](#)); teleconference ([Acierno 2021](#)); or online ([Littleton 2016](#)) modalities.

To deliver the intervention, 25 studies ensured the intervention delivery personnel were qualified either via qualifications, training or prior experience ([Abrahams 2010](#); [Anderson 2010](#); [Bass 2013](#); [Bass 2016](#); [Bowland 2012](#); [Brady 2021](#); [Covers 2021](#); [Echeburua 1996](#); [Falsetti 2008](#); [Feske 2008](#); [Foa 1991](#); [Foa 1999](#); [Foa 2005](#); [Foa 2006](#); [Gray 2020](#); [Katz 2014](#); [Kelly 2021](#); [Krakow 2001](#); [Nixon 2016](#); [Rajan 2020](#); [Resick 2002](#); [Resick 2008a](#); [Rothbaum 1997](#); [Schnurr 2007](#); [Surís 2013](#)). For three studies, this detail was not applicable due to video or computerised delivery ([Creech 2021](#); [Miller 2015](#); [Walsh 2017](#)), whilst eight studies did not provide sufficient information ([Acierno 2021](#); [Bell 2019](#); [Belleville 2018](#); [Bomyea 2015](#); [Galovski 2016](#); [Littleton 2016](#); [Rothbaum 2005](#); [Sikkema 2018](#)).

Number of sessions and duration of interventions

The median number of *planned* sessions across the 60 interventions was 11, and this ranged from 1 session to 20 sessions.

In studies that reported the mean number of sessions *completed*, this ranged from 1 to 17 ([Brady 2021](#)) completed sessions. It was possible to compare the number of sessions planned with the number of sessions completed. For example, in both active arms of the [Acierno 2021](#) study, 12 to 15 sessions were planned whilst 6.80 (SD 4.14) sessions were completed in the prolonged exposure via home-based telemedicine group and 6.28 (SD 4.33) sessions were completed in the group that received face-to-face prolonged exposure. The most sessions delivered in any study was 26 ([Brady 2021](#)).

The length of time over which interventions were delivered ranged from one week (e.g. [Walsh 2017](#)) to 40 weeks ([Bass 2016](#)). In 29 studies, interventions were delivered over 12 or fewer weeks. In seven studies, intervention sessions were delivered over 13 to 40 weeks ([Acierno 2021](#); [Bass 2013](#); [Bass 2016](#); [Belleville 2018](#); [Brady 2021](#); [Galovski 2016](#); [Littleton 2016](#)).

The reported total amount of time that individuals spent in an intervention ranged from nine minutes ([Miller 2015](#); [Walsh 2017](#)) to 27 hours and 30 minutes ([Belleville 2018](#)). Some studies reported that individuals were asked to do 'homework' or activities outside of the intervention. For example, [Rothbaum 2005](#) reported how individuals participating in the prolonged exposure intervention were asked to listen to tape recordings of their trauma narratives (which lasted 45 to 60 minutes) on a daily basis over five weeks. [Resick 2002](#) reported the number of hours in which the intervention involved homework and this ranged from 22.6 hours to 44.8 hours in the cognitive processing therapy and prolonged exposure interventions respectively.

Delivery setting

In addition to the recruitment settings, we considered the settings where the interventions took place. The majority of studies (11/36) delivered interventions in academic settings ([Belleville 2018](#); [Bomyea 2015](#); [Bowland 2012](#); [Foa 1991](#); [Foa 1999](#); [Galovski 2016](#); [Krakow 2001](#); [Resick 2002](#); [Resick 2008a](#); [Rothbaum 1997](#); [Rothbaum 2005](#)). [Feske 2008](#) used a university-affiliated outreach clinic. Of the seven that recruited veterans and active service individuals ([Acierno 2021](#); [Creech 2021](#); [Gray 2020](#); [Katz 2014](#); [Kelly 2021](#); [Schnurr 2007](#); [Surís 2013](#)), six delivered interventions in American Veterans Affairs settings, such as medical centres, and one used a dedicated private office space for delivery of the intervention ([Gray 2020](#)). Five studies provided the interventions in an acute setting for forensic and medical care after rape or sexual assault ([Abrahams 2010](#); [Covers 2021](#); [Miller 2015](#); [Nixon 2016](#); [Walsh 2017](#)). Counselling services and clinics were used by three studies ([Echeburua 1996](#); [Foa 2006](#); [Rajan 2020](#)). [Sikkema 2018](#) offered their intervention in a primary care setting for those with HIV. The two studies by Bass and colleagues were delivered in the community ([Bass 2013](#); [Bass 2016](#)). The university cohorts received their interventions in the university setting ([Anderson 2010](#); [Littleton 2016](#)). [Foa 2005](#) used a combination of a community clinic for rape survivors and a centre dedicated to treatment and study of anxiety. Similarly, [Falsetti 2008](#) delivered their intervention at a centre dedicated to the care and support of individuals who have been victims of crime. [Brady 2021](#) delivered their intervention in charity-based therapeutic services. Although not entirely clear, [Bell 2019](#) likely used an experimental setting for their study of neurofeedback versus biofeedback.

Outcomes

Primary outcomes

All 36 studies reported on one or more of our primary outcomes. A summary is provided in [Table 2](#) of which studies assessed the four primary outcomes (PTSD symptoms, depressive symptoms, treatment dropout and adverse events). Most studies measured PTSD symptoms using PSS-I (e.g. [Foa 1999](#); [Gray 2020](#); [Littleton 2016](#)), CAPS (e.g. [Bomyea 2015](#); [Resick 2002](#)) and PCL-5 (e.g. [Bell 2019](#); [Sikkema 2018](#)). Studies reported a variety of validated questionnaires, including BDI-I (e.g. [Bomyea 2015](#); [Falsetti 2008](#); [Foa 1999](#); [Resick 2002](#)); BDI-II (e.g. [Feske 2008](#)); GDS (e.g. [Bowland 2012](#)); PHQ-9 (e.g. [Brady 2021](#)) and CES-D (e.g. [Littleton 2016](#)). Outcomes were either self-reported by participants or observed by clinicians. We only extracted outcomes reported at the end of treatment and at three, six and 12 months follow-up. Studies used a variety of scales to assess the primary and secondary outcomes; where appropriate, we chose the measure that was used most often, to reduce heterogeneity of outcomes.

Secondary outcomes

Twenty-four of the 36 included studies addressed one or more of the secondary outcomes defined in this review. There was a large variety of validated questionnaires used to capture anxiety, including STAI-state (e.g. [Rothbaum 2005](#)), STAI-trait (e.g. [Foa 1999](#); [Rothbaum 1997](#)) and BAI (e.g. [Bowland 2012](#); [Feske 2008](#); [Foa 2006](#)). Studies reported global mental health functioning/distress using several different questionnaires, including Brief Symptom Inventory (e.g. [Feske 2008](#)) and GHQ12 (e.g. [Rajan 2020](#)). Trauma-related beliefs such as feelings of guilt, shame or self-blame in the aftermath of sexual assault were assessed using measures like Rape Aftermath Symptom Scale (e.g. [Rothbaum 1997](#)) and the Post-traumatic Cognitions Inventory (e.g. [Katz 2014](#)). Substance use was measured in a small number of studies using tools such as the AUDIT (e.g. [Creech 2021](#)). In [Table 3](#), we provide a summary of which studies assessed the secondary outcomes. No studies assessed self-harm or suicidality or sexual violence outcomes.

Study funding sources

The 36 included studies were funded by a variety of sources, including research funding bodies such as National Institute of Mental Health ([Acierno 2021](#); [Bomyea 2015](#); [Falsetti 2008](#); [Feske 2008](#); [Foa 1991](#); [Foa 1999](#); [Foa 2005](#); [Foa 2006](#); [Galovski 2016](#); [Krakow 2001](#); [Littleton 2016](#); [Resick 2002](#); [Resick 2008a](#); [Rothbaum 2005](#); [Sikkema 2018](#)), South African Medical Research Council ([Abrahams 2010](#)), Blue Angels Foundation ([Gray 2020](#)), Australian Rotary Health Research Fund ([Nixon 2016](#)), the Oak Foundation ([Brady 2021](#)) and National Institute on Drug Abuse ([Walsh 2017](#)). Four studies reported university financial support ([Echeburua 1996](#); [Krakow 2001](#); [Rothbaum 1997](#); [Sikkema 2018](#)); one reported a particular centre ([Miller 2015](#)) and a recent trial of EMDR ([Covers 2021](#)) reported several sources in the charity and private sectors - Achmea Association Victims & Society, Innovatiefonds Zorgverzekeraars, EMDR Research Foundation, Vereniging EMDR Nederland, and PAOS fonds. Governmental bodies were reported by seven studies ([Acierno 2021](#); [Bass 2013](#); [Bass 2016](#); [Creech 2021](#); [Kelly 2021](#); [Rajan 2020](#); [Schnurr 2007](#); [Surís 2013](#)). Five studies did not disclose their sponsorship source ([Anderson 2010](#); [Bell 2019](#); [Belleville 2018](#); [Bowland 2012](#); [Katz 2014](#)).

Excluded studies

In summary, 149 reports were excluded as irrelevant. The reasons for exclusion were grouped as 'studies not randomised' (57); 'ineligible populations' (73); and 'ineligible interventions' (19). Of these, we selected 31 studies that required closer examination before being excluded on the basis of ineligible population. These are reported in the [Excluded studies](#) table.

Studies awaiting classification

One study, [Dutton 2021](#), is awaiting classification as more information is required from the researchers to make a decision about inclusion (see [Studies awaiting classification](#) table).

Ongoing studies

Nine ongoing studies were identified in the searches. A list of these studies is provided below, with more comprehensive details of the studies outlined in the [Ongoing studies](#) table.

- [NCT02808468](#): Brief Cognitive Therapy versus assessment only
- [NCT04124380](#): Imaginal Exposure then alcohol skills training versus alcohol skills training then Imaginal Exposure versus alcohol skills training, no additional treatment versus Imaginal Exposure, no additional treatment versus supportive telehealth
- [NCT03429166](#): Skills Training in affective and interpersonal regulation versus Present-centred Therapy
- [NCT03794986](#): Motivational Interviewing versus Motivational Interviewing with trauma-informed sexual gender minorities affirmative care
- [NCT03703258](#): app-based Cognitive Behavioural Intervention versus assessment only
- [ISRCTN16806208](#): online Cognitive Therapy versus internet-delivered Stress Management versus wait-list
- [NCT03019497](#): Cognitive Behavioural Therapy with specific modules about a specific related problem versus Cognitive Behavioural Therapy without specific modules
- [NCT04582695](#): Written Exposure Therapy integrated with CBT versus Written Exposure Therapy
- [IRCT20120619010063N8](#): Mindfulness-based art therapy versus wait-list

Risk of bias in included studies

We performed risk of bias assessment using the RoB 2 tool for all primary outcomes (where data were provided) and summarised the results of this assessment in the results level RoB 2 tables. Note that some studies produced more than one result for the same outcome in instances where there were multiple experimental arms that could be individually compared to the control arm. Most studies provided sufficient information to allow for potential risk of bias assessment with regard to PTSD (for details, see [link](#)), depression (for details, see [link](#)) and, to a lesser degree, treatment completion (for details, see [link](#)) and adverse events (for details, see [link](#)).

For PTSD at post-treatment, there were 21 results to assess from 16 studies. We assumed an overall risk of bias with some concerns: half the overall results were judged to be of some concern, 43% (9 results from 6 studies) were at high risk ([Bell 2019](#); [Falsetti 2008](#); [Foa 1999](#); [Foa 2005](#); [Miller 2015](#); [Rothbaum 1997](#)) and two studies at low risk ([Creech 2021](#); [Gray 2020](#)). Studies performed relatively well on the measurement of PTSD (86% low risk), on deviation from

the intervention (71% low risk) and on the selection of the reported result (33% low risk). However, seven out of 21 PTSD results were at high risk of bias with regard to randomisation (Bell 2019; Falsetti 2008; three comparisons from Foa 1999; Miller 2015; Rothbaum 1997) and four for missing data (Falsetti 2008; two comparisons from Foa 2005; Miller 2015).

For depression at post-treatment, we assessed 17 results from 12 studies. We assumed an overall high risk of bias for depression on the basis that 59% of results were judged at high risk (Abrahams 2010; Falsetti 2008; three comparisons from Foa 1999; two from Foa 2005; Rothbaum 1997; two comparisons from Rothbaum 2005) and 41% raised some concerns (Bomyea 2015; Bowland 2012; Brady 2021; Foa 2006; Littleton 2016; two from Resick 2002). Measurement of depression was at low risk for all 17 results. Also, selection of the reported result was at low risk in 18% of results (Brady 2021; and the two results arising from Resick 2002) and of some concern for the remaining 82%. For randomisation, the level of risk of bias was similar to the PTSD outcome with seven results from four studies being at high risk (Falsetti 2008; Foa 1999; Rothbaum 1997; Rothbaum 2005). For deviations from the intended intervention, two results were at high risk (Abrahams 2010; Falsetti 2008). For missing data, three results were at high risk (Falsetti 2008; two comparisons from Foa 2005).

For treatment dropout, we assessed five results from five studies. We assumed an overall risk of bias with some concerns: 60% of studies generated some concerns (Bomyea 2015; Brady 2021; Foa 2006) and 40% were high risk (Bell 2019; Littleton 2016). Treatment dropout generally worked more effectively as an outcome in comparisons of active interventions, given the need for intervention completion data; it was less meaningful to assess dropout from usual care, wait-lists or no-treatment controls. Therefore, only included in this assessment are those five studies with comparators that we considered minimal interventions and for which studies reported dropout. Measurement issues led to the high risk assessment for Littleton 2016, whilst a lack of information about randomisation led to the high risk assessment for Bell 2019. Treatment dropout should be relatively straightforward to report and assess, as merely a count of those who completed the intervention expressed as a proportion of the numbers randomised. This outcome was at low risk for deviations from the intended interventions and bias due to missing data. However, it was complicated by poor reporting of data in flow diagrams and lack of clarity around thresholds for completion (e.g. how many sessions needed to be completed to be regarded as treatment completion?). Where these cut-offs have not been stated prior to commencing the study, researchers may select thresholds that suit the conclusions they hope to demonstrate (be that favourable completion rates or tolerance of the intervention or to, in some way, influence who gets included in per protocol analyses).

For adverse events, there were six studies in Comparison 1 reporting results for adverse events/effects quantitatively by group. We assumed an overall risk of bias with some concerns with 50%

of studies generating some concerns (Abrahams 2010; Brady 2021; Gray 2020). We assessed Rajan 2020 as being at low risk. Two studies were at high risk due to missing outcome data, which meant we could not assess why people had exited studies or if negative outcomes or experiences correlated with high attrition (Krakow 2001; Littleton 2016). On the other hand, these six were the only studies out of 23 studies in the main comparison that reported adverse events by arm.

Effects of interventions

See: **Summary of findings 1** Summary of findings table - Psychosocial interventions compared to inactive control for survivors of sexual violence and abuse

See: **Summary of findings 1** and forest plots. We undertook two sets of comparisons. The first set compares psychosocial interventions with inactive control arms only and includes subgroup analyses by intervention types (versus controls).

The second set of comparisons represents head-to-head comparison of active interventions, incorporating the set of studies that compared trauma-focused interventions to any other intervention that did not involve exposure to the trauma (i.e. non-trauma-focused psychosocial interventions).

Comparison 1. Psychosocial interventions versus inactive controls

Primary outcomes

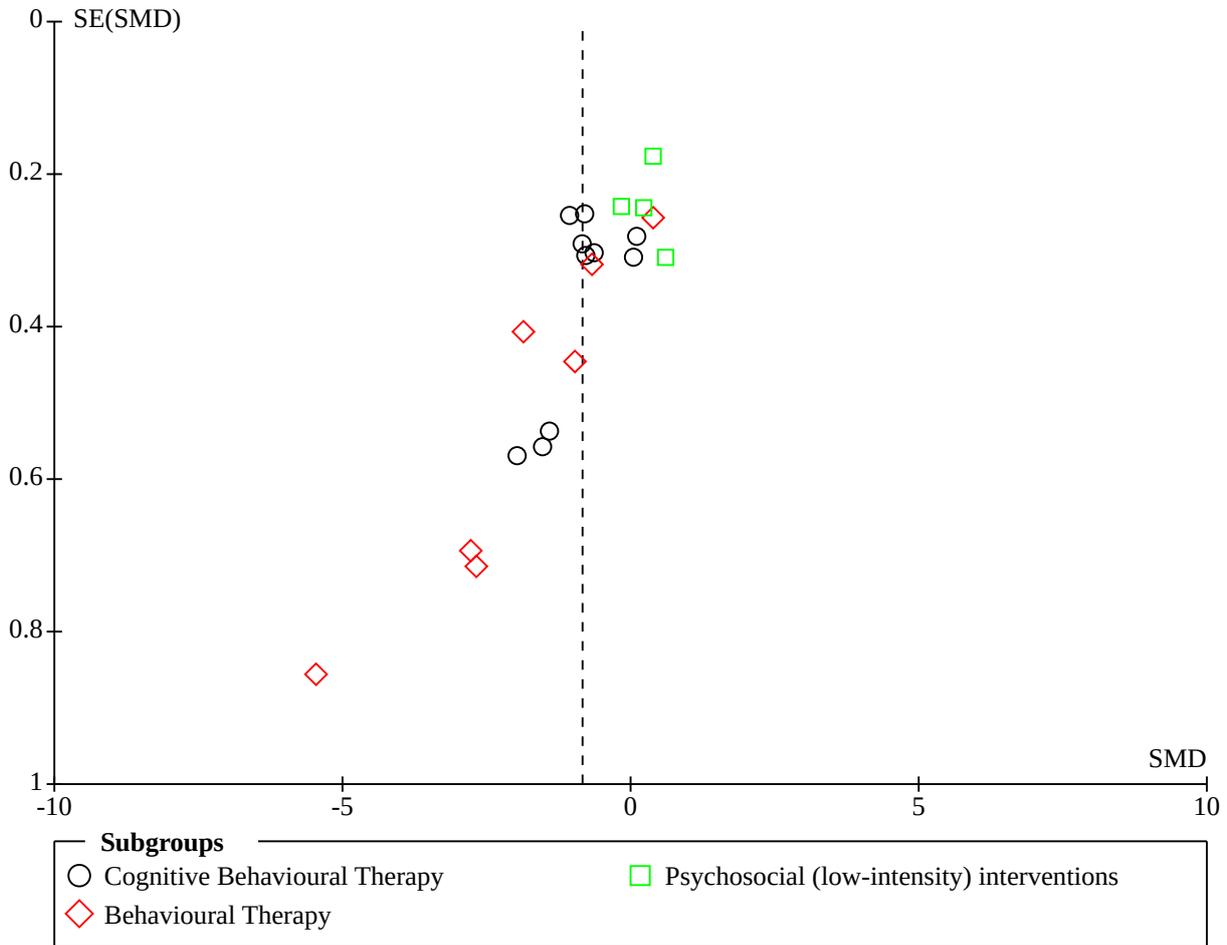
PTSD symptoms

A total of 16 studies reported PTSD symptoms for this comparison post-treatment (Bell 2019; Bomyea 2015; Brady 2021; Creech 2021; Falsetti 2008; Foa 1999; Foa 2005; Foa 2006; Gray 2020; Littleton 2016; Miller 2015; Rajan 2020; Resick 2002; Rothbaum 1997; Sikkema 2018; Walsh 2017). Seven studies also compared PTSD symptoms at three months, two studies at six months and only one study at 12 months follow-up. These studies consistently reported means and standard deviations, which enabled pooling.

We pooled all available studies post-treatment into a random-effects meta-analysis. In the pooled analysis, there was a standardised mean difference (SMD) of -0.83 (95% CI -1.22 to -0.44; $P < 0.001$, $I^2 = 87%$; 16 studies, 1130 participants; low-certainty evidence; **Analysis 1.1**), favouring the experimental group. Using Cohen's D as a basis for interpreting the SMD, this suggests a large effect. The three-month time point revealed a SMD of -0.13 (95% CI -0.42 to 0.17; $P = 0.41$, $I^2 = 72%$; 7 studies, 770 participants; **Analysis 1.2**), suggesting there may be no difference between groups at three months. An insufficient number of studies was available for the six-month and 12-month time points to conduct analyses.

We observed a tendency towards symmetrical funnel plots in **Figure 2**, disregarding possible reporting and publication biases.

Figure 2. Funnel plot for the comparison of psychosocial interventions versus inactive control for PTSD symptoms at post-treatment



Sensitivity analyses for PTSD symptoms

For the post-treatment time point, we performed separate sensitivity analyses removing high risk of bias studies to reveal a SMD of -0.66 (95% CI -1.21 to -0.12; P = 0.02, I² = 90%; 10 studies, 710 participants). In another sensitivity analysis, given the high heterogeneity amongst all studies reporting PTSD symptoms at post-treatment (I² = 87%; P < 0.001), we removed studies that were clinically diverse in terms of being low-intensity interventions (i.e. they did not involve psychotherapy); this revealed a SMD of -1.13 (95% CI -1.57 to -0.70; P < 0.001, I² = 84%; 13 studies, 808 participants; analysis not shown). Thus, there was a large effect size but no detectable improvement in heterogeneity, suggesting it may arise from additional methodological and clinical characteristics.

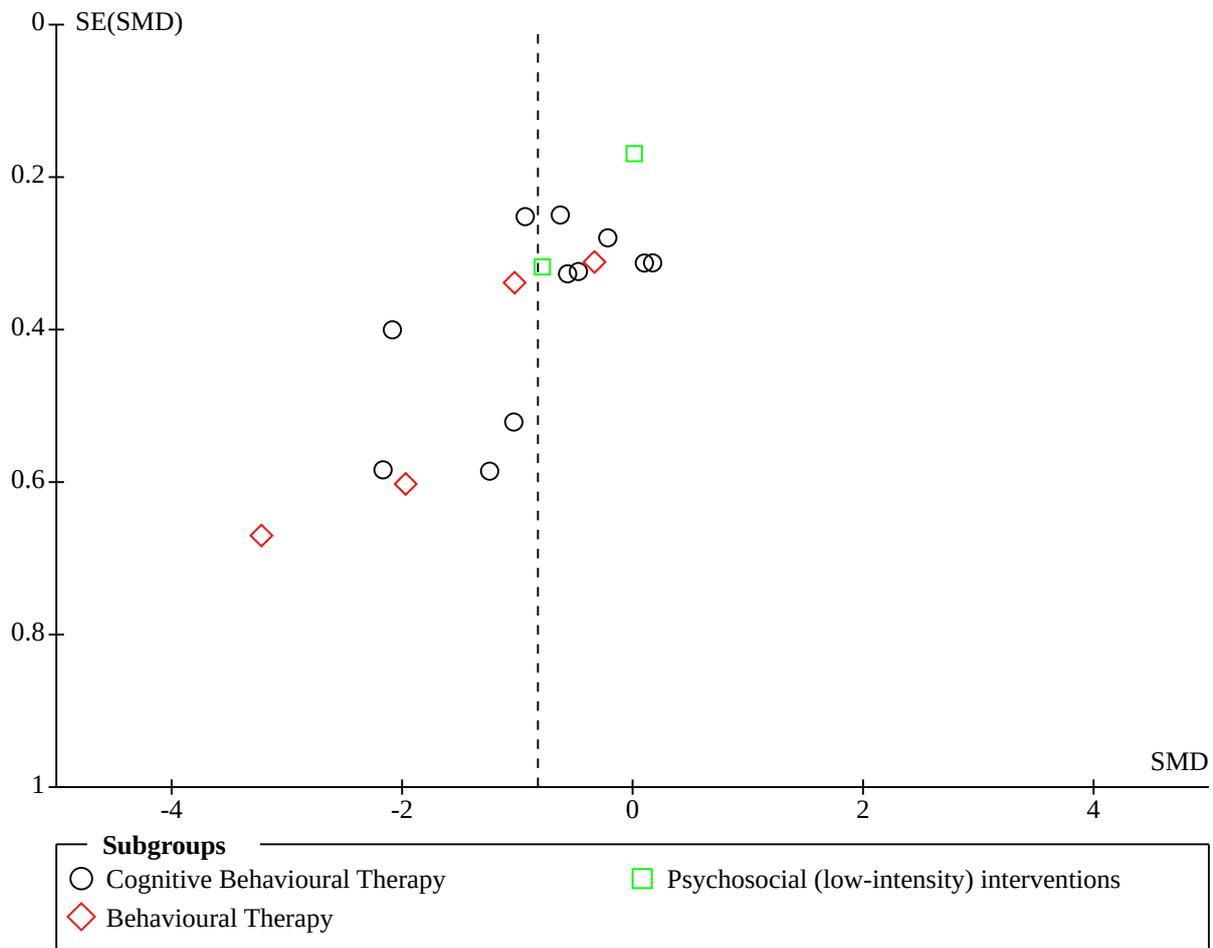
Depressive symptoms

Depressive symptoms were reported by 12 studies at post-treatment for this comparison (Abrahams 2010; Bomyea 2015;

Bowland 2012; Brady 2021; Falsetti 2008; Foa 1999; Foa 2005; Foa 2006; Littleton 2016; Resick 2002; Rothbaum 1997; Rothbaum 2005). We pooled depressive symptom scores into a random-effects meta-analysis. The result of the analysis at post-treatment favoured the experimental group with a SMD of -0.82 (95% CI -1.17 to -0.48; P < 0.001, I² = 78%; 12 studies, 901 participants; low-certainty evidence; Analysis 1.3). Using Cohen’s D as a basis for interpreting the SMD, this suggests a large effect. For the three-month time point, we calculated a SMD (SMD -0.05, 95% CI -0.39 to 0.29; P = 0.77, I² = 38%; 3 studies, 376 participants; Analysis 1.4), which suggested no group difference. There was an insufficient number of studies to pool data for the other two time points.

We observed a tendency towards symmetrical funnel plots in Figure 3, disregarding possible reporting and publication biases.

Figure 3. Funnel plot for the comparison of psychosocial interventions versus inactive control for depressive symptoms at post-treatment



Sensitivity analyses for depressive symptoms

We performed separate sensitivity analyses removing high risk of bias studies for the post-treatment time point to reveal a SMD of -0.65 (95% CI -1.16 to -0.13; P = 0.01, I² = 79%; 6 studies, 360 participants). For the second sensitivity analysis we removed studies that were clinically diverse in terms of being low-intensity interventions. This revealed a SMD of -0.90 (95% CI -1.28 to -0.52; P < 0.001, I² = 76%; 10 studies, 718 participants; analysis not shown). There was no detectable improvement in heterogeneity, suggesting it arises from additional methodological and clinical characteristics.

Dropout from treatment

Dropout from treatment could be assessed in the five studies (242 participants) that compared psychosocial interventions to control groups that were defined as minimal interventions (Bell 2019; Brady 2021; Bomyea 2015; Foa 2006; Littleton 2016). We conducted a random-effects meta-analysis and revealed a risk ratio of 0.85 (95% CI 0.51 to 1.44; P = 0.55, I² = 35%; low-certainty evidence; Analysis 1.5), suggesting there was a lack of evidence about how exposure to the groups may affect dropout from treatment.

Adverse events

We considered adverse events within the 23 studies comparing a psychosocial intervention to an inactive control. Twenty-one adverse events were reported in seven studies (801 participants) (Abrahams 2010; Brady 2021; Foa 2005; Gray 2020; Krakow 2001; Littleton 2016; Rajan 2020). Only six of the studies (622 participants) presented data by condition: three had zero adverse events in either condition (Abrahams 2010; Gray 2020; Rajan 2020) and three had minimal adverse events (Brady 2021; Krakow 2001; Littleton 2016). Upon pooling the six studies, a RR of 1.92 was revealed (95% CI 0.30 to 12.41; P = 0.49, I² = 30%; 6 studies; 622 participants; very low-certainty evidence; Analysis 1.6), suggesting there was a lack of evidence of a group difference.

In addition to counts of adverse events, and as Table 4 shows, studies considered harm experiences by examining rates of non-completion of the intervention, and reporting the reasons for this. However, studies lacked feedback from large numbers of non-completers and those that dropped out from follow-up assessments, thus potentially missing harms of exposure to interventions and/or research participation. It was more common for studies to report on participation bias by comparing treatment

completers and non-completers on baseline factors, which is a related but distinct issue. The third approach to considering harm was to report worsening of symptoms based on outcome measures (usually PTSD). Finally, a small number of studies observed levels of distress or negative affect following therapy sessions; however, a temporary increase in negative mood was not necessarily viewed as problematic, rather, being part of a pathway to improved health.

Secondary outcomes

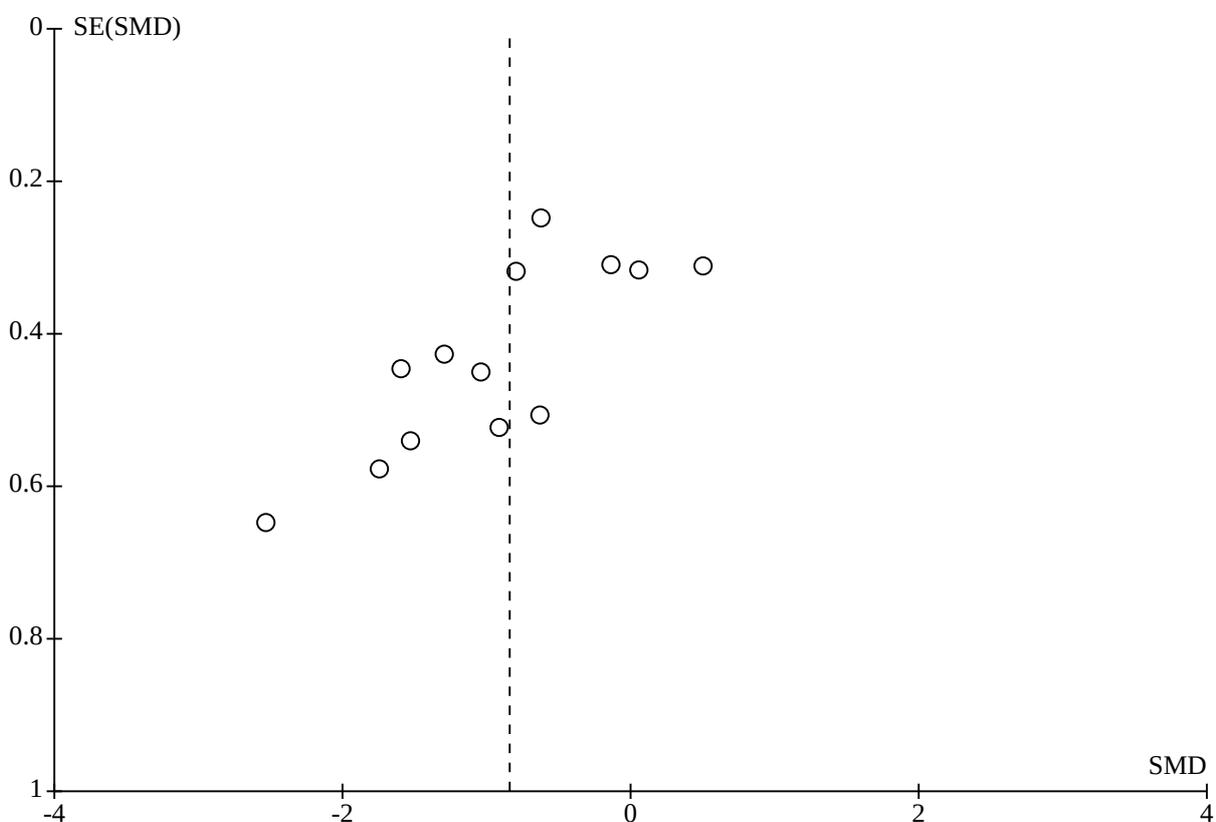
Anxiety symptoms

A total of 10 studies (436 participants) reported a measure of anxiety symptoms post-treatment (Bell 2019; Bomyea 2015; Bowland 2012;

Brady 2021; Foa 1999; Foa 2006; Littleton 2016; Miller 2015; Rothbaum 1997; Rothbaum 2005).

We entered all data for anxiety symptoms in a random-effects meta-analysis, which showed a SMD of -0.84 at post-treatment (95% CI -1.26 to -0.42, $P < 0.001$, $I^2 = 73\%$; 10 studies, 436 participants; Analysis 1.7). This showed a large effect size favouring the experimental group. For the three-month time point, we pooled four studies and revealed a SMD of -0.26 (95% CI -0.44 to -0.07; $P = 0.007$, $I^2 = 0\%$; 449 participants; Analysis 1.8); this was a small effect favouring the experimental group. An insufficient number of studies reported anxiety symptoms at 6 and 12 months. We observed a tendency towards symmetrical funnel plots in Figure 4, disregarding possible reporting and publication biases.

Figure 4. Funnel plot for the comparison of psychosocial interventions versus inactive control for anxiety symptoms at post-treatment



Global mental health functioning/distress

Three studies reported global mental health/distress symptoms (Anderson 2010; Rajan 2020; Rothbaum 1997). Post-treatment, a pooled meta-analysis revealed a SMD of -0.92 (95% CI -1.70 to -0.13; $P = 0.02$, $I^2 = 61\%$; 3 studies, 80 participants; Analysis 1.9). We interpreted the SMD as a large effect favouring the experimental condition. There were insufficient studies to pool for the other time points.

Trauma-related beliefs, substance misuse, dissociation and quality of life

An insufficient number of studies reported on these outcomes at post-treatment, three months, six months and 12 months to conduct analyses.

Subgroup analyses

Where data permitted and sufficient studies were available to pool, we conducted our planned subgroup analyses.

PTSD symptoms

The test for subgroup differences found evidence of a difference between different types of psychosocial interventions ([Analysis 1.1](#), test for subgroup differences: $\text{Chi}^2 = 27.45$, $\text{df} = 2$ ($P < 0.001$, $I^2 = 92.7\%$)). This analysis suggests that while both CBT (SMD -0.77 , 95% CI -1.12 to -0.42 ; 6 studies, 575 participants) and Behavioural Therapy (SMD -1.85 , 95% CI -3.00 to -0.70 ; 7 studies, 233 participants) may result in a reduction in PTSD symptoms compared to inactive control, there may be no evidence of a difference between psychosocial (low-intensity) interventions and inactive controls (SMD 0.26 , 95% CI -0.04 to 0.55 ; 4 studies, 322 participants).

Depressive symptoms

The test for subgroup differences found no evidence of a difference between different types of psychosocial interventions for this outcome ([Analysis 1.3](#), test for subgroup differences: $\text{Chi}^2 = 3.00$, $\text{df} = 2$ ($P = 0.22$), $I^2 = 33.4\%$). This analysis suggests that while both CBT (SMD -0.73 , 95% CI -1.13 to -0.33 ; 7 studies, 595 participants) and Behavioural Therapy (SMD -1.51 , 95% CI -2.58 to -0.44 ; 4 studies, 123 participants) may result in a reduction in depressive symptoms compared to inactive control, there may be no evidence of a difference between psychosocial (low-intensity) interventions and inactive control (-0.34 , 95% CI -1.12 to 0.44 ; 2 studies, 183 participants).

Comparison 2. Trauma-focused versus non-trauma-focused interventions

Primary outcomes

PTSD symptoms

We pooled studies in a random-effects meta-analysis to reveal a SMD at post-treatment (SMD -0.18 , 95% CI -0.48 to 0.13 ; $P = 0.26$, $I^2 = 67\%$; 10 studies, 727 participants; [Analysis 2.1](#)), suggesting there may be no group difference in PTSD symptoms at post-treatment. Interpreting the result at three months using Cohen's D, there was evidence of a small effect favouring trauma-focused interventions, with a SMD of -0.33 (95% CI -0.49 to -0.16 ; $P < 0.001$, $I^2 = 30\%$; 8 studies, 584 participants; [Analysis 2.2](#)). There may be no effect at six months (SMD -0.21 , 95% CI -0.43 to 0.01 ; $P = 0.06$, $I^2 = 26\%$; 5 studies, 533 participants; [Analysis 2.3](#)). Fewer than three studies were available for pooling at 12 months.

Depressive symptoms

Pooling of studies for depressive symptoms at post-treatment revealed a SMD of -0.21 (95% CI -0.54 to 0.12 ; $P = 0.21$, $I^2 = 69\%$; 9 studies, 673 participants; [Analysis 2.4](#)), suggesting there may be no difference between groups at post-treatment. At three months, a SMD of -0.56 was revealed (95% CI -0.97 to -0.15 ; $P = 0.008$, $I^2 = 72\%$; 7 studies, 535 participants; [Analysis 2.5](#)), suggesting there may be a moderate effect favouring trauma-focused interventions. At six months, the SMD was -0.68 (95% CI -1.49 to 0.13 ; $P = 0.10$, $I^2 = 94\%$; 5 studies, 532 participants; [Analysis 2.6](#)), suggesting there may be no group difference at six months. An insufficient number of studies was available for pooling at 12 months.

Dropout from treatment

We pooled 10 studies (859 participants) in a random-effects meta-analysis to reveal a risk ratio of 1.43 (95% CI 1.08 to 1.87 ; $P = 0.01$, $I^2 = 18\%$; [Analysis 2.7](#)). The results favoured non-trauma-focused

interventions; those exposed to trauma-focused interventions may have an increased risk of dropping out from treatment.

Adverse events

We pooled five studies (591 participants) and revealed a risk ratio of 0.63 (95% CI 0.29 to 1.37 ; $P = 0.24$, $I^2 = 4\%$; [Analysis 2.8](#)), suggesting there may be no group difference in adverse events. [Table 5](#) outlines additional data reported by the included studies.

Secondary outcomes

Anxiety symptoms

We pooled seven studies for the post-treatment time point comparing trauma-focused and non-trauma-focused interventions. This meta-analysis revealed a SMD of -0.15 (95% CI -0.42 to 0.13 ; $P = 0.29$, $I^2 = 38\%$; 7 studies, 540 participants; [Analysis 2.9](#)), suggesting a lack of evidence for a group difference in anxiety. The three-month and six-month time points also revealed SMDs (three months: SMD -0.23 , 95% CI -0.49 to 0.02 ; $P = 0.07$, $I^2 = 11\%$; 5 studies, 403 participants; [Analysis 2.10](#); six months: SMD -0.05 , 95% CI -0.37 to 0.28 ; $P = 0.79$, $I^2 = 47\%$; 3 studies, 399 participants; [Analysis 2.11](#)), suggesting there may be no group differences in anxiety at three and six months.

Trauma-related beliefs

At post-treatment, a SMD of 0.16 was revealed after pooling three studies (95% CI -0.17 to 0.50 ; 152 participants; $P = 0.34$, $I^2 = 0\%$; [Analysis 2.12](#)), suggesting there may be a lack of evidence for a group difference in trauma-related beliefs. There was an insufficient number of studies for pooling at three, six and 12 months.

Global mental health functioning/distress

Three studies reported global mental health/distress at post-treatment. This meta-analysis revealed a SMD of 0.07 (95% CI -0.36 to 0.51 ; $P = 0.74$, $I^2 = 35\%$; 3 studies, 342 participants; [Analysis 2.13](#)), and at three months we identified a SMD of -0.35 (95% CI -1.00 to 0.31 ; $P = 0.30$, $I^2 = 73\%$; 3 studies, 341 participants; [Analysis 2.14](#)). This suggests that there may be no group difference in global mental health or distress.

DISCUSSION

Summary of main results

We identified 36 studies (1991 to 2021) that were randomised controlled trials of psychosocial interventions (ranging from intensive psychotherapy to low-intensity, social, psychoeducation and other interventions) following rape, sexual assault and sexual abuse. These studies included 3992 people with exposure to trauma, assigned to 60 experimental groups (3014; 76%) and 23 inactive comparator conditions (978, 24%). Eighty-two per cent of people had sexual trauma during adulthood; 94% had a post-traumatic stress disorder (PTSD) diagnosis at baseline based on a clinical interview or clinically important symptoms based on self-report thresholds; 99% of participants were women and 60% identified as Black or as an ethnic minority.

Comparison 1. Psychosocial interventions versus controls

Taken together, and when compared to control conditions, the evidence suggests that psychosocial interventions may reduce

PTSD and depression symptoms at post-treatment (in the days and weeks following intervention). Overall, there was a low level of certainty, mainly due to heterogeneity in the studies (for example, psychosocial interventions vary considerably in their aims and mechanisms) and risk of bias. Psychosocial interventions may not decrease treatment acceptability (i.e. completion of treatment) relative to comparison groups; however, this outcome was based on a small number of studies and there was low certainty in the evidence due to not fully addressing the question about treatment acceptability. Our fourth outcome in our main comparison was adverse events/effects, with 21 events identified in seven studies. We had a very low level of certainty about this outcome; there was high non-completion across groups and attrition from studies without explanation, suggesting potential for missing wider harms of exposure to the intervention or comparison conditions and/or research participation.

Beyond post-treatment, there may be no difference between groups in PTSD and depressive symptoms at three months. However, studies included at that time point were relatively low-intensity interventions including: an economic scheme (Bass 2016); brief (Foa 2006) and online (Littleton 2016) cognitive behavioural therapy (CBT); a psychoeducation video (Miller 2015); and an intervention primarily to improve AIDS care post-sexual trauma (Sikkema 2018). Establishing benefits beyond three months was not possible due to a lack of control data - many wait-list groups were offered active interventions after the post-treatment assessment, excluding the option of longer-term comparison.

Secondary outcomes

The evidence suggests that there may be large effects for post-treatment anxiety and global mental health/distress favouring psychosocial interventions among survivors of sexual violence and abuse. At three months, a small effect persisted for anxiety. An insufficient number of studies reported global mental health/distress beyond post-treatment, and for trauma-related beliefs, dissociation and substance misuse at any time point, to conduct analyses.

Subgroup of comparison 1: analysis of three types of psychosocial intervention

- i) The CBT subgroup combined common approaches such as Prolonged Exposure and Cognitive Processing Therapy, with CBT blends (Foa 2005) and alternatives like Multiple Channel Exposure Therapy (Falsetti 2008), Imagery Rehearsal Therapy (Krakow 2001) and Clinician-Assisted Emotional Disclosure (Anderson 2010) versus inactive controls.
- ii) The behavioural interventions subgroup included a mixture of traditional EMDR studies (Rothbaum 1997; Rothbaum 2005) and Narrative Exposure Therapy (Brady 2021) and new approaches such as Reconsolidation of Traumatic Memories (Gray 2020), High Interference Control (Bomyea 2015), neurofeedback (Bell 2019) and Lifespan Integration (Rajan 2020), and a pleasant imagery and relaxation instruction video provided at an acute medical setting (Walsh 2017) versus inactive controls.
- iii) Psychosocial interventions of low intensity combined low-intensity (largely non-psychotherapeutic) interventions grouped as 'other psychosocial interventions' and 'other psychologically oriented interventions' versus inactive controls. Relative to CBT and behavioural interventions, these interventions tended to be

less manualised and did not require the same level of training for staff, which was an important part of making them accessible in acute and primary care healthcare and in low- and middle-income settings. They included brief video interventions delivered in acute settings (Miller 2015; Walsh 2017) and interventions that prioritised other health or social issues such as care for HIV/AIDS (Sikkema 2018), economic difficulties (Bass 2016) or used computerised screening and responses for multiple issues, e.g. substance misuse and intimate partner violence (Crech 2021).

For post-treatment PTSD, the test for subgroup differences found evidence of a difference between different types of psychosocial interventions and suggested that both CBT and behavioural interventions may result in a reduction in PTSD symptoms compared to inactive controls. However, there may be no evidence of a difference between psychosocial (low-intensity) interventions and inactive controls. The evidence was less conclusive for depressive symptoms at post-treatment, though it similarly suggested that CBT and behavioural interventions, but not low-intensity psychosocial interventions, may result in reductions in depression.

Comparison 2. Trauma-focused interventions compared to non-trauma-focused interventions

The next comparison was a head-to-head analysis of active interventions, addressing a key question concerning whether interventions that involved exposure to the feared memory of the traumatic event (or to cues that became associated with fear at the time of a traumatic event) would outperform interventions that did not include such exposure. The evidence suggests that trauma-focused interventions may result in little to no difference in PTSD symptoms and depressive symptoms at post-treatment compared to non-trauma-focused interventions. Further, there may be no group difference in adverse events. However, participants who underwent trauma-focused therapies had increased risk of not completing the treatment compared to those who received interventions that did not involve confronting feared memories and stimuli such as Holographic Reprocessing (Katz 2014), Stress Inoculation Therapy (Foa 1999), Present-Centred Therapy (Schnurr 2007; Surís 2013) and telephonic psychosocial support (Covers 2021), along with a range of other novel and emerging non-trauma-focused interventions (e.g. trauma-sensitive yoga; Kelly 2021). Evidence generally matched the intensity of the interventions (i.e. number and duration of therapy sessions in each group).

All interventions in both groups reported changes at post-treatment from baseline of 1 to 2 standard deviations, which is within the recommendations for establishing clinically meaningful changes (e.g. based on the clinician-assessed PTSD scale (CAPS) and self-report PTSD checklist (PCL) severity and change z scores ranging between 0.5 to 0.8 standard deviations in Stefanovics 2018).

At three months, trauma-focused interventions may result in a small important effect, with a slight reduction in PTSD, and a moderate effect for depressive symptoms. There may be no group differences in these primary outcomes at six months and there were insufficient studies to pool at 12 months. There was a lack of evidence on group differences for the secondary outcomes.

The improvement in mental health at three months favouring trauma-focused intervention needs to be balanced against treatment acceptability. It suggests that among those who are safe

and no longer exposed to the trauma, have achieved stabilisation and express a preference for such approaches, offering treatment with a trauma focus may be appropriate. For others, and those that opt to exit trauma-focused treatments early, structured non-trauma-focused approaches provide a viable alternative.

Overall completeness and applicability of evidence

Our review considers randomised controlled trials of a wide range of psychosocial interventions for survivors of sexual violence and abuse. These included TF-CBT, EMDR and other behavioural approaches, non-trauma-focused CBT and other psychotherapeutic and psychosocial interventions, using mainly individual, face-to-face delivery (see [Included studies](#)). Studies included participants from different countries and backgrounds, who had been exposed to sexual violence and abuse across a range of contexts and circumstances, reflected in the approach to recruitment and settings of intervention delivery (see [Included studies](#)). The majority of studies reported on the use of qualified and experienced therapists, and an encouraging proportion included assessment of adherence to a treatment protocol (see [Included studies](#) table).

Starting with country of origin, trials of interventions for PTSD generally ([Bisson 2013](#)) and for specific populations such as military-related trauma survivors ([Steenkamp 2015](#)) and sexual violence and abuse survivors, derive mainly from the USA (72% of studies in this review). Interventions tested in the USA tend to be trauma-exposure based, have strong links with responses to military-based trauma and involved clinical settings and treatment-seeking populations. This contrasts with the four studies (12%) that came from the African continent (South Africa and the Democratic Republic of the Congo (DRC)), notably more 'psychosocial' than psychotherapeutic, with a primary focus on promoting HIV care ([Sikkema 2018](#)), post-exposure prophylaxis after rape ([Abrahams 2010](#)) and economic factors ([Bass 2016](#)); the one study that did consist of Cognitive Processing Therapy, [Bass 2013](#), omitted the trauma narrative in a bid to enhance feasibility and reach. These studies highlighted co-morbidities and other major health concerns for rape, sexual assault and sexual abuse. All included efforts to use culturally adapted measures, local-language versions of well-established measures, or translated and adapted interventions to meet the needs of the local women. No studies in the current review arose from Asia although one UK study of migrant people seeking care after exposure to trafficking did include people from parts of Asia ([Brady 2021](#)). Three additional studies derived from Europe - Sweden ([Rajan 2020](#)), the Netherlands ([Covers 2021](#)) and Spain ([Echeburua 1996](#)). The remaining two studies were from Australia ([Nixon 2016](#)) and Canada ([Belleville 2018](#)). To summarise, there were 32 studies from high-income countries, two from middle-income countries and two from low-income countries.

Studies were more balanced on ethnicity than country; over 60% of participants had ethnicities other than White/Caucasian, demonstrating an important shift away from ethnocentrism common to this field of enquiry ([IOM 2008](#)). Just two studies focused specifically on recruiting a minority sample: low-income, African-American women ([Feske 2008](#)) and international survivors of people trafficking ([Brady 2021](#)). Evidence from our review, however, is strongly weighted towards the experiences of women, with just four studies engaging men (making up only 1% of the total randomised sample). Whilst the global burden of sexual violence

and abuse is shouldered by women and girls, men's experiences in this sphere remain under-represented. Related to this is the lack of emphasis on wider aspects of gender and sexual identities: with few exceptions ([Creech 2021](#)), transgender and non-binary people's experiences were omitted, as was reference to sexual identity or orientation in participant characteristics across studies.

There were generally no upper limits on age across studies: mean ages ranged from 19 years among a university sample ([Anderson 2010](#)) to 61 years in a study that specifically recruited older women ([Bomyea 2015](#)), with a weighted mean age of 35.9 years across all participants. Despite the levels of sexual violence and abuse experienced by migrant and refugee populations, these groups were under-represented in this evidence, the recent UK study being an exception ([Brady 2021](#)). This study attempted to overcome barriers of language by engaging interpreters in the research. Similarly, those with learning and communication disabilities, people affected by substance misuse, suicidality and severe mental health difficulties, and those currently at risk of domestic abuse were routinely excluded. Whilst the rationale for some of these exclusions is understood in the context of conducting a RCT (e.g. safety and for establishing mechanisms of change), it is important to point out the gaps in this evidence as regards who it does and does not apply to and the risk of excluding individuals whose complex needs make treatment more difficult ([Bisson 2013](#)). In particular, we draw attention to the exclusion of individuals with more complex trauma histories in intervention trials. Complex PTSD (CPTSD; ICD-11; [WHO 2021](#)) can arise for individuals who have experienced chronic, repeated and prolonged traumas, such as childhood sexual abuse or domestic abuse. CPTSD is associated with the experience of complex reactions extending beyond those typically observed in PTSD in three key domains: emotion regulation, self-identity and relational capacities ([WHO 2021](#)).

To enhance the overall completeness of the evidence base, future research needs to be cautious about what subgroups of survivors are excluded from trials. Recognising the challenges related to involving survivors of rape, sexual assault and sexual abuse in research, we are cautious to recommend that studies need to solely focus on minority groups as this may not be feasible. However, the evidence could be enhanced by taking steps to report results for different subgroups to allow meta-analyses related to participant characteristics.

Quality of the evidence

We judged certainty of the evidence for all four primary outcomes using GRADE. Heterogeneity was one of the main problems in the main comparison but it was not unanticipated given that we drew such a wide range of interventions together in one analysis. In any case, since we detected substantial heterogeneity ([Deeks 2021](#)) for PTSD and depression, we downgraded on this basis; dropout (treatment acceptability) and adverse events/effects were not affected to the same extent and therefore we did not downgrade these for inconsistency. Given the wide range of intervention types, we carried out a sensitivity analysis to exclude low-intensity psychosocial interventions. Whilst this led to increases in effect sizes, it did not improve heterogeneity significantly. This suggests the heterogeneity may have arisen from additional methodological and clinical characteristics, such as sample sizes and time since trauma.

The threat of bias was another reason for downgrading the evidence. We observed i) poor reporting or execution of the randomisation process and ii) the potential for systematic bias relating to missing outcome data and the associated risk that attrition from studies was associated with trauma burden, thus affecting primary outcomes for mental health but also adverse events. We additionally observed instances of including treatment completers only in analyses and in summaries of baseline characteristics. However, intention-to-treat analyses were commonplace in the more recently published reports. Some problems such as lack of blinding to the intervention were more enduring but the RoB 2 tool does not penalise study results if it can be demonstrated that there is a low likelihood that the lack of blinding of personnel and participants influenced the outcome in the groups. We had concerns that adverse events may suffer a reporting bias as it was addressed by so few studies overall. Sensitivity analyses that excluded high-risk results showed a reduced PTSD and depression effect size, from high to medium.

We also had concerns that treatment acceptability (dropout) may suffer from indirectness, not quite addressing a key question about whether psychosocial interventions are associated with higher treatment non-completion than other conditions. Dropout also suffered from a high level of imprecision. Similarly, the adverse events/effects outcome was affected by imprecision due to very few events being reported/included in the analysis, and there was inconsistency in the approach to measuring this outcome. Thus, we downgraded these outcomes twice.

Although not formally reported using GRADE, the second comparison of trauma-focused interventions compared to non-trauma-focused interventions provided a much more robust picture about treatment acceptability and adverse events. It addresses whether or not available research evidence can be directly used to answer the question about whether interventions for sexual violence and abuse lead to harm and non-completion. Risk of bias was less frequent in the more recent studies and studies in the head-to-head comparison were more recent; further, the evidence suffered neither inconsistency (reporting I^2 mainly in a range unlikely to be important (Deeks 2021)) nor imprecision (e.g. narrow confidence intervals). Thus, although not included in our summary of findings table, Comparison 2 delivered a promising level of certainty about the evidence.

Potential biases in the review process

We believe the various strategies described in the Methods section will have effectively minimised the potential biases in the review process. The most important among them has been the engagement of authors from several different institutions across aspects of the review and consultation with people with lived experience of sexual violence or abuse. We have also engaged widely with authors of included studies to try and gather missing/subgroup data and gain input on categorising novel interventions. We have indicated where we successfully accessed data from authors in the [Included studies](#) table. On rare occasions, we were unable to access disaggregated data to check if a study population contained a sufficient proportion of sexual violence survivors to be included in our review. There are also many RCTs of interventions targeting domestic abuse survivors where participants will have been subjected to rape, sexual assault and sexual abuse by partners or ex-partners that could be relevant to our review both in terms of population and intervention. However, we took the decision to

exclude domestic abuse interventions due to another Cochrane Review (Hameed 2020). There are many elements of the review that rely on authors' judgement, including interpretation of the certainty of the evidence, so it is possible that a different review team may not have agreed with all our assessments or decisions.

Agreements and disagreements with other studies or reviews

Several previous reviews of interventions for PTSD have included sexual violence and abuse survivors as a subset of the overall trauma population (Hetrick 2010; Kitchiner 2019; Roberts 2015; Roberts 2016; Steenkamp 2015), and several have called for a focus on specific populations (Bisson 2013; Regehr 2013). Our review has succeeded in increasing the representation of survivors of adulthood sexual violence and abuse to 81% of the total number of people randomised.

A Cochrane Review of psychological interventions for chronic PTSD in any population underscored the need for reviews of trauma interventions within specific populations given the degree of clinical and methodological diversity observed across studies (Bisson 2013). That review included 13 studies of sexual violence and abuse survivors, of which three compared TF-CBT to other therapies and identified no differences in PTSD at follow-up. Many relevant studies have been added to the literature since 2013; we incorporated 10 studies of TF-CBT compared to other therapies, and noted clinically relevant improvements for both TF-CBT and non-exposure treatments at post-treatment, and a small effect favouring the trauma-exposed group at three months. We also identified increased likelihood of dropout in the TF-CBT group. These findings are consistent with the Steenkamp 2015 review, which found that TF-CBT (CPT and Prolonged Exposure) was marginally superior to non-trauma focused psychotherapies among military personnel and veterans experiencing PTSD (Steenkamp 2015). Our review diverges from previous findings in respect of EMDR (Kitchiner 2019), where no benefit was detected for reducing PTSD in active duty and ex-serving military personnel with PTSD. This is consistent with guidance that recommends EMDR as an option for sexual violence and abuse survivors, but not for military-related trauma (e.g. NICE 2018).

Our review supports and strengthens findings from another review involving adult sexual violence and abuse survivors (Regehr 2013). Based on six studies, Regehr 2013 reported that cognitive and behavioural interventions had "a statistically significant effect" on PTSD and depressive symptoms in comparison to the control groups.

A contribution of the current review is the synthesis of several novel treatments across a range of areas including Lifespan Integration (LI), neurofeedback, Reconsolidation of Traumatic Memories (RTM) and trauma-sensitive yoga. Some of these interventions have been shown to be effective among survivors of a range of types of trauma not including sexual abuse and violence experienced as an adult (e.g. see Gray 2019 for a study of RTM; Panish 2020 for a review of neurofeedback), whilst the others have very little robust evidence in any population, with research limited by methodological problems such as lack of control groups or randomisation (Kelly 2021; Panish 2020). We identified four studies, one for each type of novel intervention discussed. Studies examining the effectiveness of LI (Rajan 2020), neurofeedback (Bell

2019) and RTM (Gray 2020) were included in our main comparison (i.e. compared to inactive controls). A study of trauma-sensitive yoga was included in Comparison 2 (Kelly 2021), a head-to-head comparison of active treatments, which performed similarly to the gold standard treatment, CPT. Our review provides further support for the promise of these interventions, some of which (LI and RTM) are shorter than traditional approaches such as CPT and PE, with implications for the reduction of treatment dropout and more effective use of limited available resources. However, we also support the conclusions of the authors of the studies (Bell 2019; Gray 2020; Kelly 2021; Rajan 2020) and review (Panish 2020) that further RCTs are required to more firmly establish the evidence base for these more recently developed interventions.

Taken together, these findings indicate the value of our review in terms of filling a gap in relation to the specific needs of sexual violence and abuse survivors and increasing overall certainty of the evidence about what works in this context.

AUTHORS' CONCLUSIONS

Implications for practice

This synthesis of findings from 36 studies represents the most comprehensive analysis to date on the efficacy of psychotherapies and other psychosocial interventions for survivors of sexual violence and abuse in adulthood.

Our review suggests adult survivors of rape, sexual violence and sexual abuse may experience a large reduction in post-traumatic stress disorder (PTSD) symptoms in the days and weeks following psychosocial interventions compared to controls. Post-treatment reduction in PTSD exceeded an effect size criterion for clinical significance (standardised mean difference (SMD) ≥ 0.8) suggested by Kitchiner 2019. Psychosocial interventions may also reduce depressive symptoms. The evidence suggests that psychosocial interventions may not reduce treatment completion or increase adverse events when compared to controls. However, since treatment non-completion and study attrition were high in both groups, the potential wider harms of exposure to different interventions and/or research participation itself may be missed. The estimates of effect may be biased because of poor randomisation processes and dropout from studies. There was also much variation in the studies (design, sample sizes and, importantly, the aims/nature of interventions). An observational test for subgroup differences found evidence of a difference between types of psychosocial interventions: cognitive behavioural therapy (CBT) and behavioural interventions may result in reductions in PTSD and depression, whilst psychosocial interventions of low intensity may result in little or no difference in mental health burden.

Based on our second comparison, the current review suggests that CBT with a trauma focus such as Prolonged Exposure and Cognitive Processing Therapy and other exposure-based therapies (e.g. eye movement desensitisation and reprocessing (EMDR)) probably benefit survivors of sexual violence and abuse. However, trauma-focused interventions may result in higher treatment non-completion and may leave some survivors with a high symptom load post-treatment. For example, despite achieving minimal clinically important differences (Stefanovics 2018) over inactive controls at post-treatment and over other active interventions at three months, endpoint group means reported in several studies

still exceeded thresholds for probable PTSD, e.g. 50 on the Clinician-Administered PTSD Scale (CAPS) and 20 on the PTSD Scale-Interview (PSS-I) (Steenkamp 2015); 34 on the Post-Traumatic Stress Disorder Checklist for DSM-5 (PCL-5) and 46 on Impact of Events Scale-Revised (IES-R) (Murphy 2017).

In response to the limits of trauma-focused interventions, there have been calls for more effective approaches to the management of PTSD (Bisson 2013; Kitchiner 2019; Steenkamp 2015), and for sexual violence and abuse exposure specifically (Regehr 2013). One contribution of the current review is the synthesis of several novel treatments across a range of promising new areas such as Reconsolidation of Traumatic Memories (RTM); trauma-sensitive or trauma-informed yoga; Lifespan Integration (LI); and neurofeedback. Some of these have been shown to be effective among survivors of other types of trauma (e.g. RTM; Gray 2019), whilst others have little evidence in any population.

Our review consolidates evidence on mainstay treatments for PTSD, supporting the continued use of trauma-focused psychotherapies such as EMDR, Cognitive Processing Therapy and Prolonged Exposure as first-line treatments for PTSD (NICE 2018; VA/DoD 2017). It extends the evidence base by finding these PTSD treatments to be applicable to survivors of sexual violence and abuse. It acknowledges the limitations associated with trauma-focused (exposure-based) approaches. Non-exposure-based approaches, including several emerging areas, may offer opportunities for second-line options to practitioners and service users. These variously include features of shorter duration; minimal or no focus on details of the trauma or associated cognitive and emotional effects; computer-based or minimal interpersonal contact with a therapist; and somatic practice/movement as the main modality. Our analyses suggest that interventions do not necessarily need to involve a large number of sessions to be effective; however, they do require well-trained, qualified therapists delivering interventions based on manualised, standardised treatment protocols. Low-intensity psychosocial interventions (e.g. psychoeducation alone/videos; community interventions where the emphasis on sexual violence and abuse was secondary to other social or health concerns) may not reduce PTSD and depression, but that conclusion is based on low-certainty evidence. Further, there are other important outcomes not measured in this review that may arise from such interventions; these include perceived support, advocacy, access to health services and legal advice.

It is the responsibility of practitioners and therapists to make decisions about treatments appropriate to the circumstances of their clients, in consultation with them and their families, carers or guardians. Further insight into factors that shape the treatment preferences of survivors, their families and professionals can be found in our related Cochrane Review (Brown 2020). The need to distinguish between PTSD and complex PTSD (CPTSD) has been argued since Judith Herman first proposed the diagnoses in the 1980s, with CPTSD added to the International Classification of Diseases 11th revision (ICD-11) (WHO 2021). Recognising the distinction when considering suitable trauma treatment is important, as CPTSD may be less amenable to trauma-focused approaches (Bradley 2005; Gray 2020). It underscores the value of a wide range of treatment options and alternatives to first line therapies. Many such alternative treatments could have relevance to clinical and policy decisions because they are often shorter and

therefore less costly, easier to deliver, may be deliverable online, more feasible for survivors to access and scalable.

Implications for research

Some participants in the included studies had PTSD scores above a clinical threshold following treatment; low-intensity psychosocial interventions may not have reduced mental health problems; and a third of those receiving exposure-based interventions did not complete treatment. Thus, there is a need for further evaluation of new interventions to improve mental health in this population. We propose that future research includes high-quality trials with regard to these intervention types and other novel approaches such that, in the future, survivors can be offered a range of evidence-based interventions in line with their varying needs and preferences. Such interventions can benefit from comparisons with inactive (wait-lists, no-treatment control) conditions, as well as head-to-head comparisons, with the gold standard trauma-focused treatments, or suitable non-trauma-focused comparators, such as Present-Centred Therapy. Comparison with active standard care (for example, in [Nixon 2016](#)) is also feasible, though researchers need to be cautious about how they bring together different comparators because usual care in a specialist sexual assault setting will look very different to usual care in health settings (e.g. mental health services or primary care).

Many of the contemporary intervention types did not map easily to the psychological therapies listed by former Cochrane groups CCDAN and CCMD based on our experience and feedback from experts/researchers; thus, we recommend updating classification systems to allow greater confidence, for example, in standardising how interventions are grouped for subgroup analyses.

The majority of interventions we examined were delivered individually and face-to-face. However, the alternative modalities have never been more important and relevant, given the magnitude of change precipitated by the COVID-19 pandemic ([WHO 2020](#)). This period saw the therapeutic milieu necessarily re-invent itself online and through telephonic and video-based support in order to initiate or maintain support to survivors. The remote delivery of care is likely to continue, and thus growing evidence on the efficacy of treatments delivered using diverse modalities is a priority in a post-COVID-19 era.

We classified nine studies as ongoing and of potential interest in updates to the current review ([Ongoing studies](#)). These are studies of both trauma-focused psychotherapies (e.g. imaginal exposure ([NCT04124380](#))), and non-trauma-focused approaches (e.g. skills training in affective and interpersonal regulation, which is compared to present-centred therapy in a Canadian trial ([NCT03429166](#))). Several of the studies examine different versions of CBT and target comorbid alcohol misuse ([NCT04124380](#); [NCT03703258](#); [NCT04582695](#)) and a range of other health problems ([NCT03019497](#)) associated with sexual violence and abuse. What is notable about these studies is a clear shift in emphasis to testing new modalities of delivery. These studies employ web-based apps, online delivery and telehealth approaches. For example, a UK trial potentially meeting the inclusion criteria for the review ([ISRCTN16806208](#)), compares internet-delivered trauma-focused cognitive therapy for PTSD with internet-delivered (non-trauma-focused) stress management therapy. These trials have strong potential to further strengthen the level of certainty about the effectiveness of a wide range of interventions.

To improve the certainty of the evidence, larger samples are needed. It is acknowledged that survivors of sexual violence and abuse are often minoritised and hard to reach; multi-site trials, which have been rare, may alleviate some of these difficulties. Over four-fifths of participants in our review represented the target group; however, we believe that heterogeneity would improve by incorporating sexual violence and abuse suffered in adulthood as an inclusion criterion, which is more common in recently published and ongoing trials. The participants were diverse in age; cultural and ethnic background; indicators of deprivation; education; and employment. However, the research largely represents North America.

Given the female bias in the studies included in this Review, we encourage greater gender diversity across recruited samples, and for studies to report the findings for minorities separately to aid meta-analyses in different population subgroups. There is a clear need for the field to acknowledge male and gender diverse survivors of sexual violence and abuse in adulthood. In one ongoing study ([NCT03794986](#)), motivational interviewing is being used to engage male survivors. Reducing the barriers to access that men face is assisted by ensuring the inclusion of male survivors in developing the evidence base to treat PTSD and other impacts from sexual violence and abuse. Furthermore, strict study eligibility criteria may reduce the applicability of the research of those affected by complex PTSD and by severe mental health difficulties. It is understandable that safety and stabilisation of circumstances are important for commencing PTSD treatments. On the other hand, efforts need to be made to avoid this leading to the exclusion of certain groups in need of intervention. The health inequality that faces people in this context with complex PTSD, from migrant backgrounds, those who are homeless and people with learning difficulties, is reflected here in the exclusion of these groups from the research.

PTSD, depression and/or anxiety were included in nearly every study, and several measures of distress or mental wellbeing were employed, which we combined as 'global mental health/distress'. There were also quite a few studies that assessed trauma-related cognitions, mainly using the Post-Traumatic Cognitions Inventory (PTCI), which assesses negative beliefs about the self, the world and self-blame. Other domains of importance to survivors may be overlooked but trials and systematic reviews are often necessarily restricted in the number of primary and secondary outcomes they can include. This highlights the importance of conducting process evaluations of trials and building the qualitative evidence base to allow understanding of the broader dimensions of people's experiences during and following interventions ([Brown 2020](#)). Ideally studies would: undertake clinical interviews using the Clinician-Administered PTSD Checklist for DSM-5 (CAPS-5) or PTSD Symptom Scale – Interview (PSS-I) at baseline and follow-up; report clearly on proportions meeting clinical thresholds before and after treatments; employ validated self-report PTSD assessments, reporting baseline and follow-up means and standard deviations. There also needs to be improved reporting of the number of adverse events by group, or for studies to pre-define the approach to harm assessment at the outset. Also, intention-to-treat analyses need to be given precedence, and researchers should follow strict protocols around randomisation and be clear in study protocols about selected thresholds for treatment completion. Such approaches will help standardise future research and increase

the certainty of evidence by reducing methodological diversity and risk of bias.

Whilst the question about whether benefits are sustained over time persists, attaining such evidence in studies that lack an active comparison group may be impractical and even unethical. Thus, in searching for evidence of long-term benefit, we recommend studies of head-to-head comparisons of different intervention types, with follow-ups of over a year and longer-term cohort studies.

Sexual violence and abuse has devastating physical, social and mental health impacts across the lifespan. No community is free of sexual assault, rape and abuse. As well as enabling access to justice, governments and societies have a duty to enable access to safe and effective treatments that preserve the well-being of victims and survivors, address mental health sequelae, and minimise long-term disability and the costs associated with sexual violence and abuse. We hope this review will provide useful insights on the state of the art in psychosocial interventions for sexual violence and abuse.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Abrahams 2010

Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Duration of study: August 2007 to May 2008</p> <p>Location of study: Eastern Cape Province and Western Cape, South Africa</p> <p>Randomisation method: a computer-generated randomisation list was generated by the study statistician, and random block sizes of 4, 6 and 8 were used to ensure balance in the 2 arms. Participants were allocated to an arm by the study co-ordinator after the initial data had been collected and leaflet explained. The contact information of intervention group participants was forwarded to the counsellors, who commenced the intervention within 12 h.</p> <p>Ethics approvals: ethical approval granted by the Medical Research Council</p>
Participants	<p>Baseline characteristics</p> <p>Other psychosocial interventions (telephonic psychosocial support)</p> <ul style="list-style-type: none"> • <i>Participants (at randomisation):</i> 136 • <i>Gender:</i> 100% female participants

Abrahams 2010 (Continued)

- Age: 10.4% < 10 years, 18.4% 10 years to 14 years, 19.2% 15 years to 17 years, 30.4% 18 years to 22 years, 21.6% > 22 years
- Ethnicity (% white, Black, other): 100% Black
- Disability: not given
- Time since trauma in months, M (SD): < 7 d
- Income: not given
- Education (% grade): 25.6% < 8, 25.6% 8 or 9, 39.2 10 or 11, 9.6% school completion or beyond
- Employment: 29.5% employed, 33.3% not employed, 37.2% student
- Sexual violence in adulthood: 52%
- Comorbid conditions: not given
- Baseline PTSD: not given
- Partnered: not given
- Randomised (N): 136
- Completed post-treatment assessment (N): 125
- Dropped out or removed prior to analysis (N): 11
- Numbers analysed at final applicable time point (N): 125
- Number of sessions, M (SD): 14.9 (9.8)
- Treatment completion: 119 (88.8%)

Usual care

- Participants (at randomisation): 138
- Gender: 100% female participants
- Age: 4.7% < 10 years, 20.3% 10 years to 14 years, 22.7% 15 years to 17 years, 25.8% 18 years to 22 years, 26.6% > 22 years
- Ethnicity: 100% Black
- Disability: not given
- Time since trauma: not given
- Income: not given
- Education (% grade): 26.6% < 8, 18.7% 8 to 9, 43.7% 10 to 11, 10.9% school completion or beyond
- Employment: 34.9% employed, 34.9% not employed, 30.1% student
- Sexual violence in adulthood: 52.4%
- Comorbid conditions: not given
- Baseline PTSD: not given
- Partnered: not given
- Randomised (N): 138
- Completed post-treatment assessment (N): 128
- Dropped out or removed prior to analysis (N): 10
- Numbers analysed at final applicable time point (N): 128
- Number of sessions: not given
- Treatment completion: N/A

Overall

- Participants (at randomisation): 274
- Gender: 100% female participants
- Age: not given
- Ethnicity: 100% Black
- Disability: not given
- Time since trauma in months, M (SD): last 7 d
- Income: not given
- Education: not given
- Employment: not given
- Sexual violence in adulthood: 52%

Abrahams 2010 (Continued)

- *Comorbid conditions*: not given
- *Baseline PTSD*: not given
- *Partnered*: not given
- *Approached*: 2011
- *Ineligible (N)*: 1701
- *Declined (N)*: 31
- *Other (N)*: 5
- *Randomised (N)*: 274
- *Completed post-treatment assessment (N)*: 253
- *Dropped out or removed prior to analysis (N)*: 21
- *Numbers analysed at final applicable time point (N)*: 253
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Inclusion criteria

- Female victims of rape
- For children younger than 16 years, the carer became the focus of the intervention, was shown the leaflet and was provided with the telephonic adherence support.

Exclusion criteria

- Rape victims who did not get PEP because they were HIV-positive or did not take an HIV test
- Those who were unable to give consent for the research for reasons of severe injury or severe mental distress (including severely distressed guardians)
- Those who were not contactable telephonically

Pretreatment: none reported

Interventions

Intervention characteristics

Other psychosocial interventions (telephonic psychosocial support)

- *Intensity of intervention (sessions)*: 12
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: telephone
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: yes, counselors had HIV and rape trauma counselling skills
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: unclear
- *Treatment fidelity (yes, no, unclear, with explanation)*: unclear; checklists were used during each call but no rating given to quality of fidelity to intervention and not used in analysis
- *Intervention aim and theoretical basis*: main purpose of the intervention was to test the hypothesis that the provision of telephonic psychosocial support to rape survivors and their families would lead to greater adherence to PEP for HIV over 28 d than would provision of a leaflet, adherence diary and standard post-rape care; not a particularly strong theoretical basis beyond encouraging adherence to ART
- *Duration of intervention*: not specified, although it was for the period of 28 d of taking PEP

Usual care

- *Intensity of intervention*: N/A
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: face-to-face
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate*: N/A
- *Research allegiance or conflict of interest*: N/A
- *Treatment fidelity*: N/A

Abrahams 2010 (Continued)

- *Intervention aim and theoretical basis:* a leaflet, adherence diary and standard post-rape care, which consisted of psychological 'containment', medical examination and collection of forensic evidence and HIV testing with precounselling and postcounselling

Outcomes

Depression (data requested)

- Outcome type: continuous outcome
- Scale used: CES-D
- Direction: lower is better
- Score range: 0 to 60
- Data value: endpoint

Treatment dropout (intervention only)

- Outcome type: dichotomous outcome

Identification

Sponsorship source: Irish Aid and South African Medical Research Council

Country: South Africa

Setting: sexual assault services

Authors name: Naeemah Abrahams

Institution: Gender & Health Research Unit, Medical Research Council, Cape Town

Email: nabraham@mrc.ac.za

Year: 2010

Notes

No baseline data available for outcome

Communicated with author(s) for purpose of review

Data included in meta-analysis

Acierno 2021
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: 30 October 2014 to 10 September 2019

Location of study: Southeastern USA

Randomisation method: eligible veterans were randomised by the project co-ordinator using REDCap 1:1 to PE using HBT or in-person PE, and REDCap generated assignments that were saved as they were made and reviewed by the study statistician; thereby, no modification or skipping of assignments was possible.

Ethics approvals: not given

Participants

Baseline characteristics

CBT (PE via HBT)

- *Participants:* 69

Acierno 2021 (Continued)

- *Gender*: 100% female participants
- *Age, M (SD)*: 41.55 years (12.10 years)
- *Ethnicity*: 30.43% white, 62.32% African American, 7.25% other
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 52.90 (12.91)
- *Partnered*: not given
- *Randomised (N)*: 69
- *Completed post-treatment assessment (N)*: 46
- *Dropped out or removed prior to analysis (N)*: 27
- *Numbers analysed at final applicable time point (N)*: 42
- *Number of sessions, M (SD)*: 6.80 (4.14)
- *Treatment completion*: 34 (49.27%)

CBT (PE via in-person)

- *Participants*: 67
- *Gender (% female, male, other)*: 100% female participants
- *Age in years (M, SD)*: 45.31 (10.63)
- *Ethnicity*: 28.36% white, 65.67% African American, 5.97% other
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 52.30 (12.42)
- *Partnered*: not given
- *Randomised (N)*: 67
- *Completed post-treatment assessment (N)*: 49
- *Dropped out or removed prior to analysis (N)*: 22
- *Numbers analysed at final applicable time point (N)*: 45
- *Number of sessions, M (SD)*: 6.28 (4.33)
- *Treatment completion*: 33 (49.25%)

Overall

- *Participants*: 136
- *Gender*: 100% female participants
- *Age, M (SD)*: 43.40 years (11.51 years)
- *Ethnicity*: 29.41% white, 63.97% African American, 6.62% other
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: 100%

Acierno 2021 (Continued)

- Comorbid conditions: not given
- Baseline PTSD, *M (SD)*: 52.60 (12.63)
- Partnered: not given
- Approached (*N*): 172
- Ineligible (*N*): 19
- Declined (*N*): 16
- Other (*N*): 1
- Randomised (*N*): 136
- Completed post-treatment assessment (*N*): 95
- Dropped out or removed prior to analysis (*N*): 49
- Numbers analysed at final applicable time point (*N*): 87
- Number of sessions, *M (SD)*: 6.54 (4.23)
- Treatment completion: 67 (49.26%)

Inclusion criteria

- An MST-related index event as identified on the Stressful Events for Veterans Questionnaire
- Met criteria for PTSD related to MST based on the Clinician-Administered PTSD Scale

Exclusion criteria

- Active psychosis or dementia at screening
- Current suicidal ideation with clear intent
- Current severe substance use disorder
- Concurrently enrolled in a clinical trial for PTSD or depression or if they had a household member in the study
- Further, medication stabilisation was ensured with a 4-week waiting period after recent medication change prior to enrolling in the study for more information about study design.

Pretreatment: those assigned to the in-person delivery condition were more likely to be Hispanic, but no other group differences were identified.

Interventions

Intervention characteristics

CBT (PE via HBT)

- *Planned number of intervention sessions*: 12 to 15
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: teleconference (video/audio)
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: unclear, no information given
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: no, team is committed to establishing if HBT delivery brings benefits and has used the technology in several other trials, but there is no clear evidence of a conflict of interest.
- *Treatment fidelity (yes, no, unclear, with explanation)*: no, information not given
- *Intervention aim and theoretical basis*: PE is a manualised treatment (Foa 2007) that includes the following components: 1) psychoeducation and treatment rationale (Sessions 1 and 2); 2) repeated in vivo exposure to traumatic stimuli (in vivo exercises are assigned as homework during Sessions 3 through 11); 3) repeated, prolonged, imaginal exposure to traumatic memories (imaginal exposure is implemented during Sessions 3 through 11, and participants listen to session audiotapes for homework between sessions), and 4) relapse prevention strategies and further treatment planning (Session 12).
- *Duration of intervention*: 12 weeks to 15 weeks

CBT (PE via in-person)

- *Planned number of intervention sessions*: 12 to 15

Acierno 2021 (Continued)

- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* unclear, no information given
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* unclear, no information given
- *Intervention aim and theoretical basis:* in the case of women with a history of MST, accessibility will be enhanced by removing a barrier to care associated with the treatment environment that can potentially elicit an anxiety and avoidance response in the target population. HBT care is delivered using via Movi/Jabber software packages installed on standard tablet devices or home computers with standard internet connections to teleconference (video and audio) in real time.
- *Duration of intervention:* 12 weeks to 15 weeks

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: PCL-5
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint

Depression

- Outcome type: continuous outcome
- Scale used: BDI-II
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint

Treatment dropout

- Outcome type: dichotomous outcome

Identification

Sponsorship source: Department of Defense (W81XWH-14-1-0264; PI: Acierno) and from the NIMH (T32 MH18869, PIs: Kilpatrick and Danielson)

Country: USA

Setting: VA Medical Centre; individuals from range of VA support services and affiliated community clinics screening positive for MST-related PTSD

Authors name: Ronald Acierno

Institution: McGovern Medical School, University of Texas

Email: ronald.acierno@uth.tmc.edu

Address: N/A

Year: unpublished

Notes

Unpublished data. This study is under review. This paper should not be used for any other purpose or shared with anyone else.

Data not included in meta-analysis

Communicated with the author(s) for purpose of review

Anderson 2010
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: not identified

Location of study: Midwestern USA

Randomisation method: not provided

Ethics approvals: not provided

Participants

Baseline characteristics

CBT (clinician-assisted emotional disclosure)

- *Participants (select at randomisation if available):* 15
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* not given
- *Education (% high school, college or apprentice, university or years of education):* 100% university
- *Employment:* not given
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 2.91 (0.80)
- *Partnered:* not given
- *Randomised (N):* 15
- *Completed post-treatment assessment (N):* 13
- *Dropped out or removed prior to analysis (N):* 2
- *Numbers analysed at final applicable time point (N):* 13
- *Number of sessions, M (SD):* 4 (0)
- *Treatment completion:* 13 (87%)

No-treatment control

- *Participants (select at randomisation if available):* 13
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* not given
- *Education (% high school, college or apprentice, university or years of education):* 100% university
- *Employment:* not given
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 2.88 (0.63)
- *Partnered:* not given
- *Randomised (N):* 13
- *Completed post-treatment assessment (N):* 13
- *Dropped out or removed prior to analysis (N):* 0

Anderson 2010 (Continued)

- Numbers analysed at final applicable time point (N): 13
- Number of sessions: N/A
- Treatment completion: N/A

Overall

- Participants (select at randomisation if available): 28
- Gender: 100% female participants
- Age, M (SD): 19.3 years (1.09 years)
- Ethnicity: 85.7% white
- Disability: not given
- Time since trauma: not given
- Income: not given
- Education (% high school, college or apprentice, university or years of education): 100% university
- Employment: not given
- Sexual violence in adulthood (%): 100%
- Comorbid conditions: not given
- Baseline PTSD: not given
- Partnered: not given
- Approached (N): 670
- Ineligible (N): 627
- Declined (N): 6
- Other (N): 9
- Randomised (N): 28
- Completed post-treatment assessment (N): 26
- Dropped out or removed prior to analysis (N): 2
- Numbers analysed at final applicable time point (N): 26
- Number of sessions: N/A
- Treatment completion: N/A

Inclusion criteria

- Experience of sexual assault that involved coerced or forced vaginal, oral or anal penetration
- Score of 59 or above on the Outcome Questionnaire-45

Exclusion criteria: none reported

Pretreatment: none reported

Interventions
Intervention characteristics

CBT (clinician-assisted emotional disclosure)

- Planned number of intervention sessions: 4
- Mode of delivery (face-to-face, online, video, telephone, blend, with explanation): face-to-face
- Format (group, individual, blend): individual
- Therapist qualifications and training appropriate (yes, no, unclear, with explanation): yes, presumably qualified therapists completed a 2-day workshop and had at least 1 supervised training case
- Research allegiance or conflict of interest (yes, no, unclear, with explanation): no
- Treatment fidelity (yes, no, unclear, with explanation): unclear, used a manualised and replicable protocol but no recording of sessions, for example
- Intervention aim and theoretical basis: an adaptation of emotion-focused therapy (Elliot 2004; Greenberg 1993) including 1) systematic evocative unfolding of emotional narratives and 2) emotional focusing, for experientially tracking emotions at a moment-to-moment level; 4 sessions over 10 d, ideally 4 consecutive days
- Duration of intervention: 2 weeks

Anderson 2010 (Continued)

No-treatment control

- *Planned number of intervention sessions:* N/A
- *Mode of delivery:* N/A
- *Format:* N/A
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* N/A
- *Duration of intervention:* N/A

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: IES-R Avoidance
- Direction: lower is better
- Score range: 0 to 4
- Data value: endpoint

PTSD

- Outcome type: continuous outcome
- Scale used: IES-R Intrusion
- Direction: lower is better
- Score range: 0 to 4
- Data value: endpoint

PTSD

- Outcome type: continuous outcome
- Scale used: IES-R Hyperarousal
- Direction: lower is better
- Score range: 0 to 4
- Data value: endpoint

Global mental health

- Outcome type: continuous outcome
- Scale used: Inventory of Interpersonal Problems
- Direction: lower is better
- Score range: 0 to 4
- Data value: endpoint

Identification

Sponsorship source: not given

Country: USA

Setting: university undergraduates

Authors name: Timothy Anderson

Institution: Ohio University

Email: andersot@ohio.edu

Year: 2010

Notes

Included in meta-analysis

Bass 2013
Study characteristics

Methods

Study design: cluster-randomised controlled trial

Study grouping: parallel group

Duration of study: December 2010 to January 2012

Ethics approvals: IRBs at the Johns Hopkins Bloomberg School of Public Health and Kinshasa School of Public Health approved the protocol

Location of study: 14 villages in South Kivu province and 2 villages on the border in North Kivu province, Democratic Republic of the Congo

Randomisation method: the 16 study villages, each with 1 psychosocial assistant, were grouped into blocks of 2 to 4 villages on the basis of proximity and shared language and were randomly assigned to provide CPT or individual support. After therapy training, 1 psychosocial assistant was excluded because training-based quizzes and skill observation raised competency concerns; therefore, the village in which the assistant worked was excluded. The trial included 15 study villages (7 that provided therapy and 8 that provided individual support).

Participants

Baseline characteristics

CPT (no trauma narrative)

- *Participants (at randomisation):* 7 villages, 157
- *Gender:* 100% female participants
- *Age, M (SD):* 36.9 years (13.4 years)
- *Ethnicity:* 100% Black
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* not given
- *Education, M (SD) years:* 1.8 (2.8)
- *Employment:* not given
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 1.9 (0.6)
- *Partnered:* 59%
- *Approached:* 222
- *Ineligible (N):* 32
- *Declined (N):* 0
- *Other (N):* 33
- *Randomised (N):* 157
- *Completed post-treatment assessment (N):* 114
- *Dropped out or removed prior to analysis (N):* 19
- *Numbers analysed at final applicable time point (N):* 138
- *Number of sessions, M (SD):* 8.5
- *Treatment completion:* 141 (90%)

Other psychosocial interventions (individual support)

- *Participants (at randomisation):* 8 villages, 248
- *Gender:* 100% female participants
- *Age, M (SD):* 33.8 years (12.4 years)
- *Ethnicity:* 100% Black

Bass 2013 (Continued)

- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education, M (SD) years*: 2.3 (3.1)
- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 2.2 (0.5)
- *Partnered*: 43%
- *Approached (N)*: 273
- *Ineligible (N)*: 25
- *Declined (N)*: 0
- *Other (N)*: 0
- *Randomised (N)*: 248
- *Completed post-treatment assessment (N)*: 156
- *Dropped out or removed prior to analysis (N)*: 73
- *Numbers analysed at final applicable time point (N)*: 175
- *Number of sessions*: not given
- *Treatment completion*: 182 (73%)

Overall

- *Participants (at randomisation)*: 15 villages, 405
- *Gender*: 100% female participants
- *Age*: not given
- *Ethnicity*: 100% Black
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: not given
- *Baseline PTSD*: not given
- *Partnered*: not given
- *Approached (N)*: 495
- *Ineligible (N)*: 57
- *Declined (N)*: 0
- *Other (N)*: 33
- *Randomised (N)*: 405
- *Completed post-treatment assessment (N)*: 270
- *Dropped out or removed prior to analysis (N)*: 92
- *Numbers analysed at final applicable time point (N)*: 313

Inclusion criteria

Clusters

- 14 villages in South Kivu province and 2 villages on the border in North Kivu province were selected from among 23 villages served by 3 Congolese nongovernmental organisations. Selection was based on accessibility, security and the availability of psychosocial assistants.

Individuals

- Women who had experienced or witnessed sexual violence

Bass 2013 (Continued)

- A total symptom score of at least 55 (i.e. an average score of 1 for each of 55 symptoms, comprising the Hopkins Symptom Checklist, the PTSD Checklist items and additional locally relevant symptoms)
- A functional-impairment score of at least 10 (i.e. dysfunction on at least half the activities)

Exclusion criteria: suicidality that was judged by clinical staff to require immediate treatment

Pretreatment: women in the comparison group were younger, less likely to be married, lived with fewer people, and had higher levels of distress and stigma than the intervention group.

Interventions

Intervention characteristics

CPT (no trauma narrative)

- *Planned number of intervention sessions:* 12 (23 h)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* group
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, all psychosocial assistants had 1 year to 9 years of experience providing case management and individual SC to survivors of sexual violence and at least 4 years of post-primary school education. All underwent a 5-day to 6-day training session conducted by the IRC in case management and specific topics, including counselling, family mediation, stress management, clinical care of survivors and prevention of HIV infection and other sexually transmitted infections. Psychosocial assistants who provided therapy underwent 2 weeks of in-person training with trainers based in the USA (fourth and fifth authors), with the use of a manual that was adapted and translated locally. Ongoing supervision was provided through a multitiered supervision system. Congolese psychosocial supervisors who were employees of the IRC provided direct supervision to psychosocial assistants through weekly telephone or in-person meetings; a bilingual clinical social worker trained in the USA provided in-country supervision and communicated with the US trainers through weekly calls for supervision and quality assurance.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, fidelity to the therapy protocol was assessed with the use of checklists of key treatment elements and global ratings of treatment knowledge and skills, as observed by supervisors during group sessions.
- *Intervention aim and theoretical basis:* CPT is a protocol-based therapy for treating depression, anxiety, and PTSD in sexual violence survivors. The group format was chosen to reach large numbers of women. They used the cognitive-only model (i.e. without a trauma narrative) because its efficacy is similar to that of the full version of the therapy, while providing greater ease of administration in groups and greater retention by participants. One individual session (1 h) was held, followed by 11 group sessions (2 h).
- *Duration of intervention:* 17 weeks

Other psychosocial interventions (individual support)

- *Planned number of intervention sessions:* as desired
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* as previous
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, monthly visits by IRC supervisors and reviews of interim monitoring forms
- *Intervention aim and theoretical basis:* psychosocial assistants invited women to receive individual support services as desired, including psychosocial support and economic, medical and legal referrals. Psychosocial assistants were available throughout the treatment period for women who sought their services.
- *Duration of intervention:* 17 weeks

Outcomes

PTSD

Bass 2013 (Continued)

- Outcome type: continuous outcome
- Scale used: PCL-C
- Direction: lower is better
- Score range: 17 to 85
- Data value: endpoint, 6 months

PTSD

- Outcome type: dichotomous outcome
- Scale used: PCL-C
- Direction: lower is better
- Score range: 17 to 85
- Data value: endpoint, 6 months

Global mental health

- Outcome type: continuous outcome
- Scale used: Hopkins Symptom Checklist
- Direction: lower is better
- Score range: 1 to 4
- Data value: endpoint, 6 months

Global mental health

- Outcome type: dichotomous outcome
- Scale used: Hopkins Symptom Checklist
- Direction: lower is better
- Score range: 1 to 4
- Data value: endpoint, 6 months

Treatment dropout

- Outcome type: dichotomous outcome

Stigma

- Outcome type: continuous outcome
- Scale used: Perceived and Internalised Stigma
- Direction: lower is better
- Score range: 1 to 4
- Data value: endpoint, 6 months

Identification

Sponsorship source: funded by the US Agency for International Development Victims of Torture Fund and the World Bank

Country: Democratic Republic of the Congo

Setting: community

Authors name: Judith K Bass

Institution: Johns Hopkins Bloomberg School of Public Health

Email: jkbass@jhsph.edu

Year: 2013

Notes

The CPT had no trauma component.

Note there is a correction paper as well as the original.

Bass 2013 (Continued)

Data also taken from [Murray 2018](#)

Not included in meta-analysis

Bass 2016
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: October 2010 to August 2012 (intervention ran from April 2011 to April 2012)

Location of study: 9 communities in South Kivu, Democratic Republic of the Congo

Randomisation method: 66 VSLA groups with 301 study women were available for randomisation in March 2011. The 66 groups were randomised into immediate start (intervention; 33 groups) and delayed start (control; 33 groups). The control groups did not receive VSLA training until year 2, when follow-up data collection was completed.

Ethics approvals: study protocols were reviewed and approved by IRBs at the Johns Hopkins School of Public Health and Kinshasa School of Public Health.

Participants

Baseline characteristics

Other psychosocial interventions (VSLAs)

- *Participants (select at randomisation if available):* 159
- *Gender:* 100% female participants
- *Age, M (SD):* 40.1 years (11.7 years)
- *Ethnicity:* 100% Black
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* not given
- *Education, M (SD) years:* 2 (3.1)
- *Employment:* 18.9 h (16.5 h) of paid work in past 7 d
- *Sexual violence in adulthood:* 54.7% personally experienced sexual violence; 81.1% personally witnessed sexual violence
- *Comorbid conditions:* not given
- *Baseline PTSD:* not given
- *Partnered:* 54.1%
- *Randomised (N):* 159
- *Completed post-treatment assessment (N):* 135
- *Dropped out or removed prior to analysis (N):* 0
- *Numbers analysed at final applicable time point (N):* 159
- *Number of sessions:* not given
- *Treatment completion:* not given

Wait-list

- *Participants (select at randomisation if available):* 142
- *Gender:* 100% female participants
- *Age, M (SD):* 41.5 years (12.8 years)
- *Ethnicity:* 100% Black
- *Disability:* not given

Bass 2016 (Continued)

- *Time since trauma*: not given
- *Income*: not given
- *Education, M (SD) years*: 1.9 (3.0)
- *Employment*: 22.5 h (19.9 h) paid work in past 7 d
- *Sexual violence in adulthood*: 68.3% personally experienced sexual violence; 85.9% personally witnessed sexual violence
- *Comorbid conditions*: not given
- *Baseline PTSD*: not given
- *Partnered*: 53.5%
- *Randomised (N)*: 142
- *Completed post-treatment assessment (N)*: 115
- *Dropped out or removed prior to analysis (N)*: 0
- *Numbers analysed at final applicable time point (N)*: 142
- *Number of sessions*: not given
- *Treatment completion*: not given

Overall

- *Participants (select at randomisation if available)*: 301
- *Gender*: 100% female participants
- *Age*: not given
- *Ethnicity*: 100% Black
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: 61%
- *Comorbid conditions*: not given
- *Baseline PTSD*: not given
- *Partnered*: 54%
- *Approached (N)*: 695
- *Ineligible (N)*: 236
- *Declined (N)*: 2
- *Other (N)*: 156
- *Randomised (N)*: 301
- *Completed post-treatment assessment (N)*: 250
- *Dropped out or removed prior to analysis (N)*: 0
- *Numbers analysed at final applicable time point (N)*: 301
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Inclusion criteria

- Women aged 18 years of age or older
- Living in 1 of the 9 study sites
- Personally experienced or witnessed sexual violence (defined as rape locally)
- A score of at least 10 on the function assessment (i.e. some dysfunction on at least half of the tasks questions)
- A score of at least 55 on the mental health assessment (i.e. an average score of 1 for each symptom)

Exclusion criteria: severe suicidality

Bass 2016 (Continued)

Pretreatment: women in the control group reported more types of traumatic events, were more ethnically diverse, worked more hours, had more people they could rely on, expressed greater group membership and spent more money on food for the household.

Interventions

Intervention characteristics

Other psychosocial interventions (VSLAs)

- *Intensity of intervention:* 10 months
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* group
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, the IRC is experienced at delivering the intervention.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no, none declared
- *Treatment fidelity (yes, no, unclear, with explanation):* no, although the programme is described in detail in supplementary materials, there is no information on fidelity to the protocol.
- *Intervention aim and theoretical basis:* VSLA model was developed by CARE International, based on indigenous savings and loans groups in Africa. VSLAs provide a community-managed mechanism for savings, loans and insurance for people who cannot access banks or microfinance institutions. It was hypothesised that participation in VSLAs would provide women who lacked access to financial services access to savings and loans in the safety of a trusted group. It was also hypothesised that for women who had experienced sexual violence, participation in the group-based economic programme would improve their ability to care for themselves and contribute to their family's well-being, resulting in improved self-efficacy and a reduction in mental health symptoms; it was hypothesised that women who had experienced sexual violence would improve their social connectedness through being part of the economic group and that this, together with increased economic benefits, would reduce their experience of stigma.

Wait-list

- *Intensity of intervention:* N/A
- *Mode of delivery:* N/A
- *Format:* N/A
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* N/A

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: Harvard Trauma Questionnaire
- Direction: lower is better
- Score range: 1 to 4
- Data value: endpoint

Depression

- Outcome type: continuous outcome
- Scale used: Hopkins Symptom Checklist
- Direction: lower is better
- Score range: 1 to 4
- Data value: endpoint

Anxiety

- Outcome type: continuous outcome
- Scale used: Hopkins Symptom Checklist

Bass 2016 (Continued)

- Direction: lower is better
- Score range: 1 to 4
- Data value: endpoint

Stigma

- Outcome type: continuous outcome
- Scale used: Perceived and Internalised Stigma
- Direction: lower is better
- Score range: 1 to 4
- Data value: endpoint

Global mental health

- Outcome type: continuous outcome
- Scale used: Hopkins Symptom Checklist-adapted
- Direction: lower is better
- Score range: 1 to 4
- Data value: endpoint

Identification

Sponsorship source: United States Agency for International Development Victims of Torture Fund and the World Bank. Part of the analysis was supported by UK Aid from the UK Department for International Development for the benefit of developing countries.

Country: Democratic Republic of the Congo

Setting: women in the community who had sought support or disclosed to community-based organisations about mental health problems due to potential trauma

Authors name: Judith K Bass

Institution: Johns Hopkins School of Public Health

Email: jrbass@jhu.edu

Year: 2016

Ethics Approvals: study protocols were reviewed and approved by IRBs at the Johns Hopkins School of Public Health and Kinshasa School of Public Health.

Notes

This study was included in meta-analysis

Review team selected imputed data, but numbers per group included in analysis were not entirely clear.

Bell 2019

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: not given

Ethics approvals: Saybrook IRB approved the study

Location of study: greater Denver-Boulder, Colorado, USA, area

Bell 2019 (Continued)

Randomisation method: 24 eligible adults were enrolled on a first-come, first-served basis and alternately assigned between the LZNF group and HRVB group according to the order in which they returned their prescreening materials.

Participants

Baseline characteristics

Behavioural (LZNF)

- *Participants (select at randomisation if available):* 12
- *Gender:* not given
- *Age, M (SD):* 43.73 years (8.79 years)
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 46.17 (14.23)
- *Partnered:* not given
- *Randomised (N):* 12
- *Completed post-treatment assessment (N):* 12
- *Dropped out or removed prior to analysis (N):* 0
- *Numbers analysed at final applicable time point (N):* 12
- *Number of sessions:* not given
- *Treatment completion:* 12 (100%)

Minimal intervention (HRVB)

- *Participants (select at randomisation if available):* 11
- *Gender:* not given
- *Age, M (SD):* 44.58 years (13.06 years)
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 49.82 (10.16)
- *Partnered:* not given
- *Randomised (N):* 12
- *Completed post-treatment assessment (N):* 11
- *Dropped out or removed prior to analysis (N):* 1
- *Numbers analysed at final applicable time point (N):* 11
- *Number of sessions:* not given
- *Treatment completion:* 11 (92%)

Overall

- *Participants (at randomisation):* 23
- *Gender:* not given
- *Age in years, M (SD):* 44

Bell 2019 (Continued)

- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: 65%
- *Comorbid conditions*: 91% reported at least 1 comorbid psychiatric disorder; physical assault (61%), childhood abuse or neglect (52%), life-threatening illness or injury (48%), natural disaster (35%), work-related trauma (e.g. first responders; 26%) and military combat (13%)
- *Baseline PTSD*: not given
- *Partnered*: not given
- *Approached*: not given
- *Ineligible*: not given
- *Declined*: not given
- *Other*: not given
- *Randomised (N)*: 24
- *Completed post-treatment assessment (N)*: 23
- *Dropped out or removed prior to analysis (N)*: 1
- *Numbers analysed at final applicable time point (N)*: 23

Inclusion criteria

- Self-reported having experienced a traumatic event
- 6 months or more had passed since the traumatic event
- Total score on the PCL-5 was > 20
- Proficient in English
- Between the ages of 18 years and 80 years

Exclusion criteria

- Moderate to severe brain injury
- Current diagnosis of a seizure disorder
- Current diagnosis of a personality disorder
- Active psychosis
- Active suicidal ideation
- Pregnancy

Pretreatment: the largest baseline differences were in the HRV measures, for which the LZNF group had higher initial levels. The LZNF group reported a larger number of comorbid diagnoses at baseline (LZNF = 21, HRVB = 15).

Interventions
Intervention characteristics

Behavioural (LZNF)

- *Planned number of intervention sessions*: 15 (20 min of direct training, divided into 4 rounds of 5 min)
- *Made of delivery (face-to-face, online, video, telephone, blend, with explanation)*: brain-computer interface
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate*: N/A
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: no
- *Treatment fidelity (yes, no, unclear, with explanation)*: yes, as a way of standardising an individualised training modality, NeuroGuide's Symptom Checklist-Neural Network Match method was utilised to generate each participant's training protocol ([Thatcher 2013](#)).

Bell 2019 (Continued)

- *Intervention aim and theoretical basis:* the purpose of this study was to assess the effectiveness and specificity of LZNF training, as compared to HRVB training, for reducing mental health symptoms, improving autonomic regulation, and regulating abnormal brainwave activity in adults with chronic PTSD (i.e. symptoms for a minimum of 6 months following a traumatic event).
- *Duration of intervention:* 8 weeks

Minimal intervention (HRVB)

- *Planned number of intervention sessions:* 15 (20 min of direct training, divided into 4 rounds of 5 min)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* brain-computer interface
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, the HRVB protocol for this study was largely based on the resonant frequency training protocol outlined by [Lehrer 2000](#). This is one of the most common protocols in HRVB training and has previously demonstrated effectiveness for reducing PTSD symptoms ([Tan 2011](#)).
- *Intervention aim and theoretical basis:* HRVB training utilises electrocardiography and a respiratory belt, paired with a breath pacer and audiovisual feedback, to train the heart towards healthier levels of HRV. This modality of biofeedback has previously demonstrated effectiveness for reducing PTSD symptoms, even when compared to various control conditions. Here, it was viewed as a more ethical option than sham neurofeedback for this sensitive population.
- *Duration of intervention:* 8 weeks

Outcomes

PTSD (PCL-5)

- Outcome type: continuous outcome
- Scale used: PCL-5
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint

Anxiety

- Outcome type: continuous outcome
- Scale used: BAI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint

Treatment dropout

- Outcome type: dichotomous outcome

Identification

Sponsorship source: not reported

Country: USA

Setting: academic/experimental; individuals with chronic PTSD recruited through advertisements on social media, in health and mental health centres, and in various community locations

Authors name: Ashlie Bell

Institution: Saybrook University, Oakland, California

Email: abell@saybrook.edu

Year: 2019

Bell 2019 (Continued)

Notes	No indication of gender breakdown
	Included in meta-analysis
	Communicated with author for purpose of the review

Belleville 2018

Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Duration of study: 2 years and 3 months; recruitment from March 2013 to January 2015; assessments conducted March to June 2015</p> <p>Location of study: city of Quebec, Canada</p> <p>Randomisation method: an independent evaluator who was not involved with assessment or treatment completed randomisation using a random number generator.</p>
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Participants	<p>Baseline characteristics</p> <p>CBT (IRT + PE)</p> <ul style="list-style-type: none"> • <i>Participants:</i> 7 • <i>Gender:</i> 100% female participants • <i>Age:</i> not given • <i>Ethnicity:</i> not given • <i>Disability:</i> not given • <i>Time since trauma:</i> not given • <i>Income:</i> not given • <i>Education:</i> not given • <i>Employment:</i> not given • <i>Sexual violence in adulthood:</i> 100% • <i>Comorbid conditions:</i> not given • <i>Baseline PTSD, M (SD):</i> 65.57 (12.54) • <i>Partnered:</i> not given • <i>Randomised (N):</i> 7 • <i>Completed post-treatment assessment (N):</i> 4 • <i>Dropped out or removed prior to analysis (N):</i> 3 • <i>Numbers analysed at final applicable time point (N):</i> 4 • <i>Number of sessions:</i> not given • <i>Treatment completion:</i> 57% <p>CBT (PE only)</p> <ul style="list-style-type: none"> • <i>Participants:</i> 9 • <i>Gender:</i> 100% female participants • <i>Age:</i> not given • <i>Ethnicity:</i> not given • <i>Disability:</i> not given • <i>Time since trauma:</i> not given • <i>Income:</i> not given
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Belleville 2018 (Continued)

- *Education*: not available
- *Employment*: not available
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 69.17 (22.14)
- *Partnered*: not given
- *Randomised (N)*: 9
- *Completed post-treatment assessment (N)*: 8
- *Dropped out or removed prior to analysis (N)*: 1
- *Numbers analysed at final applicable time point (N)*: 8
- *Number of sessions*: not given
- *Treatment completion*: 89%

Overall

- *Participants*: 16
- *Gender*: 100% female participants
- *Age*: not given
- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not available
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 67.59 (18.10)
- *Partnered*: not given
- *Approached*: not given
- *Ineligible*: not given
- *Declined*: not given
- *Other*: not given
- *Randomised (N)*: 16
- *Completed post-treatment assessment (N)*: 12
- *Dropped out or removed prior to analysis (N)*: 4
- *Numbers analysed at final applicable time point (N)*: 12

Inclusion criteria

- 18 years and older
- Able to understand and speak French
- History of unwanted sexual experience
- PTSD diagnosis
- Sleep complaints (score of ≥ 5 and mean of ≥ 1 nightmare per week for at least 1 month on Pittsburgh Sleep Quality Index)
- Psychotropic medication dosage unchanged for 3 months
- Available for in-person assessments and therapy sessions

Exclusion criteria

- Past or present psychotic episode, bipolar disorder or organic mental disorder
- Current substance use disorder
- Sleep apnoea diagnosis
- Use of prazosin to treat nightmares

Belleville 2018 (Continued)

- Currently in treatment for psychological difficulties
- Suicidal thoughts requiring immediate intervention
- Participants had to agree to keep their medication unchanged and not receive any other interventions.

Pretreatment: none reported

Interventions
Intervention characteristics
CBT (IRT + PE)

- *Planned number of intervention sessions:* 20 (5 sessions of IRT followed immediately by 15 sessions of CBT)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* no (supervised graduate psychology students following manual)
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, all therapy sessions were filmed, and independent judges reviewed a randomly selected 25% of the videos of completed treatments to evaluate treatment integrity. The evaluation revealed that no elements of IRT were presented in the control condition and that all of the appropriate strategies were presented in each condition.
- *Intervention aim and theoretical basis:* IRT (designed to alter the conditioned association between nightmares and sleep via rehearsal of a modified dream script during daytime); used French-language translation of IRT protocol by [Nappi 2010](#); PE protocol ([Germain 2009](#), adapted from [Foa 2007](#))
- *Duration of intervention:* 20 weeks (5 × 60 min + 15 × 60 min to 90 min)

CBT (PE only)

- *Planned number of intervention sessions:* 15 (15 sessions CBT, which followed 5-week 'waiting period' that included short (5-minute) weekly telephone calls to provide support and monitor suicidal thoughts)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* no (supervised graduate psychology students following manual)
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* as previous
- *Intervention aim and theoretical basis:* PE protocol ([Germain 2009](#), adapted from [Foa 2007](#)) including psychoeducation, breathing techniques, exposure to traumatic memories, feared objects, activities and situations
- *Duration of intervention:* 15 weeks (× 60 min to 90 min)

Outcomes
PTSD

- Outcome type: continuous outcome
- Scale used: MPSS-SR
- Direction: lower is better
- Score range: 0 to 119
- Data value: endpoint

Global mental health

- Outcome type: continuous outcome
- Scale used: SF-36 Mental
- Direction: higher is better
- Score range: 0 to 100

Belleville 2018 (Continued)

- Data value: endpoint

Identification

Sponsorship source: none

Country: Canada

Setting: sexual assault victims seeking treatment, recruited from university, community, rape crisis and mental health organisations, intervention delivered in academic setting

Authors name: Geneviève Belleville

Institution: Laval University, Quebec

Email: genevieve.belleville@psy.ulaval.ca

Year: 2018

Notes

Review team have reported on the 16 participants who experienced sexual assault at 18+ years supplied by the authors. Data on population characteristics for this subsample were not available to the Review.

Communicated with the author(s) for purpose of review

This study has not been included in meta-analysis.

Bomyea 2015

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: not given

Ethics approvals: approved by the IRBs at the University of California, San Diego and San Diego State University

Location of study: California, USA

Randomisation method: individuals who completed all baseline assessments were randomly assigned to the high-interference control condition or the low-interference control condition based on a computer-generated random number system prior to attending the first training session. Conditions were assigned by an independent third party using computer software so that participants and research personnel remained blind to participants' conditions.

Participants

Baseline characteristics

Behavioural (high-interference control)

- *Participants (select at randomisation if available):* 22
- *Gender:* 100% female participants
- *Age, M (SD):* 29.82 years (1.71 years)
- *Ethnicity:* 73% white, 9% Black, 18% other
- *Disability:* not given
- *Time since trauma, M (SD):* 146.91-month (159.33-month) duration of PTSD
- *Income:* 36% < USD 15,000, 36% USD 20,000 to USD 50,000, 23% > USD 50,000
- *Education (% high school, college or apprentice, university or years of education):* 14% 12 years; 50% 13 years to 15 years; 27% 16 years; 9% > 16 years

Bomyea 2015 (Continued)

- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 61.41 (12.54)
- *Partnered*: 19%
- *Randomised (N)*: 22
- *Completed post-treatment assessment (N)*: 13
- *Dropped out or removed prior to analysis (N)*: 0
- *Numbers analysed at final applicable time point (N)*: 22
- *Number of sessions*: not given
- *Treatment completion*: 15 (68%)

Minimal intervention (low-interference control)

- *Participants (select at randomisation if available)*: 20
- *Gender*: 100% female participants
- *Age, M (SD)*: 26.00 years (10.6 years)
- *Ethnicity*: 65% white, 5% Black, 30% other
- *Disability*: not given
- *Time since trauma, M (SD)*: 97.25-month (113.46-month) duration of PTSD
- *Income*: 60% < USD 15,000, 30% USD 20,000 to USD 50,000, 10% > USD 50,000
- *Education (% high school, college or apprentice, university or years of education)*: 5% < 12 years, 20% 12 years; 40% 13 years to 15 years; 25% 16 years, 10% > 16 years
- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 67.35 (15.0)
- *Partnered*: 47%
- *Randomised (N)*: 20
- *Completed post-treatment assessment (N)*: 8
- *Dropped out or removed prior to analysis (N)*: 0
- *Numbers analysed at final applicable time point (N)*: 20
- *Number of sessions*: not given
- *Treatment completion*: 10 (50%)

Overall

- *Participants (select at randomisation if available)*: 42
- *Gender*: 100% female participants
- *Age*: not given
- *Ethnicity*: 69% white, 7% Black, 24% other
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: 48% < USD 15,000, 33% USD 20,000 to USD 50,000, 17% > USD 50,000
- *Education (% high school, college or apprentice, university or years of education)*: 2% < 12 years, 17% 12 years, 45% 13 years to 15 years, 26% 16 years; 10% > 16 years
- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: 52.4% major depressive disorder or other mood disorders, 47.6% anxiety disorders, 9.5% substance abuse, 4.8% eating disorders
- *Baseline PTSD*: not given
- *Partnered*: 32%
- *Approached (N)*: 139
- *Ineligible (N)*: 15

Bomyea 2015 (Continued)

- Declined (N): 2
- Other (N): 80
- Randomised (N): 42
- Completed post-treatment assessment (N): 21
- Dropped out or removed prior to analysis (N): 0
- Numbers analysed at final applicable time point (N): 42
- Number of sessions: not given
- Treatment completion: 25 (60%)

Inclusion criteria

- Women between the ages of 18 years and 65 years diagnosed with PTSD secondary to sexual trauma
- In the case where a participant had experienced multiple traumatic events, she was considered eligible for the study if sexual assault was subjectively considered the most distressing event.
- Participants taking medications (N = 6) were required to meet a 6-week stability criterion.
- English-language proficiency

Exclusion criteria

- Current trauma- or PTSD-focused psychosocial treatment
- Recent change in non-trauma-focused psychosocial treatment
- Active suicidality (i.e. expression of intent or plan to commit suicidal gestures, or suicide attempt within the past 6 months)
- Evidence of substance dependence in the past 6 months
- Evidence of current or past schizophrenia, bipolar disorder or organic mental disorder (individuals with additional diagnoses were not excluded as long as PTSD was the primary diagnosis)

Pretreatment: participants in the 2 groups did not differ in age or measures of clinical features, including CAPS total severity, duration of PTSD symptoms, number of trauma types experienced, STAI-Trait, BDI-II, Self-Directed Search Questionnaire, or OSpan performance. No differences were identified in participant ethnic background, education, income or marital status.

Interventions

Intervention characteristics

Behavioural (high-interference control)

- Planned number of intervention sessions: 8
- Mode of delivery (face-to-face, online, video, telephone, blend, with explanation): computer trial
- Format (group, individual, blend): individual
- Therapist qualifications and training appropriate: N/A
- Research allegiance or conflict of interest (yes, no, unclear, with explanation): yes
- Treatment fidelity: N/A
- Intervention aim and theoretical basis: ability to regulate cognitions is related to PTSD and linked to persistence of distressing and intrusive thoughts. Interference control is a key regulatory process in modulating intrusive cognitions. Performance during working memory capacity tasks is associated with intrusive thoughts during deliberate thought suppression attempts. Interference control training aims to alter the functioning of basic cognitive systems hypothesised to regulate re-experiencing symptoms.
- Duration of intervention: 4 weeks

Minimal intervention (low-interference control)

- Planned number of intervention sessions: 8
- Mode of delivery (face-to-face, online, video, telephone, blend, with explanation): computer trial
- Format (group, individual, blend): individual
- Therapist qualifications and training appropriate: N/A
- Research allegiance or conflict of interest (yes, no, unclear, with explanation): yes

Bomyea 2015 (Continued)

- *Treatment fidelity*: N/A
- *Intervention aim and theoretical basis*: control programme
- *Duration of intervention*: 4 weeks

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: CAPS
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint

Depression

- Outcome type: continuous outcome
- Scale used: BDI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint

Anxiety

- Outcome type: continuous outcome
- Scale used: STAI-Trait
- Direction: lower is better
- Score range: 20 to 80
- Data value: endpoint

PTSD

- Outcome type: continuous outcome
- Scale used: CAPS-Avoidance
- Direction: lower is better
- Score range: 0 to 28
- Data value: endpoint

PTSD

- Outcome type: continuous outcome
- Scale used: CAPS-Arousal
- Direction: lower is better
- Score range: 0 to 28
- Data value: endpoint

Treatment dropout

- Outcome type: dichotomous outcome

Identification

Sponsorship source: NIMH F31 MH0881704

Country: USA

Setting: intervention delivered in academic setting; women diagnosed with PTSD secondary to sexual trauma recruited through university participant pool and community mental health providers

Authors name: Jessica A Bomyea

Institution: University of California

Bomyea 2015 *(Continued)*
Email: jbomyea@ucsd.edu

Year: 2015

Notes

Uses imputed data in ITT analyses

Communicated with the author(s) for purpose of review

Included in meta-analysis

Bowland 2012
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: 2 years: recruitment February 2006 to July 2007; intervention July 2006 to January 2008

Ethics approvals: Human Research Protection Office, Washington University in St. Louis, Missouri

Location of study: St. Louis, Missouri, USA

Randomisation method: women were paired on scores from a spiritual distress scale and then randomised into treatment or control groups using a random number table.

Participants

Baseline characteristics

Other psychologically oriented interventions (spiritually focused group therapy)

- *Participants (completers):* 21
- *Gender:* 100% female participants
- *Age, M (SD):* 60.33 years (4.6 years)
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* 44% < USD 50,000
- *Education (% high school, college or apprentice, university or years of education):* 48% college
- *Employment:* not given
- *Sexual violence in adulthood:* 48%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 19.43 (9.65)
- *Partnered:* 50%
- *Randomised (N):* 22
- *Completed post-treatment assessment (N):* 21
- *Dropped out or removed prior to analysis (N):* 1
- *Numbers analysed at final applicable time point (N):* 21
- *Number of sessions:* not given
- *Treatment completion:* not given

No-treatment control

- *Participants (completers):* 22
- *Gender:* 100% female participants
- *Age, M (SD):* 62.32 years (7.7 years)

Bowland 2012 (Continued)

- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: 56% < USD 50,000
- *Education (% high school, college or apprentice, university or years of education)*: 52% college
- *Employment*: not given
- *Sexual violence in adulthood*: 50%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 16.10 (9.32)
- *Partnered*: 50%
- *Randomised (N)*: 22
- *Completed post-treatment assessment (N)*: 22
- *Dropped out or removed prior to analysis (N)*: 0
- *Numbers analysed at final applicable time point (N)*: 22
- *Number of sessions*: not given
- *Treatment completion*: not given

Overall

- *Participants (completers)*: 43
- *Gender*: 100% female participants
- *Age, M (range)*: 61.3 years (55 years to 83 years)
- *Ethnicity*: 84% white, 14% Black, 2% other
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: 65% < USD 50,000
- *Education (% high school, college or apprentice, university or years of education)*: 61% associate or bachelor degree
- *Employment*: not given
- *Sexual violence in adulthood*: 49% sexual violence in adulthood; all participants reported > 1 traumatic event (child sexual or physical abuse or both, domestic violence, sexual assault)
- *Comorbid conditions*: not given
- *Baseline PTSD*: not given
- *Partnered*: 52%
- *Approached (N)*: 129
- *Ineligible (N)*: 60
- *Declined (N)*: 0
- *Other (N)*: 25
- *Randomised (N)*: 44
- *Completed post-treatment assessment (N)*: 43
- *Dropped out or removed prior to analysis (N)*: 1
- *Numbers analysed at final applicable time point (N)*: 43
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Inclusion criteria

- Current trauma-related distress
- History in the Christian tradition

Exclusion criteria

- In current psychotherapy
- Significant cognitive impairments
- Actively suicidal or psychotic

Bowland 2012 (Continued)

Pretreatment: none reported

Interventions

Intervention characteristics

Other psychologically oriented interventions (spiritually focused group therapy)

- *Planned number of intervention sessions:* 11
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* group
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* unclear, as Fallot designed intervention as an offshoot of the Trauma Recovery and Empowerment Model
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, mean adherence score for 18 sessions was 83.3% (SD = 19.40%; range 40% to 100%)
- *Intervention aim and theoretical basis:* manualised psychoeducational, CR and skill-building approach to addressing spiritual struggles in recovery (Fallot and The Spirituality Workgroup 2001-2004). Offshoot of the Trauma Recovery and Empowerment Model (Harris 1998). Feminist perspective used to raise questions, for instance, about endurance and sacrifice of self for others, based on a critique of patriarchal Christianity and potentially harmful interpretations and practices (see Brock 2001; Jonker 1992)
- *Duration of intervention:* 11 weeks

No-treatment control

- *Planned number of intervention sessions:* N/A
- *Mode of delivery:* N/A
- *Format:* N/A
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* N/A
- *Duration of intervention:* N/A

Outcomes

Treatment dropout (intervention group only)

- Outcome type: dichotomous outcome

Depression

- Outcome type: continuous outcome
- Scale used: Geriatric Depression Scale
- Direction: lower is better
- Score range: 0 to 30
- Data value: endpoint

Anxiety

- Outcome type: continuous outcome
- Scale used: BAI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint

Identification

Sponsorship source: not given

Country: USA

Setting: older survivors recruited through community and university hospital; academic setting for delivery

Bowland 2012 (Continued)

Authors name: Sharon Bowland

Institution: Washington University in St. Louis

Email: sbowland@utk.edu

Year: 2012

Notes	<p>Population characteristics are reported for intervention completers. The Posttraumatic Diagnostic Scale data were not given for the control group.</p> <p>Communicated with the author(s) for purpose of review</p> <p>Included in meta-analysis</p>
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Brady 2021
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Duration of study: recruitment May 2017 and September 2018</p> <p>Location of study: UK</p> <p>Randomisation method: after diagnostic assessment and completion of baseline outcome measures, a research assistant randomised participants to either trial condition using a virtual coin toss programme.</p> <p>Ethics approvals: the study was approved by the ethics committee of University College London (813/002).</p>
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Participants	<p>Baseline characteristics</p> <p>Behavioural (NET)</p> <ul style="list-style-type: none"> • <i>Participants:</i> 15 • <i>Gender:</i> 73% female participants, 4 male participants • <i>Age, M (SD):</i> 26.73 years (9.35 years) • <i>Ethnicity:</i> 47% African, 53% other • <i>Disability:</i> not given • <i>Time since trauma:</i> not given • <i>Income:</i> not given • <i>Education:</i> not given • <i>Employment:</i> not given • <i>Sexual violence in adulthood:</i> 53% • <i>Comorbid conditions:</i> not given • <i>Baseline PTSD, M (SD):</i> 43 (34) • <i>Partnered:</i> not given • <i>Randomised (N):</i> 15 • <i>Completed post-treatment assessment (N):</i> 13 • <i>Dropped out or removed prior to analysis (N):</i> 2 • <i>Numbers analysed at final applicable time point (N):</i> 13 • <i>Number of sessions, M (SD):</i> 17 (4.07) • <i>Treatment completion:</i> 13 (87%)
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Brady 2021 (Continued)

Minimal intervention (psychoeducation + wait-list)

- *Participants*: 10
- *Gender*: 80% female participants, 2 male participants
- *Age, M (SD)*: 32.8 years (10.96 years)
- *Ethnicity*: 20% African, 80% other
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: 70%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 46 (25)
- *Partnered*: not given
- *Randomised (N)*: 10
- *Completed post-treatment assessment (N)*: 7
- *Dropped out or removed prior to analysis (N)*: 3
- *Numbers analysed at final applicable time point (N)*: 7
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Overall

- *Participants*: 25
- *Gender*: 76% female participants, 24% male participants
- *Age*: not given
- *Ethnicity*: 36% African, 66% other
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: 60%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 43 (17)
- *Partnered*: 45.1%
- *Approached (N)*: 55
- *Ineligible (N)*: 20
- *Declined (N)*: 9
- *Other (N)*: 1
- *Randomised (N)*: 25
- *Completed post-treatment assessment (N)*: 20
- *Dropped out or removed prior to analysis (N)*: 5
- *Numbers analysed at final applicable time point (N)*: 20
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Inclusion criteria

- Adult survivors of trafficking meeting DSM-5 diagnostic criteria for PTSD
- Not having received any type of trauma-focused therapy previously
- Willing to engage in NET

Brady 2021 (Continued)

Exclusion criteria

- Recent suicide attempt or persistent severe self-harm
- Significant and frequent substance misuse
- Severe preoccupation with social or legal issues that would interfere with engagement in regular therapy sessions
- Facing imminent removal from the UK
- Currently in a situation of abuse or exploitation

Pretreatment: randomisation did not yield equal allocation across the 2 groups. There were also some notable group differences in the distribution of other participant characteristics, including whether the participant was an English speaker, and in terms of country of origin. Those in the wait-list group reported more dissociative symptoms.

Interventions

Intervention characteristics

Behavioural (NET)

- *Intensity of intervention (sessions):* 90 min to 120 min × 20
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, NET sessions were delivered by 7 female psychological therapists (6 clinical psychologists and 1 psychotherapist); all had training and prior experience in working with survivors of trafficking and in delivering NET (trained by FB, EW and KR and supervised by FB and EW).
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no, declaration of interest considered/made and does not appear to affect allegiance to the therapy
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, treatment fidelity was monitored through the recording of therapy sessions and regular case supervision by clinical psychologists with extensive experience of NET.
- *Intervention aim and theoretical basis:* as directed by the NET manual, the majority of time in sessions was spent on facilitation of the participant's detailed narration of traumatic experiences to 'process' the trauma memory, facilitate attachment repair and make meaning of traumatic and adverse experiences. Where time permitted, positive life events were also explored. A written narrative was created following the therapy sessions; this was read back and given to participants in the final therapy session. Through detailed narration, NET processes and contextualises traumatic memories and helps individuals to establish a coherent autobiographical narrative of their experiences.
- *Duration of intervention:* 20 weeks

Minimal intervention (psychoeducation + wait-list)

- *Intensity of intervention (sessions):* 3
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* psychoeducation sessions were delivered by NET therapists and trained assistant psychologists.
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity (yes, no, unclear, with explanation):* interpreters were used where required. The study used protocolised psychoeducation about PTSD symptoms and symptom management strategies.
- *Intervention aim and theoretical basis:* irrespective of group, each participant was initially offered 3 sessions of protocolised psychoeducation about PTSD symptoms and symptom management strategies.
- *Duration of intervention:* N/A

Outcomes

PTSD

- Outcome type: continuous outcome

Brady 2021 (Continued)

- Scale used: Clinician-Administered PTSD Scale
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, post-treatment, 6 months and 12 months (NET only)

PTSD

- Outcome type: continuous outcome
- Scale used: PCL-5
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, post-treatment

Depression

- Outcome type: continuous outcome
- Scale used: Patient Health Questionnaire
- Direction: lower is better
- Score range: 0 to 27
- Data value: endpoint, post-treatment

Anxiety

- Outcome type: continuous outcome
- Scale used: Generalized Anxiety Disorder Scale
- Direction: lower is better
- Score range: 0 to 21
- Data value: endpoint, post-treatment

Dissociation

- Outcome type: continuous outcome
- Scale used: Shutdown Dissociation Scale
- Direction: lower is better
- Score range: 0 to 39
- Data value: endpoint, post-treatment

Treatment dropout

- Outcome type: dichotomous outcome

Identification

Sponsorship source: this project was supported by a grant from the Oak Foundation (ref: OCAY-15-286).

Country: UK

Setting: people seeking care post-trafficking at either a charity or other support services

Authors name: Francesca Brady

Institution: The Helen Bamber Foundation, London, UK; Woodfield Trauma Service, Central and North West London NHS Foundation Trust, London, UK; and Department of Clinical, Educational and Health Psychology, University College London, UK

Email: francesca@helenbamber.org

Year: 2021

Notes

Data obtained from author

Covers 2021

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: recruitment between March 2018 and January 2020

Location of study: the Netherlands

Randomisation method: per centre (4), a randomisation sequence was computer-generated. Service users were randomly assigned to 1 of the 2 study conditions on a 1:1 ratio: EMDR therapy or TAU.

Ethics approvals: the study was approved by the Medical Ethical Committee of the University Medical Centre Utrecht.

Participants

Baseline characteristics

Behavioural (EMDR)

- *Participants (at randomisation):* 29
- *Gender:* 100% female participants
- *Age, M (SD):* 25.52 years (7.93 years)
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma, M (SD):* 2 weeks to 4 weeks post-rape
- *Income:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 45.69 (13.45)
- *Partnered:* not given
- *Randomised (N):* 29
- *Completed post-treatment assessment (N):* 23
- *Dropped out or removed prior to analysis (N):* 6
- *Numbers analysed at final applicable time point (N):* 20
- *Number of sessions:* not given
- *Treatment completion:* 26 (90%)

TAU

- *Participants (at randomisation):* 28
- *Gender:* 95% female participants (1 male participant)
- *Age, M (SD):* 25.88 years (8.23 years)
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma, M (SD):* 2 weeks to 4 weeks post-rape
- *Income:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* not given

Covers 2021 (Continued)

- *Baseline PTSD, M (SD): 47.84 (13.65)*
- *Partnered: not given*
- *Randomised (N): 28*
- *Completed post-treatment assessment (N): 20*
- *Dropped out or removed prior to analysis (N): 8*
- *Numbers analysed at final applicable time point (N): 17*
- *Number of sessions: not given*
- *Treatment completion: 22 (79%)*

Overall

- *Participants (at randomisation): 57*
- *Gender: 98% female participants (1 male participant)*
- *Age, M (SD): 25.81 years (8.18 years)*
- *Ethnicity: not given*
- *Disability: not given*
- *Time since trauma: 2 weeks to 4 weeks post-rape*
- *Income: not given*
- *Education: not given*
- *Employment: not given*
- *Sexual violence in adulthood: 100%*
- *Comorbid conditions: not given*
- *Baseline PTSD, M (SD): 46 (13.5)*
- *Partnered: not given*
- *Approached (N): 796*
- *Ineligible (N): 475*
- *Declined (N): 58*
- *Other (N): 206*
- *Randomised (N): 57*
- *Completed post-treatment assessment (N): 43*
- *Dropped out or removed prior to analysis (N): 14*
- *Numbers analysed at final applicable time point (N): 37*
- *Number of sessions: not given*
- *Treatment completion: 48 (84%)*

Inclusion criteria

- Victims of rape who contacted 1 of the participating sexual assault centres within 1 week after they experienced rape

Exclusion criteria

- Those younger than 16 years
- Those with cognitive disabilities
- Non-Dutch-speaking
- Those who required immediate psychological care for psychoses, suicidal ideation or addiction
- Those who received concurrent trauma-focused treatment for prior experiences

Pretreatment: some imbalance at baseline in prior trauma and prior trauma-based treatment but not on study measures, gender or age

Interventions

Intervention characteristics

Behavioural (EMDR)

- *Intensity of intervention (sessions): 3.5 h of therapy across 2 sessions*

Covers 2021 (Continued)

- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes. Therapists were 8 licenced psychologists who completed an accredited course of EMDR therapy and were trained in the application of the study protocol.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no indication of risk of allegiance or conflict of interest
- *Treatment fidelity (yes, no, unclear, with explanation):* yes. Video recordings of the sessions were made for bimonthly supervision by 2 EMDR Europe-accredited trainers in EMDR therapy. An EMDR-specific treatment integrity checklist was used. Twenty-five per cent of the 48 video recordings were assessed by 2 independent psychology graduates. There were no inconsistencies in these 2 assessments, and treatment fidelity proved high (97%).
- *Intervention aim and theoretical basis:* the trauma memory was conceptualised as a memory lasting from a period of time from the rape until the day of treatment.
- *Duration of intervention:* 2 weeks

TAU (other psychosocial interventions)

- *Intensity of intervention (sessions):* 2 × 30 min
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* telephone
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, a case manager based at the sexual assault centre
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* unclear but anticipated to meet standard practice at the centres
- *Intervention aim and theoretical basis:* psychoeducation and emotional support in accordance with a watchful waiting protocol, which stipulates screening for post-traumatic stress symptoms at least 2 times during the first month post-rape and, if indicated, subsequent referral for evidence-based treatment
- *Duration of intervention:* 2 weeks

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: PCL-5
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, post-treatment, and 8 weeks and 12 weeks post-assault

Depression

- Outcome type: continuous outcome
- Scale used: HADS-Depression Scale
- Direction: lower is better
- Score range: 0 to 21
- Data value: endpoint, post-treatment, and 8 and 12 weeks post-assault

Anxiety

- Outcome type: continuous outcome
- Scale used: HADS-Anxiety Scale
- Direction: lower is better
- Score range: 0 to 21
- Data value: endpoint, post-treatment, and 8 and 12 weeks post-assault

Global mental health functioning/distress

Covers 2021 (Continued)

- Outcome type: continuous outcome
- Scale used: BSI
- Direction: lower is better
- Score range: 0 to 112
- Data value: endpoint, post-treatment, and 8 and 12 weeks post-assault

Dissociation

- Outcome type: continuous outcome
- Scale used: Dissociation Tension Scale
- Direction: lower is better
- Score range: 0 to 100
- Data value: endpoint, post-treatment, and 8 and 12 weeks post-assault

Pelvic floor

- Outcome type: continuous outcome
- Scale used: Amsterdam Overactive Pelvic Floor Scale for Women
- Direction: lower is better
- Score range: 4 to 20
- Data value: endpoint, 12 weeks post-assault

Sexual function

- Outcome type: continuous outcome
- Scale used: Female Sexual Functioning Index total score and Desire and Satisfaction
- Direction: higher is better
- Score range: 2 to 36
- Data value: endpoint, 12 weeks post-assault

Guilt and shame

- Outcome type: continuous outcome
- Scale used: items based on [Foa 1991](#)
- Direction: lower is better
- Data value: endpoint, 12 weeks post-assault

Treatment dropout

- Outcome type: dichotomous outcome

Identification

Sponsorship source: the work was supported by the Achmea Association Victims & Society, Innovatiefonds Zorgverzekeraars, EMDR Research Foundation, Vereniging EMDR Nederland and PAOS fonds.

Country: the Netherlands

Setting: sexual assault centres

Authors name: Milou Covers

Institution: National Psychotrauma Center for Children and Youth, University Medical Center Utrecht, Utrecht, the Netherlands

Email: m.l.v.covers@umcutrecht.nl

Year: 2021

Notes

Time of assessment was defined as pretreatment (Pre), post-treatment (Post), follow-up at 8 weeks post-rape and follow-up at 12 weeks post-assault.

Creech 2021
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Duration of study: May 2017 to April 2019</p> <p>Location of study: Texas, USA</p> <p>Randomisation method: after completion of the baseline assessment, the (computer) narrator “flipped a coin” and women (N = 153) were randomised into the control or SHE intervention. The randomisation sequence was known only to the computer program and optimised for balanced assignment over time between the 2 conditions.</p> <p>Ethics approvals: the study was approved by the IRB.</p>
Participants	<p>Baseline characteristics</p> <p>Other psychosocial interventions (SHE)</p> <ul style="list-style-type: none"> • <i>Participants:</i> 76 • <i>Gender:</i> 100% female participants • <i>Age, M (SD):</i> 43.46 years (9.97 years) • <i>Ethnicity:</i> 36.8% white, 47.4% African American, 15.8% other • <i>Disability:</i> not given • <i>Time since trauma:</i> not given • <i>Income:</i> not given • <i>Education (% high school, college or apprentice, university or years of education):</i> 2.6% high school, 13.2% college or apprentice, 40.8% some college, 43.4% university • <i>Employment:</i> not given • <i>Sexual violence in adulthood:</i> 100% • <i>Comorbid conditions:</i> 28.9% hazardous drinking, 55.2% intimate partner violence • <i>Baseline PTSD, M (SD):</i> 51.91 (16.95) • <i>Partnered:</i> 39.5% • <i>Randomised (N):</i> 76 • <i>Completed post-treatment assessment (N):</i> 64 • <i>Dropped out or removed prior to analysis (N):</i> 12 • <i>Numbers analysed at final applicable time point (N):</i> 66 • <i>Number of sessions:</i> N/A • <i>Treatment completion:</i> 61 (80%) <p>Assessment control</p> <ul style="list-style-type: none"> • <i>Participants:</i> 77 • <i>Gender:</i> 100% female participants • <i>Age, M (SD):</i> 43.63 years (10.28 years) • <i>Ethnicity:</i> 33.8% white, 48.1% African American, 18.1% other • <i>Disability:</i> not given • <i>Time since trauma:</i> not given • <i>Income:</i> not given • <i>Education (% high school, college or apprentice, university or years of education):</i> 13% high school, 2.6% college or apprentice, 40.3% some college, 44.2% university • <i>Employment:</i> not given • <i>Sexual violence in adulthood:</i> 97.4%

Creech 2021 (Continued)

- *Comorbid conditions*: 28.9% hazardous drinking, 54.5% intimate partner violence
- *Baseline PTSD, M (SD)*: 49.71 (17.44)
- *Partnered*: 48.1%
- *Randomised (N)*: 77
- *Completed post-treatment assessment (N)*: 67
- *Dropped out or removed prior to analysis (N)*: 10
- *Numbers analysed at final applicable time point (N)*: 69
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Overall

- *Participants*: 153
- *Gender*: 100% female participants
- *Age, M (SD)*: 43.55 years (10.10 years)
- *Ethnicity*: 35.3% white, 47.7% African American, 17% other
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education (% high school, college or apprentice, university or years of education)*: 7.8% high school, 7.8% college or apprentice, 40.5% some college, 43.8% university
- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: 28.9% hazardous drinking, 55% intimate partner violence
- *Baseline PTSD, M (SD)*: 50 (17)
- *Partnered*: 45.1%
- *Approached (N)*: 2309
- *Ineligible (N)*: 114
- *Declined (N)*: 60
- *Other (N)*: 1982
- *Randomised (N)*: 153
- *Completed post-treatment assessment (N)*: 131
- *Dropped out or removed prior to analysis (N)*: 22
- *Numbers analysed at final applicable time point (N)*: 135
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Inclusion criteria

- Self-identified female gender
- Aged between 18 years and 65 years
- History of sexual assault (defined as at least 1 incident of unwanted lifetime sexual contact)
- At least 1 current psychosocial health risk (PTSD, hazardous drinking or intimate partner violence)

Exclusion criteria

- Inability to understand study procedures in English
- Active suicidal or homicidal crisis warranting imminent clinical intervention

Pretreatment: at baseline, the group difference in number of risks was statistically significant, with those in the SHE group reporting a higher number of risks.

Interventions

Intervention characteristics

Other psychosocial interventions (SHE)

Creech 2021 (Continued)

- *Intensity of intervention (sessions):* 1 × 20 min
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* computer
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* the SHE for women to address barriers to screening for and addressing lifetime sexual assault and related psychosocial health risks of PTSD, hazardous drinking and intimate partner violence. SHE is a modular computer-based screen and brief intervention relying on psychoeducation and the principles of motivational interviewing to reduce health risks in women with lifetime sexual trauma histories.
- *Duration of intervention:* 1 week

Assessment control

- *Intensity of intervention (sessions):* N/A
- *Mode of delivery:* N/A
- *Format:* N/A
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* those randomised to the control condition completed assessments only. After baseline, they were offered a list of mental health and intimate partner violence referrals and resources. They were assisted with referrals directly any time throughout the study if requested.
- *Duration of intervention:* N/A

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: PCL-5
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, 2 months and 4 months

Intimate partner violence

- Outcome type: continuous outcome
- Scale used: Composite Abuse Scale
- Direction: lower is better
- Score range: 0 to 150
- Data value: endpoint, 2 months and 4 months

Hazardous drinking

- Outcome type: continuous outcome
- Scale used: AUDIT
- Direction: lower is better
- Score range: 0 to 40
- Data value: endpoint, 2 months and 4 months

Treatment use

- Outcome type: continuous outcome
- Scale used: Treatment Services Review
- Direction: lower scores mean less treatment use

Creech 2021 (Continued)

- Score range: N/A (measure provides information on the type, amount and efficacy of services provided)
- Data value: endpoint, 2 months and 4 months

Treatment dropout

- Outcome type: dichotomous outcome (intervention group only)

Identification

Sponsorship source: this work was supported by a grant from the Department of Defense, W81XWH-14-1-0368. ClinicalTrials.gov identifier: NCT02957747. This work was also supported by additional funds and resources from the VHA VISN 17 Center of Excellence and the Central Texas VA Health Care System.

Country: USA

Setting: veterans seeking primary care at a VHA medical centre. The study was advertised via fliers, in-person recruitment in women's primary care clinics and letters to all women who had primary care appointments scheduled in the next month.

Authors name: Suzannah Creech

Institution: Center of Excellence for Research on Returning War Veterans and the Central Texas Veterans Health Care System

Email: Suzannah.Creech@va.gov

Year: 2021

Notes

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Echeburua 1996
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: 5 years (recruitment April 1989 to March 1993)

Ethics approvals: not given

Location of study: San Sebastian, Bilbao and Vitoria, Spain

Randomisation method: assignment of participants to 1 of the 2 experimental conditions was carried out randomly in order of arrival at the Psychological Counselling Centers for Women

Participants

Baseline characteristics

CBT (CR + coping skills)

- *Participants (at randomisation):* 10
- *Gender:* 100% female participants
- *Age, M:* 24 years
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma, M:* 1 month
- *Income:* not given

Echeburua 1996 (Continued)

- *Education (% high school, college or apprentice, university or years of education):* 30% high school, 20% college
- *Employment:* not given
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 36.7 (8.59)
- *Partnered:* 20%
- *Randomised (N):* 10
- *Completed post-treatment assessment (N):* 10
- *Dropped out or removed prior to analysis (N):* 0
- *Numbers analysed at final applicable time point (N):* 10
- *Number of sessions, M (SD):* 5 (0)
- *Treatment completion, N (SD):* 10 (100%)

Behavioural (progressive relaxation)

- *Participants (at randomisation):* 10
- *Gender:* 100% female participants
- *Age, M:* 20 years
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma, M:* 1 month
- *Income:* not given
- *Education (% high school, college or apprentice, university or years of education):* 30% high school, 10% college
- *Employment:* not given
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 34.3 (7.54)
- *Partnered:* 10%
- *Randomised (N):* 10
- *Completed post-treatment assessment (N):* 10
- *Dropped out or removed prior to analysis (N):* 0
- *Numbers analysed at final applicable time point (N):* 10
- *Number of sessions, M (SD):* 5 (0)
- *Treatment completion:* 10 (100%)

Overall

- *Participants (at randomisation):* 20
- *Gender:* 100% female participants
- *Age, M (SD):* 22 years (6.9 years)
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma, M:* 1 month
- *Income:* not given
- *Education (% high school, college or apprentice, university or years of education):* 30% high school, 15% college
- *Employment:* not given
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 35.5 (7.96)
- *Partnered:* 15%
- *Approached:* 31

Echeburua 1996 (Continued)

- *Ineligible (N): 11*
- *Declined (N): 0*
- *Other (N): 0*
- *Randomised (N): 20*
- *Completed post-treatment assessment (N): 20*
- *Dropped out or removed prior to analysis (N): 0*
- *Numbers analysed at final applicable time point (N): 20*
- *Number of sessions: N/A*
- *Treatment completion: 20 (100%)*

Inclusion criteria

- Experienced sexual aggression
- Met DSM-III-R criteria for PTSD
- Within 3 months of sexual aggression

Exclusion criteria: suffering severe physical or mental disorder

Pretreatment: none reported

Interventions

Intervention characteristics

CBT (CR + coping skills)

- *Planned number of intervention sessions: 5 (× 1 h)*
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation): face-to-face*
- *Format (group, individual, blend): individual*
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation): yes, the assessment and therapy were tried with 5 people before the study. The intervention was delivered by a clinical psychologist with 5 years of experience in cognitive and behavioural treatment of victims of sexual violence.*
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation): no*
- *Treatment fidelity (yes, no, unclear, with explanation): unclear, not given*
- *Intervention aim and theoretical basis: first, explaining the normal reaction to sexual aggression and process of developing and maintaining fear; secondly, modifying negative thoughts with more adaptive ones. Traumatic event was resituated in its appropriate dimensions. Positive aspects of the new situation are pointed out. Coping skills training included progressive relaxation (Bernstein 1973), thought-stopping, cognitive distractions and instruction in gradual exposure in order to resume habitual activities.*
- *Duration of intervention: 5 weeks*

Behavioural (progressive relaxation)

- *Planned number of intervention sessions: 5 (× 1 h)*
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation): face-to-face*
- *Format (group, individual, blend): individual*
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation): as previous*
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation): no*
- *Treatment fidelity (yes, no, unclear, with explanation): unclear, not given*
- *Intervention aim and theoretical basis: first, general instruction about the psychological impact of sexual aggression; second, training in progressive muscular relaxation (Bernstein 1973)*
- *Duration of intervention: 5 weeks*

Outcomes

Depression

- Outcome type: continuous outcome
- Scale used: BDI
- Direction: lower is better

Echeburua 1996 (Continued)

- Score range: 0 to 63
- Data value: endpoint, 6 months and 12 months

Treatment dropout

- Outcome type: dichotomous outcome

PTSD

- Outcome type: continuous outcome
- Scale used: Scale of Severity of Posttraumatic Stress Disorder Symptoms
- Direction: lower is better
- Score range: 0 to 51
- Data value: endpoint, 6 months and 12 months

Anxiety

- Outcome type: continuous outcome
- Scale used: STAI
- Direction: lower is better
- Score range: 20 to 80
- Data value: endpoint, 6 months and 12 months

PTSD

- Outcome type: continuous outcome
- Scale used: SSS Reexperience
- Direction: lower is better
- Score range: 0 to 5
- Data value: endpoint, 6 months and 12 months

PTSD

- Outcome type: continuous outcome
- Scale used: SSS Avoidance
- Direction: lower is better
- Score range: 0 to 2
- Data value: endpoint, 6 months and 12 months

PTSD

- Outcome type: continuous outcome
- Scale used: SSS Arousal
- Direction: lower is better
- Score range: 0 to 3
- Data value: endpoint, 6 months and 12 months

Trauma-related beliefs

- Outcome type: continuous outcome
- Scale used: Mental Fatigue Scale-III
- Direction: lower is better
- Score range: 120 to 600 (rape section: 42 to 210)
- Data value: endpoint, 6 months and 12 months

Identification

Sponsorship source: University of the Basque Country UPV 006.230-0106/88

Country: Spain

Echeburua 1996 *(Continued)*

Setting: women seeking support following sexual victimisation at community counselling centres for women

Authors name: Enrique Echeburúa

Institution: Universidad del País Vasco

Year: 1996

Notes	Not included in meta-analysis
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Falsetti 2008
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Duration of study: 12 weeks of treatment and follow-up to 6 months</p> <p>Ethics approvals: not given</p> <p>Location of study: South Carolina, USA</p> <p>Randomisation method: not given</p>
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Participants	<p>Baseline characteristics</p> <p>CBT (M-CET)</p> <ul style="list-style-type: none"> • <i>Participants (prerandomisation assessment):</i> N/A • <i>Gender:</i> not given • <i>Age:</i> not given • <i>Ethnicity:</i> not given • <i>Disability:</i> not given • <i>Time since trauma:</i> not given • <i>Income:</i> not given • <i>Education:</i> not given • <i>Employment:</i> not given • <i>Sexual violence in adulthood:</i> not given • <i>Comorbid conditions:</i> not given • <i>Baseline PTSD:</i> not given • <i>Partnered:</i> not given • <i>Randomised (N):</i> 29 • <i>Completed post-treatment assessment (N):</i> 22 • <i>Dropped out or removed prior to analysis (N):</i> 7 • <i>Numbers analysed at final applicable time point (N):</i> 22 • <i>Number of sessions:</i> not given • <i>Treatment completion:</i> 16 (55%) <p>Wait-list</p> <ul style="list-style-type: none"> • <i>Participants (prerandomisation assessment):</i> N/A • <i>Gender:</i> not given • <i>Age:</i> not given
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Falsetti 2008 (Continued)

- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given
- *Baseline PTSD*: not given
- *Partnered*: not given
- *Randomised (N)*: 31
- *Completed post-treatment assessment (N)*: 23
- *Dropped out or removed prior to analysis (N)*: 0
- *Numbers analysed at final applicable time point (N)*: 31
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Overall

- *Participants (prerandomisation assessment)*: 62
- *Gender*: 100% female participants
- *Age, M (SD)*: 35 years (9.82 years)
- *Ethnicity*: 69% white, 24% Black, 7% other
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: 32% < USD 5000, 18% USD 15,000 to USD 25,000
- *Education (% high school, college or apprentice, university or years of education)*: 87% high school
- *Employment (% employed; unemployed, other)*: 36% employed
- *Sexual violence in adulthood*: 76% sexual violence in adulthood; 69% unwanted sexual contact before 18 years
- *Comorbid conditions*: 89% anxiety disorders (ADIS-R); moderate levels of depression (BDI)
- *Baseline PTSD*: not given
- *Partnered*: 34%
- *Approached*: 62
- *Ineligible (N)*: 2
- *Declined (N)*: 0
- *Other (N)*: 0
- *Randomised (N)*: 60
- *Completed post-treatment assessment (N)*: 43
- *Dropped out or removed prior to analysis (N)*: 7
- *Numbers analysed at final applicable time point (N)*: 53
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Inclusion criteria

- Experienced a traumatic event at least 3 months before assessment
- PTSD
- Experiencing panic attacks

Exclusion criteria

- Active psychosis
- Intellectual disability

Falsetti 2008 (Continued)

- Current suicidal or parasuicidal behaviour
- Current drug or alcohol dependency
- Illiteracy

Pretreatment: none reported

Interventions

Intervention characteristics

CBT (M-CET)

- *Planned number of intervention sessions:* 12
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* group
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, participants were treated in groups of 5 to 7 by therapists trained in M-CET. Three therapists conducted the groups, and every group had 2 therapists assigned. The third therapist was Joanne L Davis, a postdoctoral fellow at the time the study was conducted.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* yes, Falsetti and Resnick developed the treatment.
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, all therapy sessions were audiotaped. A random sampling of 20 tapes of 72 were evaluated for treatment adherence and competence by an independent evaluator trained in the treatment. There were no violations of adherence to the treatment protocol, and all tapes were rated to be satisfactory or better on therapist skills.
- *Intervention aim and theoretical basis:* with M-CET, exposure to the physiological channel is conducted through interoceptive exposure to physiological reactions. Exposure to panic symptoms decreases fear of physiological symptoms and also provides exposure to the physiological component of fear associated with trauma, thereby weakening the association of physiological arousal and the traumatic memory. The interoceptive exposure is hypothesised to decrease fear of physiological arousal symptoms experienced in panic and PTSD; thus, when exposed to traumatic memories and cues, clients may be less fearful of physiological reactions. Exposure to the cognitive channel is conducted through writing assignments about the meaning of the trauma, writings about the traumatic event itself, and challenging cognitive distortions about how the trauma has affected safety, trust, esteem, intimacy, and power and control beliefs. These components have been adapted from CPT. Finally, exposure to the behavioural channel is conducted through in vivo exposure to conditioned cues to the traumatic event.
- *Duration of intervention:* 12 weeks

Wait-list

- *Planned number of intervention sessions:* N/A
- *Mode of delivery:* N/A
- *Format:* N/A
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* N/A
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* N/A
- *Treatment fidelity (yes, no, unclear, with explanation):* N/A
- *Intervention aim and theoretical basis:* participants in the control condition were called every 2 weeks and given supportive phone counselling by 1 of the therapists. These women were told that if their condition worsened, they would receive immediate treatment.
- *Duration of intervention:* N/A

Outcomes

Depression

- Outcome type: continuous outcome
- Scale used: BDI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint

Falsetti 2008 (Continued)

PTSD

- Outcome type: continuous outcome
- Scale used: MPSS-SR
- Direction: lower is better
- Score range: 0 to 119
- Data value: endpoint

Treatment dropout (intervention group only)

- Outcome type: dichotomous outcome

Identification

Sponsorship source: NIMH grant MH-53381-01A1

Country: USA

Setting: women seeking treatment for PTSD and panic attacks at the National Crime Victims Research and Treatment Center and a community sample of women seeking help for PTSD and panic attacks

Authors name: Sherry A Falsetti

Institution: University of Illinois College of Medicine, Rockford

Email: falsetti@uic.edu

Year: 2008

Notes

62 is the number approached and assessed for inclusion but reported on in population characteristics; 60 women were randomised.

Included in meta-analysis

Feske 2008

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: recruitment timeframe not stated; up to 12 weeks of treatment and 3 months of follow-up post-treatment

Location of study: Pittsburgh, Pennsylvania, USA

Randomisation method: participants were randomly assigned to PE or TAU. Therapists were crossed with treatment condition, and participants were randomly assigned to therapists within scheduling constraints.

Ethics approval: author reports that participants provided signed informed consent in compliance with the University of Pittsburgh's IRB procedures.

Participants

Baseline characteristics

CBT (PE)

- *Participants (treatment completers only):* 9
- *Gender:* 100% female participants
- *Age:* not given

Feske 2008 (Continued)

- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 34.89 (7.64)
- *Partnered*: not given
- *Randomised (N)*: 13
- *Completed post-treatment assessment (N)*: 9
- *Dropped out or removed prior to analysis (N)*: 4
- *Numbers analysed at final applicable time point (N)*: 9
- *Number of sessions, M (SD)*: 9.3 (1.0)
- *Treatment completion*: 9 (69.2%)

Usual care

- *Participants (treatment completers only)*: 12
- *Gender*: 100% female participants
- *Age*: not given
- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 35.17 (8.31)
- *Partnered*: not given
- *Randomised (N)*: 14
- *Completed post-treatment assessment (N)*: 12
- *Dropped out or removed prior to analysis (N)*: 2
- *Numbers analysed at final applicable time point (N)*: 12
- *Number of sessions, M (SD)*: 9.5 (1.2)
- *Treatment completion*: 12 (85.7%)

Overall

- *Participants (treatment completers only)*: 21
- *Gender*: 100% female participants
- *Age, M (range)*: 43.1 years (29 years to 55 years)
- *Ethnicity*: 4.8% white, 95.2% Black
- *Disability*: 33% received disability payments
- *Time since trauma*: not given
- *Income*: 42.9% < USD 4999, 23.8% USD 5000 to USD 9999, 3.3% > USD 10,000
- *Education (% high school, college or apprentice, university or years of education)*: 38.1% high school, 33.2% some high school, 28.7% some college or vocational training
- *Employment (% employed, unemployed, other)*: 57.1% unemployed, 33.3% other, 9.6% employed
- *Sexual violence in adulthood*: 47.6% adulthood; 85.7% multiple traumas including child sexual abuse

Feske 2008 (Continued)

- *Comorbid conditions*: 95.2% had comorbid conditions – major depression (66.7%), panic disorder (38.1%), social phobia (28.6%) and generalised anxiety disorder (23.8%); 52.4% met DSM-IV criteria for borderline personality disorder
- *Baseline PTSD*: not given
- *Partnered*: 4.8% married
- *Approached (N)*: 168
- *Ineligible (N)*: 131
- *Declined (N)*: 10
- *Other (N)*: 0
- *Randomised (N)*: 27
- *Completed post-treatment assessment (N)*: 21
- *Dropped out or removed prior to analysis (N)*: 6
- *Numbers analysed at final applicable time point (N)*: 21
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Inclusion criteria

- Female
- Psychiatric outpatients attending the participating outreach clinic

Exclusion criteria

- Current depression with psychotic symptoms or suicidal ideation
- Current alcohol or substance dependence
- A lifetime diagnosis of a psychotic or organic mental disorder
- Current, clinically significant self-injurious behaviours
- Unstable life circumstances that would interfere with treatment (e.g. immediate threat of loss of housing, impending prison sentence)
- Women currently at risk of abuse by partner/assailant

Pretreatment: none reported

Interventions

Intervention characteristics

CBT (PE)

- *Planned number of intervention sessions*: 9 to 12 weekly 90-minute individual sessions
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: face-to-face
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: yes, community therapists were 5 masters-level social workers and 1 registered nurse. They did not specialise in the treatment of PTSD and had no prior training in behaviour therapy for anxiety disorders; however, they did receive 52 h of training over 6 months. The therapists were trained by the author who was trained in PE by EB Foa.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: no
- *Treatment fidelity (yes, no, unclear, with explanation)*: yes, therapists were given an adherence checklist for each protocol session. PE checklists summarised the core interventions and order in which they should be applied for each session. Therapists participated in weekly supervisory sessions with the author to review PE treatments. All sessions were videotaped. The author reviewed every second PE session using an integrity checklist and discussed any deviations from the protocol. None of the PE sessions she reviewed warranted exclusion due to treatment integrity violations. Formal treatment integrity checks were not conducted, on grounds that this was preliminary research.
- *Intervention aim and theoretical basis*: PE was based on the manual created by [Foa 1998](#) and aims to reduce PTSD by clients reliving the traumatic event by imagining it as vividly as possible and describing it aloud in the present tense several times for a total of 30 min to 60 min per session (imaginal exposure). After the exposure, therapists discussed clients' experiences during the reliv-

Feske 2008 (Continued)

ing and assigned imaginal and in vivo homework. The first 2 sessions comprised information gathering, education about PTSD, the practice of diaphragmatic breathing, explanation of the treatment rationale, and construction of the in vivo exposure hierarchy. During the remaining sessions, clients relived the traumatic event by imagining it as vividly as possible and describing it aloud in the present tense several times for a total of 30 min to 60 min per session (imaginal exposure). After the exposure, therapists discussed clients' experiences during the reliving and assigned imaginal and in vivo homework. Clients were encouraged to listen to their audiotaped imaginal exposure narratives at least once daily. In vivo exposure was conducted along a hierarchy of feared situations judged by the therapist and client to be safe. In Session 8, clients who reported an improvement in PTSD symptoms of < 70% in relation to their pretreatment PDS-I score were encouraged to participate in 3 additional PE sessions

- *Duration of intervention:* 9 weeks to 12 weeks

Usual care

- *Planned number of intervention sessions:* 9 to 12 weekly 60-minute individual sessions
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* blend
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, existing TAU therapists received additional training
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, TAU checklists summarised permitted and proscribed interventions. Therapists participated in weekly supervisory sessions with the author to review PE and TAU treatments. All sessions were videotaped. The author reviewed every second usual treatment session using an integrity checklist and discussed any deviations from the protocol. None reviewed included PE interventions.
- *Intervention aim and theoretical basis:* TAU consisted of the standard treatment provided at the clinic and included 1 weekly 60-minute individual counselling session (i.e. 1 weekly TAU protocol session). In addition, TAU clients received 1 weekly 90-minute group treatment session (e.g. anger management). TAU therapists were trained in a treatment rationale that emphasised the following: 1) It is not known whether PE is more effective for PTSD than TAU is for low-income women; 2) addressing current life problems other than PTSD is likely to reduce clients' general stress level, thereby reducing PTSD symptoms; and 3) targeting symptoms related to depression and interpersonal difficulties may have a similarly positive effect on PTSD symptoms. TAU clients who reported an improvement in PTSD symptoms of < 70% in Session 8 were encouraged to participate in 3 additional TAU sessions. TAU therapists were allowed to discuss clients' traumatic experiences and PTSD symptoms but were to refrain from using formal PE procedures (i.e. imaginal or in vivo exposure as specified in the PE manual).
- *Duration of intervention:* 9 weeks to 12 weeks

Outcomes
Depression

- Outcome type: continuous outcome
- Scale used: BDI-III
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint, 3 months

PTSD

- Outcome type: continuous outcome
- Scale used: PDS-I
- Direction: lower is better
- Score range: 0 to 51
- Data value: endpoint, 3 months

Treatment dropout (both groups)

- Outcome type: dichotomous outcome

Feske 2008 (Continued)

Anxiety

- Outcome type: continuous outcome
- Scale used: BAI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint, 3 months

Global mental health

- Outcome type: continuous outcome
- Scale used: BSI
- Direction: lower is better
- Score range: 0 to 112
- Data value: endpoint, 3 months

Adverse events

- Outcome type: adverse event
- Notes: 1 person in TAU dropped out due to worsening depression after the third TAU session.

Identification

Sponsorship source: NIMH grant MH01675

Country: USA

Setting: African American women who were psychiatric outpatients at a university-affiliated outreach clinic, recruited through fliers and referrals by mental health professionals; intervention was delivered by nonspecialist community therapists.

Authors name: Ulrike Feske

Institution: University of Pittsburgh

Email: ulf1@pitt.edu

Year: 2008

Notes

Population characteristics described for full sample of 21 PE and usual care completers only.

Included in meta-analysis

Foa 1991

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: recruitment timeframe not specified; 4.5 week treatment, 3-month follow-up post-treatment

Ethics approvals: not given

Location of study: Pennsylvania, USA

Randomisation method: eligible individuals were randomly assigned to 1 of the 4 conditions. After 10 participants were entered into the wait-list condition, subsequent admissions were randomly assigned to 1 of the 3 treatment groups.

Foa 1991 (Continued)

Participants

Baseline characteristics

CBT (SIT)

- *Participants (completers):* 14
- *Gender:* 100% female participants
- *Age, M (SD):* 29.3 years (6.3 years)
- *Ethnicity:* Black 15.4%, white 84.6%
- *Disability:* not given
- *Time since trauma, M (SD):* 120.5 months (131 months)
- *Income:* 7.7% > USD 30,000, 15.4% USD 20,000 to USD 30,000, 38.5% USD 10,000 to USD 20,000, 38.5% < USD 10,000
- *Education:* not given
- *Employment (% employed; unemployed, other):* 74.9% employed, 25% other
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 24.48 (6.62)
- *Partnered:* 30.8%
- *Randomised (N):* 17
- *Included cases at post-treatment assessment (N):* 14
- *Dropped out or removed prior to analysis (N):* 8
- *Numbers analysed at final applicable time point (N):* 9
- *Number of sessions:* not given
- *Treatment completion:* 14 (82.3%)

CBT (PE)

- *Participants (completers):* 10
- *Gender:* 100% female participants
- *Age, M (SD):* 32.7 years (7.3 years)
- *Ethnicity:* Black 30%, white 70%
- *Disability:* not given
- *Time since trauma, M (SD):* 165 months (248 months)
- *Income:* 40% > USD 30,000, 10% USD 20,000 to USD 30,000, 10% USD 10,000 to USD 20,000, 40% < USD 10,000
- *Education:* not given
- *Employment (% employed; unemployed, other):* 55.5% employed; 44% other
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 25.78 (5.01)
- *Partnered:* 30%
- *Randomised (N):* 14
- *Included cases at post-treatment assessment (N):* 10
- *Dropped out or removed prior to analysis (N):* 5
- *Numbers analysed at final applicable time point (N):* 9
- *Number of sessions:* not given
- *Treatment completion:* 10 (71.4%)

Humanistic (SC)

- *Participants (completers):* 11
- *Gender:* 100% female participants
- *Age, M (SD):* 34.2 years (9.8 years)
- *Ethnicity:* Black 27.3%, white 63.6%, other 9.1%

Foa 1991 (Continued)

- *Disability*: not given
- *Time since trauma, M (SD)*: 282 months (263 months)
- *Income*: 36.4% > USD 30,000, 9.1% USD 20,000 to USD 30,000, 36.4% USD 10,000 to USD 20,000, 18.2% < USD 10,000
- *Education*: not given
- *Employment (% employed; unemployed, other)*: 80% employed; 20% other
- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 24.39 (6.62)
- *Partnered*: 18.2%
- *Randomised (N)*: 14
- *Included cases at post-treatment assessment (N)*: 11
- *Dropped out or removed prior to analysis (N)*: 5
- *Numbers analysed at final applicable time point (N)*: 9
- *Number of sessions*: not given
- *Treatment completion*: 11 (79%)

Wait-list

- *Participants (completers)*: 10
- *Gender*: 100% female participants
- *Age, M (SD)*: 32.0 years (9.6 years)
- *Ethnicity*: Black 30%, white 70%
- *Disability*: not given
- *Time since trauma, M (SD)*: 205 months (150 months)
- *Income*: 20% > USD 30,000, 10% USD 20,000 to USD 30,000, 50% USD 10,000 to USD 20,000, 20% < USD 10,000
- *Education*: not given
- *Employment (% employed; unemployed, other)*: 50% employed, 50% other
- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 24.43 (4.64)
- *Partnered*: 20%
- *Randomised (N)*: 10
- *Included cases at post-treatment assessment (N)*: 10
- *Dropped out or removed prior to analysis (N)*: 10
- *Numbers analysed at final applicable time point (N)*: 0
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Overall

- *Participants (completers)*: 45
- *Gender*: 100% female participants
- *Age, M (SD)*: 31.8 years (8.2 years)
- *Ethnicity*: Black 25.0%, white 72.7%, other 2.3%
- *Disability*: not given
- *Time since trauma, M (SD)*: 6.2 years (6.7 years); range from 3 months to 12 years
- *Income*: 25% > USD 30,000, 11.4% USD 20,000 to USD 30,000, 34.1% USD 10,000 to USD 20,000, 29.5% < USD 10,000
- *Education*: not given
- *Employment (% employed, unemployed, other)*: 65.9% employed; 12.2% other
- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given

Foa 1991 (Continued)

- *Baseline PTSD*: not given
- *Partnered*: 25%
- *Approached (N)*: not given
- *Ineligible (N)*: not given
- *Declined (N)*: 11
- *Other (N)*: 0
- *Randomised (N)*: 55
- *Included cases at post-treatment assessment (N)*: 45
- *Dropped out or removed prior to analysis (N)*: 28
- *Numbers analysed at final applicable time point (N)*: 27
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Inclusion criteria

- Victims of rape or attempted rape who met DSM-III-R diagnostic criteria for PTSD
- Raped minimum 3 months before participation in the study

Exclusion criteria

- Current or previous diagnosis of organic mental disorder, schizophrenia or paranoid disorders as defined in the DSM-III-R
- Depression severe enough to require immediate psychiatric treatment, bipolar depression or depression accompanied by delusions, hallucinations or bizarre behaviour
- Current alcohol or drug abuse
- Assault by spouse or other family member
- Illiteracy in English

Pretreatment: significantly fewer participants in SIT group reported injury during the assault.

Interventions

Intervention characteristics

CBT (SIT)

- *Planned number of intervention sessions*: 9 (90-minute sessions twice a week)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: face-to-face
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: yes, therapists had master's or doctoral degrees in psychology or clinical social work. Therapists were trained in treatments by EB Foa and BO Rothbaum.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: no
- *Treatment fidelity (yes, no, unclear, with explanation)*: yes, 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 were noted, and suggestions for correction were provided by the supervisor. Nonparametric (Kruskal-Wallis) tests were conducted to examine possible therapist effects. The therapists did not differ in the percentage of improvement demonstrated by their patients on any of the 7 outcome measures used in the current study.
- *Intervention aim and theoretical basis*: the procedures included in this treatment programme were adapted from (Veronen 1983). The first session was devoted to information gathering through the initial interview described above. The session terminated with breathing exercises to diminish anxiety that may have been elicited by the interview. During the second session, the treatment method was described to the participant, a rationale for treatment was given, and an explanation for the origin of fear and anxiety was presented. The next 7 sessions were devoted to instruction in coping skills. During the third and fourth sessions, the participants were taught deep muscle relaxation and controlled breathing. In the fifth session, they were taught thought-stopping to counter ruminative or obsessive thinking (Wolpe 1958). The sixth session was devoted to CR (Beck 1979; Ellis 1977), the seventh to guided self-dialogue (Meichenbaum 1977), the eighth to covert modelling, and the ninth to role-playing. No instructions for exposure were included.

Foa 1991 (Continued)

- *Duration of intervention:* 4.5 weeks

CBT (PE)

- *Planned number of intervention sessions:* 9 (90-minute sessions twice a week)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* as previous
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* as previous
- *Intervention aim and theoretical basis:* the first 2 sessions were devoted to information gathering through the initial interview described above, explanation of treatment rationale, and treatment planning. The next 7 sessions were devoted to reliving the rape scene in imagination (imaginal exposure). Participants were instructed to relive the assault by imagining it as vividly as possible and describing it aloud using the present tense. The participant repeated the rape scenario several times for a total of 60 min per session. The participants' narratives were tape-recorded, and participants were 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 participant and the therapist to be safe.
- *Duration of intervention:* 4.5 weeks

Humanistic (SC)

- *Planned number of intervention sessions:* 9 (90-minute sessions twice a week)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* as previous
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* as previous
- *Intervention aim and theoretical basis:* involved gathering information through the initial interview in the first session and presenting the rationale for treatment in the second session. During the remaining sessions, participants were taught a general problem-solving technique. Therapists played an indirect and unconditionally supportive role. Homework consisted of the participants keeping a diary of daily problems and attempts at problem-solving. Participants were immediately redirected to focus on current daily problems if discussions of the assault occurred. No instructions for exposure or anxiety management were included.
- *Duration of intervention:* 4.5 weeks

Wait-list

- *Planned number of intervention sessions:* N/A
- *Mode of delivery:* N/A
- *Format:* N/A
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* N/A
- *Duration of intervention:* N/A

Outcomes
PTSD

- Outcome type: continuous outcome
- Scale used: PTSD interview
- Direction: lower is better
- Score range: 17 to 119
- Data value: endpoint, 3 months, 6 months and 12 months

Depression

Foa 1991 (Continued)

- Outcome type: continuous outcome
- Scale used: BDI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint, 3 months, 6 months and 12 months

Trauma-related beliefs

- Outcome type: continuous outcome
- Scale used: RAST
- Direction: lower is better
- Score range: 0 to 280
- Data value: endpoint, 3 months, 6 months and 12 months

Anxiety

- Outcome type: continuous outcome
- Scale used: STAI-State
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, 3 months, 6 months and 12 months

Treatment dropout

- Outcome type: dichotomous outcome

PTSD

- Outcome type: continuous outcome
- Scale used: PTSD interview Intrusion
- Direction: lower is better
- Score range: 4 to 28
- Data value: endpoint, 3 months, 6 months and 12 months

PTSD

- Outcome type: continuous outcome
- Scale used: PTSD interview Arousal
- Direction: lower is better
- Score range: 7 to 49
- Data value: endpoint, 3 months, 6 months and 12 months

PTSD

- Outcome type: continuous outcome
- Scale used: PTSD interview Avoidance
- Direction: lower is better
- Score range: 6 to 42
- Data value: endpoint, 3 months, 6 months and 12 months

Identification

Sponsorship source: NIMH grant MH42178

Country: USA

Setting: survivors of rape recruited through local providers and victim assistance agencies, media and other research; intervention delivered in academic setting

Authors name: Edna Foa

Institution: Department of Psychiatry, Medical College of Pennsylvania

Foa 1991 (Continued)

Email: foa@auhs.edu

Year: 1991

Notes

Numbers reported for population characteristics refer to those who completed the therapies.

Included in meta-analysis

Concerns about process of assigning people to wait-list led to exclusion of this arm in meta-analyses.

Foa 1999

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: recruitment timescale not specified; 9-week intervention, 12-month follow-up: 1 year and 2 months

Location of study: Philadelphia, Pennsylvania, USA

Randomisation method: participants were randomly assigned to 1 of the following 4 conditions: PE, SIT, combined treatment (PE-SIT), or wait-list. Having enrolled 10 participants into wait-list control, more participants were assigned to the 3 active groups than to wait-list.

Ethics approvals: not given

Participants

Baseline characteristics

CBT (PE)

- *Participants (select at randomisation if available):* 25
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 29.28 (9.94)
- *Partnered:* not given
- *Randomised (N):* 25
- *Completed post-treatment assessment (N):* 23
- *Dropped out or removed prior to analysis (N):* 9
- *Numbers analysed at final applicable time point (N):* 16
- *Number of sessions:* not given
- *Treatment completion:* 23 (92%)

CBT (PE + SIT)

- *Participants (select at randomisation if available):* 30

Foa 1999 (Continued)

- *Gender*: 100% female participants
- *Age*: not given
- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 29.95 (6.97)
- *Partnered*: not given
- *Randomised (N)*: 30
- *Completed post-treatment assessment (N)*: 22
- *Dropped out or removed prior to analysis (N)*: 14
- *Numbers analysed at final applicable time point (N)*: 16
- *Number of sessions*: not given
- *Treatment completion*: 22 (73%)

CBT (SIT)

- *Participants (select at randomisation if available)*: 26
- *Gender*: 100% female participants
- *Age*: not given
- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 29.42 (9.69)
- *Partnered*: not given
- *Randomised (N)*: 26
- *Completed post-treatment assessment (N)*: 19
- *Dropped out or removed prior to analysis (N)*: 12
- *Numbers analysed at final applicable time point (N)*: 14
- *Number of sessions*: not given
- *Treatment completion*: 19 (73%)

Wait-list

- *Participants (select at randomisation if available)*: 15
- *Gender*: 100% female participants
- *Age*: not given
- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: not given

Foa 1999 (Continued)

- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 32.93 (5.89)
- *Partnered*: not given
- *Randomised (N)*: 15
- *Completed post-treatment assessment (N)*: 15
- *Dropped out or removed prior to analysis (N)*: 0
- *Numbers analysed at final applicable time point (N)*: 0
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Overall

- *Participants (select at randomisation if available)*: 96
- *Gender*: 100% female participants
- *Age, M (SD)*: 34.9 years (10.6 years)
- *Ethnicity*: 63% white, 36% Black
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: household income < USD 10,000 for a third of the participants; 38% > USD 30,000
- *Education (% high school, college or apprentice, university or years of education)*: 10% some high school, 18% high school diplomas, 41% some college education, 31% bachelor's degrees or higher
- *Employment (% employed; unemployed, other)*: most employed full-time (46%) or part-time (16%)
- *Sexual violence in adulthood*: 72% (69) victims of sexual violence as index trauma; 48% reported at least 1 physical or sexual assault in adulthood prior to the index trauma, and 48% reported at least 1 incident of childhood physical or sexual abuse
- *Comorbid conditions*: not given
- *Baseline PTSD*: not given
- *Partnered*: not given
- *Approached (N)*: 117
- *Ineligible (N)*: 13
- *Declined (N)*: 0
- *Other (N)*: 8
- *Randomised (N)*: 96
- *Completed post-treatment assessment (N)*: 79
- *Dropped out or removed prior to analysis (N)*: 35
- *Numbers analysed at final applicable time point (N)*: 46
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Inclusion criteria

- Participants met the criteria for PTSD based on DSM-III-R as their primary diagnosis

Exclusion criteria

- Current schizophrenia, bipolar disorder, organic mental disorder, alcohol or drug dependence, severe suicidal ideation
- Being in intimate relationship with assailant

Pretreatment: No significant differences in demographics or pretreatment measures of psychopathology. There was an observed trend towards group differences on employment status – 19% of PE participants were unemployed compared with 30% of SIT, 43% of PE-SIT, and 8% of wait-list participants. No pre- or post-treatment differences were detected between victims of sexual (n = 69) and nonsexual assault (n = 27).

Interventions
Intervention characteristics
Psychosocial interventions for survivors of rape and sexual assault experienced during adulthood (Review)
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Foa 1999 (Continued)

CBT (PE)

- *Planned number of intervention sessions*: 9 sessions totalling 14.5 h (2 sessions of 120 min + 7 sessions of 90 min)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: face-to-face
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: yes, PhD-level clinical psychologists were trained to use manuals that specified precise treatment guidelines for each session and received ongoing supervision by EB Foa and CV Dancu.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: no
- *Treatment fidelity (yes, no, unclear, with explanation)*: yes, in addition to precise treatment guidelines and regular supervision, 9% of sessions were videotaped and assessed for presence of 52 intervention components across the treatments. On average, therapists completed 93% (SD = 12%) of the components prescribed for a given session in the corresponding protocol
- *Intervention aim and theoretical basis*: to encourage clients to relive memories of the traumatic event (i.e. imaginal exposure) and confront situations that are avoided because they trigger distressing memories and thoughts. Based on description in [Foa 1998](#), PE focused on reliving the traumatic event in imagination (i.e. imaginal exposure). Homework assignments consisted of in vivo exposure to objectively safe situations that caused anxiety or were avoided.
- *Duration of intervention*: 5 weeks

CBT (PE + SIT)

- *Planned number of intervention sessions*: 9 sessions totalling 14.5 h (2 sessions of 120 min + 7 sessions of 90 min)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: face-to-face
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: as previous
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: no
- *Treatment fidelity (yes, no, unclear, with explanation)*: yes, as previous
- *Intervention aim and theoretical basis*: combination of PE and SIT elements as described, with the aim of demonstrating a superior outcome to either treatments alone
- *Duration of intervention*: 5 weeks

CBT (SIT)

- *Planned number of intervention sessions*: 9 sessions totalling 14.5 h (2 sessions of 120 min + 7 sessions of 90 min)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: face-to-face
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: as previous
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: no
- *Treatment fidelity (yes, no, unclear, with explanation)*: yes, as previous; however, 1 insignificant deviation was observed
- *Intervention aim and theoretical basis*: to teach clients various coping strategies to manage trauma-related anxiety (i.e. relaxation training, thought-stopping, CR and positive self-statements), adapted from [Veronen 1983](#). SIT focused on anxiety management skills (i.e. breathing retraining, thought-stopping, CR, positive affirmations and problem-solving). SIT homework assignments consisted of assigned practice of the instructed coping skill.
- *Duration of intervention*: 5 weeks

Wait-list

- *Planned number of intervention sessions*: N/A
- *Mode of delivery*: N/A
- *Format*: N/A
- *Therapist qualifications and training appropriate*: N/A
- *Research allegiance or conflict of interest*: N/A

Foa 1999 (Continued)

- *Treatment fidelity*: N/A
- *Intervention aim and theoretical basis*: N/A
- *Duration of intervention*: wait-list ceased after 5 weeks

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: PSS-I
- Direction: lower is better
- Score range: 0 to 51
- Data value: endpoint, 3 months, 6 months and 12 months

Depression

- Outcome type: continuous outcome
- Scale used: BDI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint, 3 months, 6 months and 12 months

Anxiety

- Outcome type: continuous outcome
- Scale used: STAI
- Direction: lower is better
- Score range: 20 to 80
- Data value: endpoint, 3 months, 6 months and 12 months

Treatment dropout

- Outcome type: dichotomous outcome

Identification

Sponsorship source: NIMH grant MH4217

Country: USA

Setting: academic/clinical

Comments: not clear how potential participants were approached and recruited into the study or setting of interventions. Extracted data included those for whom assessments were available rather than ITT.

Authors name: Edna Foa

Institution: Pennsylvania-Hahnemann University

Email: foa@mail.med.upenn.edu

Year: 1999

Notes

Included in meta-analysis

Foa 2005

Study characteristics

Methods

Study design: randomised controlled trial

Foa 2005 (Continued)

Study grouping: parallel group

Duration of study: recruitment took place January 1995 to September 2000

Location of study: Philadelphia, Pennsylvania, USA

Randomisation method: the study statistician assigned participants who provided informed consent to 1 of the 3 conditions using a weighted randomisation procedure such that participants were assigned to 1 of the active treatment conditions at a greater rate than to wait-list. Therapists made contact with the participants and arranged initial therapy appointments with those assigned to active treatment, and they also informed them of the specific treatment condition at the first session. Wait-list participants were informed by phone that they had been assigned to the wait-list condition.

Ethics approvals: not given

Participants

Baseline characteristics

CBT (PE)

- *Participants (select at randomisation if available):* 79
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Setting:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 34.0 (5.9)
- *Partnered:* not given
- *Randomised (N):* 79
- *Completed post-treatment assessment (N):* 52
- *Dropped out or removed prior to analysis (N):* 27
- *Numbers analysed at final applicable time point (N):* 52
- *Number of sessions:* not given
- *Treatment completion:* 52 (66%)

CBT (PE + CR)

- *Participants (select at randomisation if available):* 74
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Setting:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 31.1 (8.1)
- *Partnered:* not given
- *Randomised (N):* 74

Foa 2005 (Continued)

- Completed post-treatment assessment (N): 44
- Dropped out or removed prior to analysis (N): 30
- Numbers analysed at final applicable time point (N): 44
- Number of sessions: not given
- Treatment completion: 44 (59%)

Wait-list

- Participants (select at randomisation if available): 26
- Gender: 100% female participants
- Age: not given
- Ethnicity: not given
- Disability: not given
- Time since trauma: not given
- Setting: not given
- Education: not given
- Employment: not given
- Sexual violence in adulthood: not given
- Comorbid conditions: not given
- Baseline PTSD, M (SD): 33.3 (6.2)
- Partnered: not given
- Randomised (N): 26
- Completed post-treatment assessment (N): 25
- Dropped out or removed prior to analysis (N): 1
- Numbers analysed at final applicable time point (N): 25
- Number of sessions: N/A
- Treatment completion: N/A

Overall

- Participants (select at randomisation if available): 179
- Gender: 100% female participants
- Age, M (SD): 31.3 years (9.8 years)
- Ethnicity: 49.2% white, 43.6% Black, 7.3% other
- Disability: 7.4%
- Time since trauma, M (SD): 108 months (135.6 months)
- Setting: 47.4% < USD 15,000, 24.3% USD 15,001 to USD 30,000, 16.2% USD 30,001 to USD 50,000, 12.1% > USD 50,001
- Education (% high school, college or apprentice, university or years of education): 29.9% some/high school, 43.5% some college, 26.5% BA/BS or greater
- Employment (% employed; unemployed, other): 50.6% employed, 22.7% unemployed, 26.7% other
- Sexual violence in adulthood: 68.7%
- Comorbid conditions (%): Axis I condition 67.3%; the most common comorbid conditions were as follows: major depression (41.2%), social anxiety disorder (20.4%), specific phobias (20.4%), generalised anxiety disorder (13.9%) and panic disorder (11.9%). All other disorders were present at rates of 6% or less.
- Baseline PTSD: not given
- Partnered: 21.5%
- Approached (N): 285
- Ineligible (N): 56
- Declined (N): 19
- Other (N): 31
- Randomised (N): 179
- Completed post-treatment assessment (N): 121

Foa 2005 (Continued)

- *Dropped out or removed prior to analysis (N):* 58
- *Numbers analysed at final applicable time point (N):* 121
- *Number of sessions:* N/A
- *Treatment completion:* N/A

Inclusion criteria

- Adult women
- A primary diagnosis of PTSD related to a sexual or nonsexual assault that occurred at least 3 months prior to the evaluation

Exclusion criteria

- Being in an abusive relationship
- Current diagnosis of organic mental disorder, schizophrenia or psychotic disorder
- Unmedicated, symptomatic bipolar disorder; substance dependence
- Illiteracy in English
- Women deemed at high risk for suicidal behaviour or with recent history of serious self-injurious behaviour
- Women taking psychiatric medication were required to have been taking a stable dose for at least 3 months prior to entry, and they were asked to maintain this regimen during treatment.

Pretreatment: significant site differences were found on 5 demographic variables – age, index trauma, relationship status, employment and overall comorbidity – although sites did not differ on any specific disorder. There was also a trend for a difference in ethnicity.

Interventions

Intervention characteristics

CBT (PE)

- *Planned number of intervention sessions:* 9 to 12
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, 5 clinicians with doctoral degrees in clinical psychology administered the treatments at the CTSA; 6 clinicians with master's degrees in counselling or social work administered the treatments at WOAR. In the startup phase of the study, all CTSA and WOAR therapists were trained together in a 5-day workshop led by Foa and Dancu (PE) and a second 5-day workshop led by Clark (CR). Therapists were trained to use manuals that described the procedures for each session in great detail. All therapists received ongoing supervision at the therapists' site throughout the study from Foa, Dancu and Hembree.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* unclear, as PE treatment has been developed by the co-authors, but several areas where attempts were made to minimise bias
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, adherence to treatment protocol was monitored during weekly supervision meetings. Using adherence manuals, they randomly selected and rated videotapes of 141 therapy sessions (11.5% of 1227 sessions) for fidelity to the treatment manual. Ten raters trained to conduct the adherence ratings reviewed session videotapes, rated each essential component as present or absent, and monitored for protocol violations. Of these sessions, 29 (21%) were rated independently by 2 raters. Interrater reliability was 0.88. Therapists completed 97% of the components prescribed in the protocol. Seventeen protocol violations were observed in the 141 sessions; 24% of these were observed in the CTSA sessions and 76% in the WOAR sessions.
- *Intervention aim and theoretical basis:* the first aim of this study was to compare the efficacy of PE alone with a programme that combined PE with CR (PE/CR), a potential technique for ameliorating anxiety disorders. Participants in active treatment who, at the end of 8 sessions, reached at least 70% improvement in self-reported PTSD symptoms completed treatment after Session 9. The rest were offered up to 12 sessions. They hypothesised the following: 1) there would be

Foa 2005 (Continued)

greater reduction in PTSD and depression in PE and PE/CR than in wait-list; 2) PE/CR would be superior to PE alone.

- *Duration of intervention:* 9 weeks to 12 weeks

CBT (PE + CR)

- *Planned number of intervention sessions:* 9 to 12
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* as previous
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* as previous
- *Treatment fidelity (yes, no, unclear, with explanation):* as previous
- *Intervention aim and theoretical basis:* the procedure in the PE/CR treatment was identical to PE alone with 2 exceptions. First, Session 3 was devoted to presenting the idea that post-trauma symptoms are maintained in part by trauma-related thoughts and beliefs and to practising CR. Specifically, participants were taught to identify and challenge erroneous and unhelpful beliefs and instructed to record and challenge them for homework using a daily diary. Imaginal exposure was introduced in Session 4, following a review of the preceding week's diaries. Second, all subsequent sessions included 30 min to 45 min of imaginal exposure followed by 15 min to 25 min of CR. Participants in PE/CR were given the same amount of exposure homework as those in PE, and they also practised CR using their diaries.
- *Duration of intervention:* 9 weeks to 12 weeks

Wait-list

- *Planned number of intervention sessions:* N/A
- *Mode of delivery:* N/A
- *Format:* N/A
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* participants were assigned a therapist who informed them that they would receive treatment in 9 weeks. Therapists encouraged the wait-list participants to call at anytime if they were having problems. In addition, the therapists called the wait-list participants halfway through the waiting period to check in with them and determine their state.
- *Duration of intervention:* N/A

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: PSS-I
- Direction: lower is better
- Score range: 0 to 51
- Data value: endpoint, 3 months, 6 months and 12 months

Depression

- Outcome type: continuous outcome
- Scale used: BDI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint, 3 months, 6 months and 12 months

Treatment dropout

- Outcome type: dichotomous outcome

Adverse events

Foa 2005 (Continued)

- Outcome type: adverse event
- Notes: there was no breakdown by group, so we could only include the total for the study. Twelve serious adverse events led to termination in the study, 6 of which are included in the postrandomisation removal category in [Figure 1](#) (4 participants reassaulted, 1 developing a life-threatening illness and 1 death). The remaining 6 serious adverse events were classified as dropouts (4 had severe depression and suicidal ideation that required immediate intervention, 2 of which were hospitalised, and 2 exhibited extreme dissociative symptoms).
- Adverse events: 12 serious adverse events led to termination in the study, 6 of which are included in the postrandomisation removal category (4 participants reassaulted, 1 developing a life-threatening illness and 1 death). The remaining 6 serious adverse events were classified as dropouts (4 had severe depression and suicidal ideation that required immediate intervention, 2 of which were hospitalised, and 2 exhibited extreme dissociative symptoms).

Identification	<p>Sponsorship source: this study was supported by NIMH grant MH42178.</p> <p>Country: USA</p> <p>Setting: CTSA, an academic centre, or WOAR, a community clinic for rape survivors with no experience of CBT delivery</p> <p>Authors name: Edna Foa</p> <p>Institution: University of Pennsylvania</p> <p>Email: foa@mail.med.upenn.edu</p> <p>Year: 2005</p>
Notes	Included in meta-analysis

Foa 2006

Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Duration of study: no recruitment timeframe stated: 4-week intervention, with the last follow-up at 12 months post-intervention</p> <p>Ethics approvals: not given</p> <p>Location of study: Philadelphia, Pennsylvania, USA</p> <p>Randomisation method: participants were randomly assigned to brief CBT or an assessment condition (no-treatment control); 1 year into the study, the SC condition was added, and randomisation was adjusted accordingly to increase the probability of participants being assigned to the SC condition.</p>
Participants	<p>Baseline characteristics</p> <p>CBT (brief CBT)</p> <ul style="list-style-type: none"> • <i>Participants (at randomisation):</i> 31 • <i>Gender:</i> 100% female participants • <i>Age:</i> not given • <i>Ethnicity:</i> not given • <i>Disability:</i> not given

Foa 2006 (Continued)

- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: 77%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 34.03 (7.86)
- *Partnered*: not given
- *Randomised (N)*: 31
- *Completed post-treatment assessment (N)*: 22
- *Dropped out or removed prior to analysis (N)*: 9
- *Numbers analysed at final applicable time point (N)*: 22
- *Number of sessions*: not given
- *Treatment completion*: 22 (71%)

Humanistic (SC)

- *Participants (select at randomisation if available)*: 29
- *Gender*: 100% female participants
- *Age*: not given
- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma in months*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: 38%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 35.07 (7.63)
- *Partnered*: not given
- *Randomised (N)*: 29
- *Completed post-treatment assessment (N)*: 24
- *Dropped out or removed prior to analysis (N)*: 5
- *Numbers analysed at final applicable time point (N)*: 24
- *Number of sessions*: not given
- *Treatment completion*: 24 (82.8%)

Assessment control (AC)

- *Participants (at randomisation)*: 30
- *Gender*: 100% female participants
- *Age*: not given
- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: 73%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 33.17 (6.48)
- *Partnered*: not given
- *Randomised (N)*: 30

Foa 2006 (Continued)

- Completed post-treatment assessment (N): 20
- Dropped out or removed prior to analysis (N): 10
- Numbers analysed at final applicable time point (N): 20
- Number of sessions: not given
- Treatment completion: 20 (66.7%)

Overall

- Participants (randomisation): 90
- Gender: 100% female participants
- Age, M (SD): 33.7 years (11.13 years)
- Ethnicity: 31.3% white, 62.7% Black, 6% other
- Disability: not given
- Time since trauma, M (SD): 20.5 d (range of 2 d to 46 d)
- Income: 27.2% > USD 30,000, 42.9% USD 10,000 to USD 30,000, 29.9% < USD 10,000
- Education (% high school, college or apprentice, university or years of education): 36.5% high school education or less, 43.9% some technical school or college education, 4.9% college education
- Employment: not given
- Sexual violence in adulthood: 63%
- Comorbid conditions: not given
- Baseline PTSD: not given
- Partnered: 15%
- Approached: not given
- Ineligible: not given
- Declined: not given
- Other: not given
- Randomised (N): 90
- Completed post-treatment assessment (N): 66
- Dropped out or removed prior to analysis (N): 24
- Numbers analysed at final applicable time point (N): 66

Inclusion criteria

- Recent survivors of sexual assault or nonsexual assault
- Met DSM-IV symptom (not duration) criteria for PTSD

Exclusion criteria

- Women who were assaulted by an intimate partner with whom they had an ongoing relationship
- Primary diagnoses of organic mental disorder, schizophrenia, bipolar disorder
- Current alcohol or drug dependence

Pretreatment: 77% of the brief CBT and 73% of the assessment condition reported an index trauma of sexual assault, but only 38% of the SC condition reported a sexual assault as the index trauma.

Interventions

Intervention characteristics

CBT (brief CBT)

- Planned number of intervention sessions: 4 × 2-hour sessions
- Mode of delivery (face-to-face, online, video, telephone, blend, with explanation): face-to-face
- Format (group, individual, blend): individual
- Therapist qualifications and training appropriate (yes, no, unclear, with explanation): yes, masters- and doctoral-level therapists who received ongoing supervision and followed manuals that specified guidelines for each session conducted the interventions.

Foa 2006 (Continued)

- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* unclear, the study builds on [Foa 1995](#) and there is clear expectation that brief CBT should be superior; however, there are several measures to reduce any risk of research allegiance.
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, tapes of intervention sessions were reviewed in weekly supervision to ensure adherence.
- *Intervention aim and theoretical basis:* used cognitive behavioural procedures that have been found effective for alleviating chronic PTSD in assault survivors ([Foa 1999](#); [Foa 1991](#)). These included 1) education about the normal reactions to assault; 2) breathing/relaxation training; 3) recounting the assault (imaginal exposure); 4) approaching feared, but safe, situations (in vivo exposure); and 5) CR.
- *Duration of intervention:* 4 weeks

Humanistic (SC)

- *Planned number of intervention sessions:* 4 × 2-hour sessions
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* as previous
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, tapes of intervention sessions were reviewed in weekly supervision to ensure adherence.
- *Intervention aim and theoretical basis:* intervention consisted of active listening only. Neither discussion of assault-related symptoms nor procedures aimed at promoting processing of the traumatic event were implemented. Also differed from assessment condition as there as no focus on symptoms
- *Duration of intervention:* 4 weeks

Assessment control

- *Planned number of intervention sessions:* 4 × 2-hour sessions
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* the AC condition consisted of 4 meetings weekly for 2 h each that focused on a thorough assessment of each of the PTSD symptoms and post-assault functioning by a PTSD clinician.
- *Duration of intervention:* 4 weeks

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: PSS-I
- Direction: lower is better
- Score range: 0 to 51
- Data value: endpoint, 3 months and 12 months

PTSD

- Outcome type: continuous outcome
- Scale used: PSS-SR
- Direction: lower is better
- Score range: 0 to 119
- Data value: endpoint, 3 months and 12 months

Depression

Foa 2006 (Continued)

- Outcome type: continuous outcome
- Scale used: BDI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint, 3 months and 12 months

Anxiety

- Outcome type: continuous outcome
- Scale used: BAI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint, 3 months and 12 months

Treatment dropout

- Outcome type: dichotomous outcome

Trauma-related beliefs

- Outcome type: continuous outcome
- Scale used: PBRS-self
- Direction: higher is better
- Score range: 0 to 6
- Data value: endpoint, 12 months

Identification

Sponsorship source: NIMH grant MH42173

Country: USA

Setting: urban clinic for the treatment and study of anxiety; recruitment through EDs and other medical settings, police, victim agencies and media

Authors name: Edna Foa

Institution: University of Pennsylvania; University of Washington; Case Western Reserve University

Email: foa@mail.med.upenn.edu

Year: 2006

Notes

The SC arm was added later, and systematic differences in the prevalence of sexual trauma were identified. Therefore, this group has been omitted. Not an ITT analysis, as data were only collected at follow-up from intervention completers

Included in meta-analysis

Galovski 2016

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: not given

Ethics approvals: all study procedures were approved by the IRB at the University of Missouri-St. Louis.

Galovski 2016 (Continued)

Location of study: St. Louis, Missouri, USA

Randomisation method: using a 1:1 allocation ratio, a computer-generated randomisation sequence randomised eligible participants to the ssmCPT condition or sleep-directed hypnosis condition.

Participants

Baseline characteristics

CBT (CPT)

- *Participants (at randomisation):* 56
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* not given
- *Education, M (SD) years:* 13.5 (3.19)
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 69.23 (15.74)
- *Partnered:* not given
- *Randomised (N):* 56
- *Completed post-treatment assessment (N):* 25
- *Dropped out or removed prior to analysis (N):* 21
- *Numbers analysed at final applicable time point (N):* 35
- *Number of sessions:* not given
- *Treatment completion:* 25 (52%)

CBT (CPT + hypnosis)

- *Participants (at randomisation):* 52
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* not given
- *Education, M (SD) years:* 14.7 (2.46)
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 72.48 (15.01)
- *Partnered:* not given
- *Randomised (N):* 52
- *Completed post-treatment assessment (N):* 29
- *Dropped out or removed prior to analysis (N):* 22
- *Numbers analysed at final applicable time point (N):* 30
- *Number of sessions:* not given
- *Treatment completion:* 26 (59%)

Overall

- *Participants (at randomisation):* 108

Galovski 2016 (Continued)

- *Gender*: 100% female participants
- *Age, M (SD)*: 36.87 years (11.8 years)
- *Ethnicity*: 50% predominantly Black; 50% predominantly white; 20% mixed race; 3% Hispanic
- *Disability*: not given
- *Time since trauma, M (SD)*: 196 months (170.4 months)
- *Income*: 74% < USD 20,000
- *Education (% high school, college or apprentice, university or years of education; M (SD) years)*: 50% at least some post-high school education; 14.16 years (2.89 years)
- *Employment*: not given
- *Sexual violence in adulthood*: 63% sexual violence in adulthood; complex trauma histories, with lifetime endorsements of child sexual abuse 71%, child physical abuse 58%, adult criminal victimisation 32% and domestic violence 56%
- *Comorbid conditions*: not given
- *Baseline PTSD*: not given
- *Partnered*: 46%
- *Approached (N)*: 181
- *Ineligible (N)*: 62
- *Declined (N)*: 11
- *Other (N)*: 0
- *Randomised (N)*: 108
- *Completed post-treatment assessment (N)*: 54
- *Dropped out or removed prior to analysis (N)*: 43
- *Numbers analysed at final applicable time point (N)*: 65
- *Number of sessions*: not given
- *Treatment completion*: 51 (47%)

Inclusion criteria

- Female gender
- Diagnosis of PTSD secondary to sexual or physical assault
- Clinically significant sleep impairment as indicated by a severity score of 3 or more on the CAPS sleep impairment symptom
- At least 3 months post-trauma at initial assessment
- Stable on any psychotropic medication for at least 1 month

Exclusion criteria

- Psychosis
- Learning disability
- Active suicidality, parasuicidality
- Current drug or alcohol dependence
- Individuals currently in an abusive relationship or being stalked
- No prior therapy with CPT, or current trauma- or sleep-focused therapy

Pretreatment: years of education was the only difference detected, being slightly higher in the hypnosis group.

Interventions

Intervention characteristics

CBT (cognitive processing theory)

- *Planned number of intervention sessions*: 12
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: face-to-face
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: unclear, questionable whether the therapists were sufficiently experienced to deliver the CPT and hypno-

Galovski 2016 (Continued)

sis, given the high level of dropout from treatment and average scores on independent ratings, although study was strong on supervision and fidelity checks.

- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, the CPT and hypnosis manuals and relevant readings were provided in the training. Expert CPT clinicians not otherwise affiliated with the study reviewed and rated treatment sessions for adherence and competence. Scores were acceptable, although some concerns around the drop out rate for 1 therapist and unclear if detected in the fidelity assessment
- *Intervention aim and theoretical basis:* following the 3 weeks of daily symptom monitoring, ssm-CPT participants received CPT (see [Resick 2010](#) for a complete protocol). CPT is predominantly a cognitive therapy in which patients are taught to identify, question, challenge and replace faulty assumptions and thoughts about the traumatic event and its implications in their current lives. While the patients engage with the traumatic memory, they are able to allow natural affect to run its course. CPT first targets specific, inaccurate interpretations of the trauma itself and then targets current and future maladaptive and inaccurate beliefs about world, self and others across a number of belief systems typically disrupted after experiencing a traumatic event.
- *Duration of intervention:* 15 weeks; 3 weeks of symptom monitoring plus 12 weeks of CPT

CBT (CPT + hypnosis)

- *Planned number of intervention sessions:* 15
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* as before
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* as before
- *Intervention aim and theoretical basis:* researchers hypothesised that improvements in sleep realised during hypnosis would augment CPT, such that PTSD symptom reduction (during CPT) would be greater in the CPT + hypnosis condition relative to the CPT condition. Hypnosis was conducted in accordance with a manual devised for the trial following [Wright 1987](#).
- *Duration of intervention:* 15 weeks

Outcomes
PTSD

- Outcome type: continuous outcome
- Scale used: CAPS
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, 3 months

Depression

- Outcome type: continuous outcome
- Scale used: BDI-II
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint, 3 months

Treatment dropout

- Outcome type: dichotomous outcome

Identification

Sponsorship source: National Institutes of Health

Country: USA

Setting: community sample recruited through flyers, advertisements, referrals and word-of-mouth; academic setting for intervention

Galovski 2016 (Continued)

Authors name: Tara E Galovski
Institution: University of Missouri
Email: galovskit@msx.umsl.edu
Year: 2016

Notes Not included in meta-analysis

Gray 2020
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: recruiting began during November 2015 and was completed by mid-May 2016; all treatments were completed by June 2016. Follow-ups to 1 year were completed by August 2017.

Ethics approvals: the study protocol and informed consent were approved by the NEIRB. Following NEIRB guidelines, the protocol and all aspects of participation were reviewed with participants, and signed informed consent was obtained from each participant.

Location of study: suburban municipality in northern San Diego County, California, USA

Randomisation method: participants were admitted to the study in cohorts of 10 and randomly assigned to treatment or control groups by the site manager. This assignment was based on a list of random numbers, previously generated at an independent location using Microsoft Excel 2016's random number function.

Participants
Baseline characteristics

Behavioural (RTM)

- *Participants (at randomisation):* 15
- *Gender:* not given
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 43.6 (2.5)
- *Partnered:* not given
- *Randomised (N):* 15
- *Completed post-treatment assessment (N):* 14
- *Dropped out or removed prior to analysis (N):* 1
- *Numbers analysed at final applicable time point (N):* 14
- *Number of sessions, M (SD):* 3 (0)
- *Treatment completion:* 15 (100%)

Wait-list

Gray 2020 (Continued)

- *Participants (at randomisation)*: 15
- *Gender*: not given
- *Age in years*: not given
- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 43.6 (3.5)
- *Partnered*: not given
- *Randomised (N)*: 15
- *Completed post-treatment assessment (N)*: 15
- *Dropped out or removed prior to analysis (N)*: 0
- *Numbers analysed at final applicable time point (N)*: 15
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Overall

- *Participants (at randomisation)*: 30
- *Gender*: 100% female participants
- *Age, M (SD)*: 33.7 years (14 years)
- *Ethnicity*: 76% Caucasian (understood to be white), 7% Native American, 10% Hispanic, 3% African American, 3% Asian
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment (% employed; unemployed, other)*: 47% employed
- *Sexual violence in adulthood*: 73%
- *Comorbid conditions*: not given
- *Baseline PTSD*: not given
- *Partnered*: not given
- *Approached (N)*: 46
- *Ineligible (N)*: 10
- *Declined (N)*: 6
- *Other (N)*: 0
- *Randomised (N)*: 30
- *Completed post-treatment assessment (N)*: 29
- *Dropped out or removed prior to analysis (N)*: 1
- *Numbers analysed at final applicable time point (N)*: 29
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Inclusion criteria

- Symptom assessments for PTSD above commonly used diagnostic thresholds (PSS-I > 20)
- Autonomic arousal observable to the interviewer (e.g. tearing, tensing, flushing, tremors, hesitation, changes in voice tonality) while the participant recounts the index trauma
- Reports of at least 1 flashback or nightmare during the preceding month

Gray 2020 (Continued)

Exclusion criteria

- Comorbid DSM-IV Axis I or II disorders sufficiently severe to interfere with the participant's ability to complete treatment
- PTSD symptoms judged by the interviewer or clinician to be part of the participant's identity structure
- Individuals judged by the interviewer or clinician to be incapable of sustained attention, whether through florid psychosis, inebriation or other observable alterations of consciousness; persons unable to identify a discreet traumatic event for treatment targeting

Pretreatment: none reported

Interventions

Intervention characteristics

Behavioural (RTM)

- *Planned number of intervention sessions:* 3 (120 min each)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, 1 credentialed PhD-level clinical psychologist, experienced in delivering the RTM protocol, delivered the treatments.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* yes, the authors were involved in the original development.
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, all screening and treatment sessions were video-recorded on secure digital media and stored on HIPAA-compliant cloud servers for assessment of treatment fidelity. Three experts in the administration of the RTM protocol (2 PhD-level psychologists and 1 with a Master of Social Work degree) periodically reviewed treatment videos, evaluating them for 1) adherence to the RTM procedure and 2) skills used by the clinician to track the client's arousal levels. Raters recorded compliance information using a standardised, in-house, 20-element checklist. The level of compliance was found to be high.
- *Intervention aim and theoretical basis:* RTM relies upon the hypothesis that trauma memories may be reactivated and updated using the reconsolidation mechanism (Gray 2019; Lee 2017; Nader 2000; Tylee 2017). After an activation that is too brief to support extinction, the target memory is believed to become malleable, and new information, relevant to the perceived threat, can be incorporated into its structure (Fernández 2016; Suzuki 2004; Tylee 2017). We hypothesise that reconsolidation may be used to change structural elements of the memory related to its perceptual salience and, by reducing the impact of the memory, render it nontraumatising.
- *Duration of intervention:* 3 weeks

Wait-list

- *Planned number of intervention sessions:* N/A
- *Mode of delivery:* N/A
- *Format:* N/A
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* N/A
- *Duration of intervention:* N/A

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: PSS-I
- Direction: lower is better
- Score range: 0 to 51
- Data value: endpoint

Gray 2020 (Continued)

Adverse events

- Outcome type: dichotomous outcome

Treatment dropout (intervention only)

- Outcome type: dichotomous outcome

Identification

Sponsorship source: this research was supported by a grant from the Blue Angels Foundation.

Country: USA

Setting: female US veterans and active-duty service members recruited from veterans' groups and mental health services; all treatments and evaluations were performed in a private office suite dedicated to the study in a professional office complex.

Comments: N/A

Authors name: Richard Gray

Institution: Research and Recognition Project, Corning, New York

Email: richard.gray@randrproject.com

Year: 2020

Notes

Communicated with the authors(s) as part of the review

Included in meta-analysis

Katz 2014

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: not given

Ethics approvals: study approved by local internal review board

Location of study: Seattle, Washington, USA

Randomisation method: not given

Participants

Baseline characteristics

CBT (PE)

- *Participants (at randomisation):* 17
- *Gender:* 100% female participants
- *Age, M:* 36 years
- *Ethnicity:* 12% African American, 12% Hispanic, 41% white non-Hispanic, 35% missing information
- *Disability:* 71% (This was reported with those who were unemployed and unable to work or find work.)
- *Time since trauma:* not given
- *Income:* not given
- *Education (% high school, college or apprentice, university or years of education):* 59% college or higher

Katz 2014 (Continued)

- *Employment (% employed, unemployed, other):* 12% employed
- *Sexual violence in adulthood:* 47%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 66.2 (12.9)
- *Partnered:* 6%
- *Randomised (N):* 17
- *Completed post-treatment assessment (N):* 10
- *Dropped out or removed prior to analysis (N):* 7
- *Numbers analysed at final applicable time point (N):* 10
- *Number of sessions, M:* 5.2
- *Treatment completion:* 10 (59%)

Integrative therapy (holographic reprocessing)

- *Participants (at randomisation):* 17
- *Gender:* 100% female participants
- *Age, M:* 45 years
- *Ethnicity:* 24% African American, 6% Hispanic, 41% white non-Hispanic, 29% missing information
- *Disability:* 47% (This was reported with those who were unemployed and unable to work or find work.)
- *Time since trauma:* not given
- *Income:* not given
- *Education (% high school, college or apprentice, university or years of education):* 42% college or higher
- *Employment (% employed; unemployed, other):* 24% employed
- *Sexual violence in adulthood:* 71%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 54.31 (13.6)
- *Partnered:* 24%
- *Randomised (N):* 17
- *Completed post-treatment assessment (N):* 16
- *Dropped out or removed prior to analysis (N):* 1
- *Numbers analysed at final applicable time point (N):* 16
- *Number of sessions, M:* 10
- *Treatment completion:* 16 (94%)

Humanist (person-centred therapy)

- *Participants (select at randomisation if available):* 17
- *Gender:* 100% female participants
- *Age, M:* 42 years
- *Ethnicity:* 24% African American, 17% Hispanic, 47% white non-Hispanic, 12% missing information
- *Disability:* 41% (This was reported with those who were unemployed and unable to work or find work.)
- *Time since trauma:* not given
- *Income:* not given
- *Education (% high school, college or apprentice, university or years of education):* 54% college or higher
- *Employment (% employed, unemployed, other):* 24% employed
- *Sexual violence in adulthood:* 41%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 51.6 (17.8)
- *Partnered:* 29%
- *Randomised (N):* 17

Katz 2014 (Continued)

- Completed post-treatment assessment (N): 11
- Dropped out or removed prior to analysis (N): 6
- Numbers analysed at final applicable time point (N): 11
- Number of sessions: not given
- Treatment completion: 11 (65%)

Overall

- Participants (at randomisation): 51
- Gender: 100% female participants
- Age, M (SD): 42 years (12.34 years)
- Ethnicity: 20% African American, 12% Hispanic; 43% white non-Hispanic, 25% missing information
- Disability: 53% (This was reported with those who were unemployed and unable to work or find work.)
- Time since trauma: not given
- Income: not given
- Education (% high school, college or apprentice, university or years of education): 48% college or higher
- Employment (% employed, unemployed, other): 20% employed
- Sexual violence in adulthood: 53% sexual violence in adulthood, 86% MST, 71% domestic abuse, 80% child sexual abuse
- Comorbid conditions: not given
- Baseline PTSD: not given
- Partnered: 20%
- Approached (N): 53
- Ineligible (N): 2
- Declined (N): 0
- Other (N): 0
- Randomised (N): 51
- Completed post-treatment assessment (N): 37
- Dropped out or removed prior to analysis (N): 14
- Numbers analysed at final applicable time point (N): 37
- Number of sessions: not given
- Treatment completion: 37 (73%)

Inclusion criteria: history of sexual trauma (e.g. childhood, adult or military sexual assault; molestation; or domestic violence)

Exclusion criteria

- Suicidal attempts or hospitalisations in the last 6 months prior to treatment
- Psychotic symptoms or suffering from a psychotic-related disorder
- Actively using alcohol or drugs for at least 3 months prior to the study
- Strong tendency to dissociate to the point that it could interfere with ability to participate in this study

Pretreatment: none reported

Interventions

Intervention characteristics

CBT (PE)

- Planned number of intervention sessions: 10
- Mode of delivery (face-to-face, online, video, telephone, blend, with explanation): face-to-face
- Format (group, individual, blend): individual

Katz 2014 (Continued)

- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, trainees were given weekly individual supervision by the licenced psychologist.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, as a post hoc fidelity test, 2 chart notes were randomly printed for each participant in the study. Two raters (certified research assistants) sorted the notes into the 3 groups following the guidelines of a brief written description of each of the 3 therapies. Both sorted the notes with 100% accuracy. Based on supervision and documentation of treatment, it appears that the therapists in this study (minus 1) followed their respective protocols.
- *Intervention aim and theoretical basis:* using imaginal exposure and in vivo exposure, clients reduce their fear, desensitise to memories, and learn that they can venture to places previously avoided.
- *Duration of intervention:* 10 weeks

Integrative therapy (holographic reprocessing)

- *Planned number of intervention sessions:* 10
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, trainees were given weekly individual supervision by the licenced psychologist.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* yes, the lead researcher also designed the therapy, and it is unclear if that researcher also delivered the therapies and if other therapists were listed as co-authors.
- *Treatment fidelity (yes, no, unclear, with explanation):* yes
- *Intervention aim and theoretical basis:* holographic reprocessing uses a low-arousing method of revisiting a formative event (e.g. representative of the person's hologram) to facilitate holistic reappraisal and insight. In reprocessing, participants do not revisit an act of trauma itself, as this is not an exposure treatment. Clients are instructed to recall the event as a distanced observer, describing it from the third person and noticing a larger context for the event, which facilitates broad cognitive reappraisals.
- *Duration of intervention:* 10 weeks

Humanist (person-centred therapy)

- *Planned number of intervention sessions:* 10
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, trainees were given weekly individual supervision by the licenced psychologist.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* yes
- *Intervention aim and theoretical basis:* PCT focuses on providing support and discussing and understanding here-and-now issues that are generated by clients.
- *Duration of intervention:* 10 weeks

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: PCL-C
- Direction: lower is better
- Score range: 17 to 85
- Data value: endpoint

Global mental health

- Outcome type: continuous outcome
- Scale used: BSI

Katz 2014 (Continued)

- Direction: lower is better
- Score range: 0 to 112
- Data value: endpoint

Depression

- Outcome type: continuous outcome
- Scale used: BSI
- Direction: lower is better
- Score range: 0 to 112
- Data value: endpoint

Anxiety

- Outcome type: continuous outcome
- Scale used: BSI
- Direction: lower is better
- Score range: 0 to 112
- Data value: endpoint

Self-blame

- Outcome type: continuous outcome
- Scale used: PTCI
- Direction: lower is better
- Score range: 33 to 231
- Data value: endpoint

Adverse events

- Outcome type: adverse event

Treatment dropout

- Outcome type: dichotomous outcome

Trauma-related beliefs

- Outcome type: continuous outcome
- Scale used: PCTI-total
- Direction: lower is better
- Score range: 33 to 231
- Data value: endpoint

Identification

Sponsorship source: not given

Country: USA

Setting: VA medical centre (women's mental health clinic); female veterans with sexual trauma histories seeking psychotherapy

Authors name: Lori S Katz

Institution: VA Puget Sound Healthcare System

Email: lori.katz@va.gov

Year: 2014

Notes

Included in meta-analysis

Kelly 2021

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel

Duration of study: enrolment from 2016 to 2020

Ethics approvals: the study was approved by the Emory University IRB and the appropriate VA committees

Location of study: Atlanta, Georgia, USA

Randomisation method: participants within each of 9 cohorts were randomised to the 2 groups by the block randomisation algorithm "random sorting using maximum allowable percent deviation" using the PASS v.15 power analysis software package. Randomisation sequences were generated for each cohort, initially in blocks of 24, then in 20 based on enrolment numbers. Using the randomisation sequences, the study co-ordinator set up sequentially numbered, sealed envelopes containing randomisation assignment for use at each baseline data collection. Once participants completed baseline data collection, the data collector opened the envelope to determine randomisation allocation and informed the participant and study co-ordinator.

Participants

Baseline characteristics

Other psychologically oriented interventions (trauma-sensitive yoga)

- *Participants (at randomisation):* 58
- *Gender:* not given
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 50.80 (11.74)
- *Partnered:* not given
- *Randomised (N):* 58
- *Completed post-treatment assessment (N):* 38
- *Dropped out or removed prior to analysis (N):* 20
- *Numbers analysed at final applicable time point (N):* 28
- *Number of sessions:* not given
- *Treatment completion:* 35 (60.3%)

CBT (CPT)

- *Participants (at randomisation):* 46
- *Gender:* not given
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* not given

Kelly 2021 (Continued)

- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 50.37 (12.11)
- *Partnered*: not given
- *Randomised (N)*: 46
- *Completed post-treatment assessment (N)*: 20
- *Dropped out or removed prior to analysis (N)*: 26
- *Numbers analysed at final applicable time point (N)*: 19
- *Number of sessions*: not given
- *Treatment completion*: 16 (34.8%)

Overall

- *Participants (at randomisation)*: 104
- *Gender*: 100% female participants
- *Age, M (SD)*: 48.38 years (11.1 years)
- *Ethnicity*: 91.3% African American
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: 54% USD 2000 or more per month
- *Education (% high school, college or apprentice, university or years of education)*: 16 years (median)
- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: not given
- *Baseline PTSD*: not given
- *Partnered*: 28.2%
- *Approached (N)*: 466
- *Ineligible (N)*: 225
- *Declined (N)*: 89
- *Other (N)*: 48
- *Randomised (N)*: 104
- *Completed post-treatment assessment (N)*: 58
- *Dropped out or removed prior to analysis (N)*: 46
- *Numbers analysed at final applicable time point (N)*: 47
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Inclusion criteria: PTSD related to MST diagnosed in the PTSD clinic or in the first study assessment. MST is defined as the experience of sexual assault or repeated threatening sexual harassment during military service.

Exclusion criteria

- Severe psychosis; current, active suicidal intent or plan
- Current moderate or severe alcohol or substance use disorder
- Moderate or severe cognitive impairment
- Current engagement in trauma-focused treatment or yoga practice or other activity at odds with the study interventions

Pretreatment: none reported

Interventions

Intervention characteristics

Kelly 2021 (Continued)

Other psychologically oriented interventions (trauma-sensitive yoga)

- *Planned number of intervention sessions:* 10 × 1 h
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* group
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, David Emerson, the developer of TCTSY, trained the yoga facilitators and provided weekly consultation to them during the 9 intervention cohorts
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* unclear, no explanation
- *Intervention aim and theoretical basis:* the theoretical framework of the study is psychoneuroimmunologic. Yoga is theorised to have the opposite effects on the autonomic nervous system and stress response than the dysregulating effects associated with PTSD. TCTSY, the experimental intervention in this randomised controlled trial, was developed for civilian women survivors of complex trauma, specifically childhood sexual trauma, with chronic PTSD. TCTSY focuses on interoception – that is, the sense of the physiological condition of the body – in Hatha style yoga and addresses themes related to establishing safety, individual choice, being in the present moment and taking effective action
- *Duration of intervention:* 10 weeks

CBT (CPT)

- *Planned number of intervention sessions:* 12 × 90 min
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* group
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, the CPT intervention was conducted by VA clinicians (psychologists and licenced clinical social workers) certified in CPT.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* unclear, no explanation
- *Intervention aim and theoretical basis:* the sessions focused on identifying how thoughts change as a result of trauma exposure and ways in which to evaluate maladaptive thoughts and create alternative thoughts.
- *Duration of intervention:* 12 weeks

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: CAPS-5
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, 3 months

PTSD

- Outcome type: continuous outcome
- Scale used: PCL-5
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, 3 months

Adverse events

- Outcome type: adverse event

Treatment dropout

- Outcome type: dichotomous outcome

Kelly 2021 (Continued)

- Direction: lower is better
- Notes: 2 participants in the CPT group withdrew due to increased psychological distress and were referred for individual therapy.

Identification

Sponsorship source: this material is based upon work supported by the Department of Veterans Affairs, VHA, Office of Research and Development, Health Services Research and Development, grant no. 5I01HX001087-02

Country: USA

Setting: women veterans with PTSD related to MST who were service users of a VA Health Care System (outpatients); Women's Wellness Clinics; and Primary Care Clinics

Authors name: Ursula Kelly

Institution: Atlanta VA Health Care System

Email: Ursula.Kelly@va.gov

Year: 2021

Notes

Included in meta-analysis

ClinicalTrials.gov: NCT02640690

Krakow 2001
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: 4 years (1995 to 1999)

Ethics approvals: University of New Mexico Health Sciences Center IRB

Location of study: New Mexico, USA

Randomisation method: participants mailed a postcard, and the postcard's time and date were logged into a computer and entered into a previously generated list of numbers that randomly assigned participants.

Participants

Baseline characteristics

CBT (imagery rehearsal therapy)

- *Participants (at randomisation):* 88
- *Gender:* 100% female participants
- *Age, M (SD):* completer 40 years (11.2 years), non-completer 37 years (12.7 years)
- *Ethnicity:* 69% non-Hispanic white, 31% other (mostly Hispanic)
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* 49% < USD 10,000, 51% > USD 10,000
- *Education (% high school, college or apprentice, university or years of education):* 38% college degree
- *Employment:* not given
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* not given

Krakow 2001 (Continued)

- *Baseline PTSD, M (SD):* 81.88 (16.96)
- *Partnered:* 38%
- *Randomised (N):* 88
- *Completed post-treatment assessment (N):* 44
- *Dropped out or removed prior to analysis (N):* 34
- *Numbers analysed at final applicable time point (N):* 54
- *Number of sessions:* not given
- *Treatment completion:* 66 (75%)

Wait-list

- *Participants (select at randomisation if available):* 80
- *Gender:* 100% female participants
- *Age, M (SD):* completer 36 years (9.3 years), non-completer 31 years (10.5 years)
- *Ethnicity:* 55% non-Hispanic white, 45% other (mostly Hispanic)
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* 40% < USD 10,000, 60% > USD 10,000
- *Education (% high school, college or apprentice, university or years of education):* 39% college degree
- *Employment:* not given
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 79.62 (24.37)
- *Partnered:* 43%
- *Randomised (N):* 80
- *Completed post-treatment assessment (N):* 52
- *Dropped out or removed prior to analysis (N):* 20
- *Numbers analysed at final applicable time point (N):* 60
- *Number of sessions:* N/A
- *Treatment completion:* N/A

Overall

- *Participants (at randomisation):* 168
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* 62.5% non-Hispanic white, 37.5% other (mostly Hispanic)
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* 44% < USD 10,000, 56% > USD 10,000
- *Education (% high school, college or apprentice, university or years of education):* 38% college degree
- *Employment:* not given
- *Sexual violence in adulthood:* 100% sexual violence in adulthood, 58% multiple exposures, 90% abused as children
- *Comorbid conditions:* not given
- *Baseline PTSD:* 85% reported CAPS score > 65
- *Partnered:* 40%
- *Approached (N):* 203
- *Ineligible (N):* 0
- *Declined (N):* 35
- *Other (N):* 0
- *Randomised (N):* 168

Krakow 2001 (Continued)

- Completed post-treatment assessment (N): 96
- Dropped out or removed prior to analysis (N): 54
- Numbers analysed at final applicable time point (N): 114
- Number of sessions: N/A
- Treatment completion: N/A

Inclusion criteria

- Female sexual assault survivors
- 18 years or older
- Self-reported nightmares (at least once a week for more than 6 months)
- Insomnia
- PTSD coupled with criterion A trauma link (DSM-IV)

Exclusion criteria

- Acute intoxication
- Withdrawal
- Psychosis

Pretreatment: no statistically significant baseline differences with exception of age, whereby control non-completers were younger than treatment completers

Interventions

Intervention characteristics

CBT (imagery rehearsal therapy)

- *Planned number of intervention sessions:* 3 (2 × 3-hour sessions spaced 1 week apart with a 1-hour follow-up 3 weeks later)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* group
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, although not described in any great detail, the lead author is an expert in the field of IRT for PTSD and sleep disorders. There was minimal reference to supervision and training. Treatment followed a manual and focused on nightmares within the framework of an imagery and CR paradigm.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* yes, cognitive-imagery treatment was previously tested in studies of the authors. Author links to both not-for-profit and for-profit sleep centres.
- *Treatment fidelity (yes, no, unclear, with explanation):* no, information for assessing fidelity not provided
- *Intervention aim and theoretical basis:* to determine if treating chronic nightmares with imagery rehearsal therapy reduces the frequency of disturbing dreams, improves sleep quality and decreases PTSD symptom severity. Involves story line alteration of the nightmare while awake, followed by rehearsal of a new set of images
- *Duration of intervention:* 4 weeks

Wait-list

- *Planned number of intervention sessions:* N/A
- *Mode of delivery:* N/A
- *Format:* N/A
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* contact with control participants was limited to brief telephone calls and letters to remind them of future appointments. All controls continued any treatment they were already receiving and were offered treatment at no charge on completion of their 6-month wait-list period.

Krakow 2001 (Continued)

- Duration of intervention: N/A

Outcomes	<p>Adverse events</p> <ul style="list-style-type: none"> • Outcome type: adverse event • Notes: IRT can produce imagery adverse effects, and 4 participants reported increased negative imagery and eventually withdrew; 12 of 66 who completed treatment did not complete follow-up for unknown reasons. <p>Treatment dropout (intervention only)</p> <ul style="list-style-type: none"> • Outcome type: dichotomous outcome <p>PTSD</p> <ul style="list-style-type: none"> • Outcome type: continuous outcome • Scale used: CAPS • Direction: lower is better • Score range: 0 to 80 • Data value: endpoint
Identification	<p>Sponsorship source: NIMH (MH53239) and University of New Mexico Health Sciences Centre Research Allocation Committee</p> <p>Country: USA</p> <p>Setting: academic setting for intervention delivery; sample was community, rape crisis and mental health services</p> <p>Authors name: Barry Krakow</p> <p>Institution: University of New Mexico Health Sciences Centre</p> <p>Email: bkrakow@salud.unm.edu</p> <p>Year: 2001</p>
Notes	Included in meta-analysis

Littleton 2016
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Duration of study: May 2012 to August 2014</p> <p>Ethics approvals: approval from 4 IRBs at the universities and colleges where recruitment took place</p> <p>Location of study: 4 US universities and community colleges, including East Carolina</p> <p>Randomisation method: participants were randomised to the interactive programme or psychoeducational website based on a computerised coin flip.</p>
Participants	<p>Baseline characteristics</p> <p>CBT (CBT-online)</p>

Littleton 2016 (Continued)

- *Participants (at randomisation)*: 46
- *Gender*: 100% female participants
- *Age*: not given
- *Ethnicity*: 41.3% white, 21.7% Black, 38.3% other
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education (% high school, college or apprentice, university or years of education)*: all college students
- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 23.7 (6.5)
- *Partnered*: not given
- *Randomised (N)*: 46
- *Completed post-treatment assessment (N)*: 26
- *Dropped out or removed prior to analysis (N)*: 24
- *Numbers analysed at final applicable time point (N)*: 22
- *Number of sessions*: not given
- *Treatment completion*: 26 (57%)

Minimal intervention (psychoeducation website)

- *Participants (select at randomisation if available)*: 41
- *Gender*: 100% female participants
- *Age*: not given
- *Ethnicity*: 51.2% white, 29.3% Black, 14.6% other
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education (% high school, college or apprentice, university or years of education)*: all college students
- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 23 (7.3)
- *Partnered*: not given
- *Randomised (N)*: 41
- *Completed post-treatment assessment (N)*: 29
- *Dropped out or removed prior to analysis (N)*: 20
- *Numbers analysed at final applicable time point (N)*: 21
- *Number of sessions*: not given
- *Treatment completion*: 29 (71%)

Overall

- *Participants (at randomisation)*: 87
- *Gender*: 100% female participants
- *Age, M (range)*: 22 years (18 years to 42 years)
- *Ethnicity*: 46% white, 25.3% Black, 20.7% other
- *Disability*: not given
- *Time since trauma, M*: < 4 years
- *Income*: not given

Littleton 2016 (Continued)

- *Education (% high school, college or apprentice, university or years of education):* all college students
- *Employment:* not given
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* 56.2%
- *Baseline PTSD:* not given
- *Partnered:* not given
- *Approached (N):* 150
- *Ineligible (N):* 60
- *Declined (N):* 4
- *Other (N):* 1
- *Randomised (N):* 87
- *Completed post-treatment assessment (N):* 55
- *Dropped out or removed prior to analysis (N):* 44
- *Numbers analysed at final applicable time point (N):* 43

Inclusion criteria

- Participants had to have experienced a completed rape since the age of 14 years.
- Participants had to have a PTSD diagnosis determined using the PSS-I ([Foa 1993](#)).
- Regular access to a computer and a telephone number at which they could be reliably reached
- Currently a student enrolled at one of the universities involved in the study

Exclusion criteria

- Currently receiving psychotherapy
- Lack of stability on psychotropic medication (not been on current medication and dosage for at least 3 months)
- Active suicidality as determined by interview utilising the Scale for Suicidal Ideation ([Beck 1979](#))
- Meeting DSM-IV criteria for current substance dependence assessed with substance use disorder module of Structured Clinical Interview for the DSM-IV
- Too acutely distressed to participate

Pretreatment: none identified, with the exception that women assigned to the interactive programme were more likely to report that the perpetrator used severe force

Interventions
Intervention characteristics

CBT (online)

- *Planned number of intervention sessions:* 9
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* online with feedback from therapist on exercises
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* unclear, study staff are referred to as doctoral clinical psychology students or postdoctoral fellows, but training not specified
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* unclear, but presume they have developed the online programme
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, external raters reviewed therapeutic feedback provided to participants, which was "uniformly high", although unclear who they are or against what criteria
- *Intervention aim and theoretical basis:* Survivor to Thrive Program consists of sequential modules, focusing on psychoeducation in modules 1 to 3; modules 4 and 5 introduce the cognitive model, teaching participants to identify distorted and unhelpful thoughts; the third phase focused on using a number of CBT techniques to address specific concerns among women following sexual assault.

Littleton 2016 (Continued)

- *Duration of intervention:* 14 weeks

Minimal intervention (psychoeducation website)

- *Planned number of intervention sessions:* 3; identical to Sessions 1 to 3 in other arm
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* online
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* the psychoeducational website contained the written content of the first 3 modules of the interactive programme, including the symptoms of PTSD, information about relaxing and grounding and information about healthy coping strategies.
- *Duration of intervention:* 14 weeks

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: PSS-I
- Direction: lower is better
- Score range: 0 to 51
- Data value: endpoint, 3 months

Depression

- Outcome type: continuous outcome
- Scale used: CES-D
- Direction: lower is better
- Score range: 0 to 60
- Data value: endpoint, 3 months

Anxiety

- Outcome type: continuous outcome
- Scale used: Four-Dimensional Anxiety Scale
- Direction: lower is better
- Score range: 35 to 175
- Data value: endpoint, 3 months

Adverse events

- Outcome type: continuous outcome
- Notes: adverse events – 2 in interactive programme and 1 in psychoeducational arm had increased depressive symptoms; 1 participant in interactive programme had increased anxiety at follow-up.

Treatment dropout

- Outcome type: dichotomous outcome

Identification

Sponsorship source: the research was supported by funding from the NIMH grant number 1R34MH085118.

Country: USA

Setting: university students with rape-related PTSD; online therapy

Authors name: Heather Littleton

Institution: East Carolina University

Littleton 2016 (Continued)

Email: hlittlet@uccs.edu

Year: 2017

Notes	Numbers in population characteristics are at randomisation. Number approached less ineligible is out by 1, so we added 1 to the 'Other' category. Included in meta-analysis
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Miller 2015
Study characteristics

Methods	Study design: randomised controlled trial Study grouping: parallel group Duration of study: 3 years Ethics approvals: procedures were approved by a university IRB Location of study: Tulsa, Oklahoma, USA Randomisation method: not given
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Participants	Baseline characteristics Other psychologically oriented interventions (psychoeducation and coping video) <ul style="list-style-type: none"> • <i>Participants (receiving intervention):</i> 79 • <i>Gender:</i> 100% female participants • <i>Age:</i> not given • <i>Ethnicity:</i> not given • <i>Disability:</i> not given • <i>Time since trauma, M:</i> < 72 h • <i>Income:</i> not given • <i>Education:</i> not given • <i>Employment:</i> not given • <i>Sexual violence in adulthood:</i> 100% • <i>Comorbid conditions:</i> not given • <i>Baseline PTSD, M (SD):</i> 25.82 (15.06) • <i>Partnered:</i> not given • <i>Randomised (N):</i> 94 • <i>Completed post-treatment assessment (N):</i> 31 • <i>Dropped out or removed prior to analysis (N):</i> 61 • <i>Numbers analysed at final applicable time point (N):</i> 33 • <i>Number of sessions, M (SD):</i> 1 (0) • <i>Treatment completion:</i> 79 (84%) Usual care <ul style="list-style-type: none"> • <i>Participants (at randomisation):</i> 85 • <i>Gender:</i> 100% female participants • <i>Age:</i> not given • <i>Ethnicity:</i> not given • <i>Disability:</i> not given
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Miller 2015 (Continued)

- *Time since trauma, M: < 72 h*
- *Income: not given*
- *Education: not given*
- *Employment: not given*
- *Sexual violence in adulthood: 100%*
- *Comorbid conditions: not given*
- *Baseline PTSD, M (SD): 27.76 (14.56)*
- *Partnered: not given*
- *Randomised (N): 85*
- *Completed post-treatment assessment (N): 38*
- *Dropped out or removed prior to analysis (N): 44*
- *Numbers analysed at final applicable time point (N): 41*

Overall

- *Participants (those receiving the intervention): 164*
- *Gender: 100% female participants*
- *Age, M (SD): 28.79 years (10.47 years)*
- *Ethnicity: 61.5% white, 15.4% Black, 14.7% Native American, 5.1% Hispanic, 3.2% other*
- *Disability: not given*
- *Time since trauma, M: < 72 h*
- *Income: not given*
- *Education: not given*
- *Employment: not given*
- *Sexual violence in adulthood: 100%*
- *Comorbid conditions: not given*
- *Baseline PTSD: not given*
- *Partnered: not given*
- *Approached (N): not given*
- *Ineligible (N): not given*
- *Declined (N): not given*
- *Other (N): not given*
- *Randomised (N): 179*
- *Completed post-treatment assessment (N): 69*
- *Dropped out or removed prior to analysis (N): 105*
- *Numbers analysed at final applicable time point (N): 74*

Inclusion criteria

- Women participating in a sexual assault examination at the hospital within 72 h of sexual victimisation
- English-speaking
- 18 years and over

Exclusion criteria

- Unable to provide consent because of intoxication, loss of consciousness, apparent psychosis or other reasons preventing them from providing consent (e.g. ventilator dependent, developmental delays)

Pretreatment: more individuals in standard care (usual care) reported rape (67.1%) compared to the video intervention condition (46.8%).

Interventions

Intervention characteristics

Other psychologically oriented interventions (psychoeducation and coping video)

Miller 2015 (Continued)

- *Planned number of intervention sessions*: 1
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: video, 9-minute psychoeducational video for coping with sexual assault
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate*: N/A
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: unclear, some authors appear to have developed the video intervention.
- *Treatment fidelity (yes, no, unclear, with explanation)*: yes, because it was a standard 9-minute video
- *Intervention aim and theoretical basis*: video focused on instruction of empirically effective coping strategies as well as modelling of such strategies. Provided a rationale and instructions for self-directed in vivo exposure to sexual assault-related cues. Showed methods of using repeated exposure to reduce anxiety in typical assault-related cue situations
- *Duration of intervention*: one-off video

Usual care

- *Planned number of intervention sessions*: 1
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: face-to-face
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: yes, rape crisis advocate
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: no, this was standard care offered at the hospital by the forensic nurse.
- *Treatment fidelity*: N/A
- *Intervention aim and theoretical basis*: the advocate provided information about what would happen during the examination and about services available in the community. The SANE nurse on duty provided verbal information about the examination to the survivor and performed a forensic medicolegal examination.
- *Duration of intervention*: 1 visit

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: PSS-SR
- Direction: lower is better
- Score range: 0 to 119
- Data value: endpoint, 3 months

Treatment dropout (intervention only)

- Outcome type: dichotomous outcome

Anxiety

- Outcome type: continuous outcome
- Scale used: STAI
- Direction: lower is better
- Score range: 20 to 80
- Data value: endpoint, 3 months

Identification

Sponsorship source: Oklahoma Center for Advancement of Science and Technology HR08-017

Country: USA

Setting: SANE programme at 1 hospital

Authors name: Katherine Miller

Miller 2015 (Continued)

Institution: University of Tulsa

Email: katherine-miller@utulsa.edu

Year: 2015

Notes	Total N for population characteristics excludes 15 people in the video intervention arm who did not view the video. Included in meta-analysis Communicated with author(s) for purpose of the review including additional data
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Nixon 2016
Study characteristics

Methods	Study design: randomised controlled trial Study grouping: parallel group Duration of study: June 2008 to April 2011 Ethics approvals: relevant hospital ethics committee Location of study: Adelaide, Australia Randomisation method: not given
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Participants	Baseline characteristics CBT (CPT) <ul style="list-style-type: none"> • <i>Participants (at randomisation):</i> 25 • <i>Gender:</i> 96% female participants, 4% (1) male participants • <i>Age, M (SD):</i> 32.46 years (11.43 years) • <i>Ethnicity:</i> 83% white, 17% other • <i>Disability:</i> not given • <i>Time since trauma, M:</i> < 1 month • <i>Income:</i> 26% < AUD 10,000 • <i>Education (% high school, college or apprentice, university or years of education):</i> 13.48 years (2.87 years) • <i>Employment:</i> not given • <i>Sexual violence in adulthood:</i> 100% • <i>Comorbid conditions:</i> 52% mood, 44% anxiety, 26% substance • <i>Baseline PTSD, M (SD):</i> 70.52 (25.51) • <i>Partnered:</i> not given • <i>Randomised (N):</i> 25 • <i>Completed post-treatment assessment (N):</i> 15 • <i>Dropped out or removed prior to analysis (N):</i> 1 • <i>Numbers analysed at final applicable time point (N):</i> 24 • <i>Number of sessions:</i> not given • <i>Treatment completion:</i> 9 (37.5%) Integrative <ul style="list-style-type: none"> • <i>Participants (at randomisation):</i> 22
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Nixon 2016 (Continued)

- *Gender*: 100% female participants
- *Age, M (SD)*: 29.95 years (8.48 years)
- *Ethnicity*: 91% white, 9% other
- *Disability*: not given
- *Time since trauma, M*: < 1 month
- *Income*: 18% < AUD 10,000
- *Education (% high school, college or apprentice, university or years of education)*: 13.91 years (2.74 years)
- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: 73% mood, 64% anxiety, 32% substance
- *Baseline PTSD, M (SD)*: 79.77 (21.21)
- *Partnered*: not given
- *Randomised (N)*: 22
- *Completed post-treatment assessment (N)*: 17
- *Dropped out or removed prior to analysis (N)*: 0
- *Numbers analysed at final applicable time point (N)*: 22
- *Number of sessions*: not given
- *Treatment completion*: N/A

Overall

- *Participants (at randomisation)*: 47
- *Gender*: 98% female participants, 2% (1) male participants
- *Age*: not given
- *Ethnicity*: 87% white, 13% other
- *Disability*: not given
- *Time since trauma, M*: < 1 month
- *Income*: 22% < AUD 10,000
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: 60% mood, 52% anxiety, 28% substance
- *Baseline PTSD*: not given
- *Partnered*: not given
- *Approached (N)*: 158
- *Ineligible (N)*: 79
- *Declined (N)*: 10
- *Other (N)*: 22
- *Randomised (N)*: 47
- *Completed post-treatment assessment (N)*: 32
- *Dropped out or removed prior to analysis (N)*: 1
- *Numbers analysed at final applicable time point (N)*: 46
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Inclusion criteria

- 18 years or older
- Experienced rape or sexual assault in the past month
- Able to attend face-to-face counselling
- Met criteria for acute stress disorder
- Stable for at least prior 4-week period if taking psychotropic medication

Nixon 2016 (Continued)

Exclusion criteria

- Uncontrolled psychosis
- Current substance dependence requiring immediate attention
- Insufficient English
- Significant cognitive impairment or disability
- Significant suicide risk
- Ongoing traumatisation (e.g. being stalked)

Pretreatment: clinically negligible

Interventions

Intervention characteristics

CBT (CPT)

- *Planned number of intervention sessions:* 6
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, all had at least a bachelor's degree in social work and significant experience of working with assault survivors, and all were trained in delivering the 6-session CPT by the lead author.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* yes, the lead author developed the adapted version of Resick's CPT and ran the study.
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, therapy was audiotaped and assessed for adherence to CPT components and competency (rated as 'good').
- *Intervention aim and theoretical basis:* this is a modified and abbreviated version of Resick's 12-session CPT. Initial sessions introduced CR techniques; later sessions included advanced worksheets and alternative ways of thinking. Writing an account of the traumatic event happened in Session 2. Processing the traumatic event happened throughout therapy.
- *Duration of intervention:* 6 weeks

Integrative

- *Planned number of intervention sessions:* 6
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* TAU included many different types of support and may have included some CBT techniques at times.
- *Duration of intervention:* 6 weeks

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: CAPS
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, 3 months, 6 months and 12 months

Adverse events

- Outcome type: adverse event
- Notes: worsening symptoms and no other adverse events

Treatment dropout

Nixon 2016 (Continued)

- Outcome type: dichotomous outcome

PTSD

- Outcome type: continuous outcome
- Scale used: PCL-S
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, 3 months, 6 months and 12 months

PTSD

- Outcome type: continuous outcome
- Scale used: PTCI
- Direction: lower is better
- Score range: 33 to 231
- Data value: endpoint, 3 months, 6 months and 12 months

Depression

- Outcome type: continuous outcome
- Scale used: BDI-II
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint, 3 months, 6 months and 12 months

Identification

Sponsorship source: Australian Rotary Health Research Fund grant awarded to RDV Nixon

Country: Australia

Setting: sexual assault services

Authors name: Reg Nixon

Institution: Flinders University

Email: reg.nixon@flinders.edu.au

Year: 2017

Notes

Review team extracted imputed data for our analyses.

Included in meta-analysis

Rajan 2020

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: enrolment was between 26 April 2016 and 17 June 2019

Ethics approvals: the authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. All procedures involving human participants were approved by the regional ethical review board in Stockholm (2015/1868-31/2).

Rajan 2020 (Continued)

Location of study: Stockholm, Sweden

Randomisation method: after inclusion, participants were randomised to intervention or wait-list. Preparation of the trial material and randomisation was conducted by the independent data and safety monitoring board KTA via sequenced computer-generated simple randomisation with 1:1 allocation. Participants received sequentially numbered trial materials with concealed allocation. Allocation envelopes were kept and handled by the trial staff. Due to initial misunderstandings, the prepared sealed envelopes were initially not always picked in strict numeric order. However, the study was monitored and periodically reviewed by the KTA, and the misunderstanding was corrected.

Participants

Baseline characteristics

Behavioural (MLI)

- *Participants (at randomisation):* 21
- *Gender:* not given
- *Age, M (SD):* 24.2 years (6.3 years)
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma, M (SD):* 31.7 months (16.4 months)
- *Income:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 58.0 (13.7)
- *Partnered:* not given
- *Randomised (N):* 21
- *Completed post-treatment assessment (N):* 19
- *Dropped out or removed prior to analysis (N):* 2
- *Numbers analysed at final applicable time point (N):* 19
- *Number of sessions:* N/A
- *Treatment completion:* 20 (95%)

Wait-list

- *Participants (select at randomisation if available):* 17
- *Gender:* not given
- *Age, M (SD):* 24.2 years (6.3 years)
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma, M (SD):* 23.6 months (17.6 months)
- *Income:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 55.2 (14.1)
- *Partnered:* not given
- *Randomised (N):* 17
- *Completed post-treatment assessment (N):* 17
- *Dropped out or removed prior to analysis (N):* 0
- *Numbers analysed at final applicable time point (N):* 17
- *Number of sessions:* N/A

Rajan 2020 (Continued)

- *Treatment completion*: N/A

Overall

- *Participants (select at randomisation if available)*: 38
- *Gender*: 100% female participants
- *Age, M (SD)*: 24 years (6 years)
- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: not given
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given
- *Baseline PTSD*: not given
- *Partnered*: not given
- *Approached (N)*: 135
- *Ineligible (N)*: 87
- *Declined (N)*: 10
- *Other (N)*: 0
- *Randomised (N)*: 38
- *Completed post-treatment assessment (N)*: 36
- *Dropped out or removed prior to analysis (N)*: 2
- *Numbers analysed at final applicable time point (N)*: 36
- *Number of sessions*: N/A
- *Treatment completion*: N/A

Inclusion criteria

- Any gender
- Aged 15 years and above
- 1 single sexual assault 0 years to 5 years prior to inclusion

Exclusion criteria

- Poor understanding of Swedish
- Multiple traumas
- Active substance abuse
- Active psychosis
- ADHD or autism spectrum disorder as self-reported or assessed during the doctor's visit

Pretreatment: none reported

Interventions
Intervention characteristics
Behavioural (MLI)

- *Planned number of intervention sessions*: 1 × 90-minute to 140-minute plus preparation
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: face-to-face
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: yes, likely although we are only told that "the clinic is run by the nongovernmental organization WONSA. All staff at the clinic are specially trained in trauma sensitive care and treating sexually abused patients."
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: yes, the modified version of LI was developed at the WONSA clinic.

Rajan 2020 (Continued)

- *Treatment fidelity (yes, no, unclear, with explanation):* unclear
- *Intervention aim and theoretical basis:* the aim of this study was to test the hypothesis that 1 session of MLI could reduce symptoms of PTSD. In LI, the core of the PTSD symptoms is seen to be due to a failure of the index trauma to anchor as an episodic memory in the traumatised individual's chronologic autobiographic memory. Subsequently, as the index trauma is transformed into an episodic memory anchored in a chronological timeline, the limbic system stops perceiving the index trauma as a potential threat in present time, intrusion and hypervigilance stop, avoidance is no longer needed, and the cardinal symptoms of PTSD decline.
- *Duration of intervention:* 1 week

Wait-list

- *Planned number of intervention sessions:* N/A
- *Mode of delivery:* N/A
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* participants randomised to the comparison arm received an attention control in the form of the same doctor visit as the intervention arm at which they were clinically assessed, given information about the treatment and asked to prepare an 'MC list' – memory cues through a chronological timeline for each year since the index trauma up to the present time – 1 d or 2 d before the offered intervention, after the second measurement at time point 2.
- *Duration of intervention:* N/A

Outcomes

Global mental health

- Outcome type: continuous outcome
- Scale used: General Health Questionnaire 12
- Direction: lower is better
- Score range: 0 to 36
- Data value: endpoint

PTSD

- Outcome type: continuous outcome
- Scale used: IES-R total
- Direction: lower is better
- Score range: 0 to 4
- Data value: endpoint

Adverse events

- Outcome type: adverse event

Treatment dropout (intervention only)

- Outcome type: dichotomous outcome

Identification

Sponsorship source: the present study was partly funded by the Stockholm Region (ALF, Stockholm County Council) and Magnus Bergvalls Stiftelse

Country: Sweden

Setting: specialist clinic for sexually traumatised individuals

Authors name: Gita Rajan

Institution: Karolinska Institutet, Huddinge, Sweden

Rajan 2020 (Continued)

Email: Gita.rajan@wonsa.org

Year: 2020

Notes

Study protocol is available at www.WONSA.org.

Registration number NCT03141047 at ClinicalTrials.gov (<https://register.clinicaltrials.gov/>)

Communicated with author(s) for purposes of the review

Included in meta-analysis

Resick 2002

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: dates not reported; 11 months including 6-week intervention with follow-up at 9 months; longer follow-up reported in linked papers of 5 years to 10 years

Ethics approvals: not given

Location of study: Missouri, USA

Randomisation method: not given

Participants

Baseline characteristics

CBT (CPT)

- *Participants:* 62 (at randomisation)
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 74.76 (18.77)
- *Partnered:* not given
- *Randomised (N):* 62
- *Completed post-treatment assessment (N):* 41
- *Dropped out or removed prior to analysis (N):* 36
- *Numbers analysed at final applicable time point (N):* 26
- *Number of sessions:* not given
- *Treatment completion:* 41 (66.12%)

CBT (PE)

- *Participants:* 62 (at randomisation)
- *Gender:* 100% female participants

Resick 2002 (Continued)

- Age: not given
- Ethnicity: not given
- Disability: not given
- Time since trauma: not given
- Income: not given
- Education: not given
- Employment: not given
- Sexual violence in adulthood: not given
- Comorbid conditions: not given
- Baseline PTSD, *M (SD)*: 76.60 (19.72)
- Partnered: not given
- Randomised (*N*): 62
- Completed post-treatment assessment (*N*): 40
- Dropped out or removed prior to analysis (*N*): 36
- Numbers analysed at final applicable time point (*N*): 26
- Number of sessions: not given
- Treatment completion: 40 (64.5%)

Wait-list

- Participants: 47 (at randomisation)
- Gender: 100% female participants
- Age: not given
- Ethnicity: not given
- Disability: not given
- Time since trauma: not given
- Income: not given
- Education: not given
- Employment: not given
- Sexual violence in adulthood: not given
- Comorbid conditions: not given
- Baseline PTSD, *M (SD)*: 69.85 (19.57)
- Partnered: N/A
- Randomised (*N*): 47
- Completed post-treatment assessment (*N*): 40
- Dropped out or removed prior to analysis (*N*): 47
- Numbers analysed at final applicable time point (*N*): 0

Overall

- Participants: 171 (at randomisation)
- Gender: 100% female participants
- Age, *M (SD)*: 32 years (9.9 years)
- Ethnicity: 71% white, 25% Black, 4% other
- Disability: not given
- Time since trauma, *M (SD)*: 102 months (102 months), range 3 months to 33 years
- Income: not given
- Education (% high school, college or apprentice, university or years of education): mean 14.3 years (SD=2.6)
- Employment: not given
- Sexual violence in adulthood: 48% had at least 1 additional rape; 41% reported child sexual abuse; 13.6% reported serious physical assaults; 35.6% reported attempted rape
- Comorbid conditions: 30.7% taking psychotropic medication
- Baseline PTSD: not given

Resick 2002 (Continued)

- Partnered: 24.3%
- Approached (N): 267
- Ineligible (N): 84
- Declined (N): 0
- Other (N): 12
- Randomised (N): 171
- Completed post-treatment assessment (N): 121
- Dropped out or removed prior to analysis (N): 119
- Numbers analysed at final applicable time point (N): 52

Inclusion criteria

- Individuals who have experienced an incident of rape in childhood or adulthood
- At least 3 months post-trauma (no upper limit)
- Stabilised, if taking medication
- Women with a history of substance dependence off the substance(s) for 6 months
- Those with substance abuse histories were permitted to participate if they agreed and were deemed able to desist from usage during the period of treatment.
- Those with a history of incest were not excluded as long as there was another index rape that met the primary criterion for PTSD.

Exclusion criteria

- Current psychosis
- Developmental disabilities
- Suicidal intent
- Current parasuicidal behaviour
- Current dependence on drugs or alcohol
- Illiteracy
- Being in a current abusive relationship or being stalked
- In cases of marital rape, the individuals were in the relationship not less than 6 months ago.

Pretreatment: none reported

Interventions

Intervention characteristics

CBT (CPT)

- *Planned number of intervention sessions:* 9 (1 × 60 min, 8 × 90 min)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, therapists were 8 women with doctorates in clinical or counselling psychology and a background in CBT. Assignments were balanced so that each therapist handled an approximately equal number of therapy cases in each condition. After the therapists had read the manuals, there was a 2-day workshop for each therapy. They were trained in CPT by PA Resick and in PE by E Foa. The therapists watched training tapes of the therapy being conducted and then conducted therapy on 2 clients in each of the conditions as pilot participants. Throughout the study, all of the sessions were videotaped, and therapy was closely supervised by the PI, with weekly peer-supervision sessions to ensure competence and adherence to the protocols.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* yes, CPT followed the manual written by Resick 1993; Resick is the lead author of the present study in which CPT is being trialled. However, independent raters who were not otherwise involved in the project conducted assessments of treatment adherence and therapist competence.
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, independent raters conducted assessments of treatment adherence and therapist competence. All therapy sessions were videotaped and were available at random for rating. Ratings were made with rating forms developed for this

Resick 2002 (Continued)

project. In the CPT protocol, there were 5 to 8 unique and essential items for each session (69 items in total). For adherence, the element was checked if it occurred; for competence, a rating was made on a 7-point scale (poor to excellent, with satisfactory at the midpoint). The 2 protocols had only 1 item in common, an overall rating of the therapist's skill across the sessions for a given client; ratings ranged from 1 (poor) to 7 (excellent). Adherence and competence ratings were made for 23 CPT clients, and for each, 3 randomly chosen sessions were rated. One of every 3 rated sets of tapes was sent to a second rater for a reliability check. Regarding adherence, all unique and essential elements were included in all sessions, and there were no violations of the protocols in which proscribed elements were introduced in therapy.

- *Intervention aim and theoretical basis*: CPT followed the format described by [Resick 1993](#) with only a few minor modifications. Session 1 begins with education about PTSD, an overview of treatment, and an assignment to write an impact statement about the personal meaning of the event. After reading and discussing this in Session 2, clients are introduced to the identification of and relationship among events, thoughts, and emotions. At the end of Session 3, clients are given the assignment of writing a detailed account of the trauma, including sensory details, thoughts, and emotions. They are encouraged to experience their emotions as they write their account and read it back to themselves. This account is read to the therapist in Session 4, and cognitive therapy begins with Socratic questions regarding self-blame and other distortions. The account is written and processed a second time in Session 5. The focus of the therapy shifts to teaching clients to challenge and change their beliefs about the meaning of the event and the implications of the trauma for their lives. From that point, beginning with Session 7, clients use worksheets that incorporate the earlier ones and are asked to develop and practice alternative, more balanced self-statements. From Sessions 7 to 12, clients are asked to focus on 1 theme each week (safety, trust, power-control, esteem or intimacy) and correct any overgeneralised beliefs related to that theme. At the 11th session, clients are also asked to rewrite their impact statements to reflect their current beliefs. CPT group averaged 22.6 h of homework.
- *Duration of intervention*: 6 weeks

CBT (PE)

- *Planned number of intervention sessions*: 9 (1 × 60 min, 8 × 90 min)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: face-to-face
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: as previous
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: no
- *Treatment fidelity (yes, no, unclear, with explanation)*: yes, independent raters conducted assessments of treatment adherence and therapist competence. In the PE protocol, there were 8 to 15 unique and essential elements for each session (85 items in total). Adherence and competence ratings were made for 21 PE clients, and for each, 3 randomly chosen sessions were rated. One of every 3 rated sets of tapes was sent to a second rater for a reliability check. Regarding adherence, all unique and essential elements were included in all sessions, and there were no violations of the protocols in which proscribed elements were introduced in therapy.
- *Intervention aim and theoretical basis*: the PE manual was similar to [Foa 1998](#). PE included 4 components: education-rationale, breathing retraining, behavioural exposures, and imaginal exposures. During the first session, clients are educated about the symptoms of PTSD, and the therapist provides a rationale for in vivo and imaginal exposure in the context of avoidance reduction and habituation of conditioned negative emotional responses. Clients are also introduced to breathing retraining. In Session 2, rationale and education continue, subjective units of distress ratings are introduced, the therapist and client generate an in vivo exposure hierarchy, and the first in vivo exposure assignment is given. Sessions 3 to 9 begin by reviewing homework assignments, conducting imaginal exposure for 45 min to 60 min of the 90-minute session, and processing the exposure experience with nondirective statements (e.g. education about trauma reactions, paraphrasing). Clients are instructed to listen to the tape of the imaginal exposure sessions each day and to engage in behavioural exposures with increasing difficulty for at least 45 min per day. PE group averaged 44.8 h of homework.
- *Duration of intervention*: 6 weeks

Wait-list

- *Planned number of intervention sessions*: N/A

Resick 2002 (Continued)

- *Mode of delivery:* N/A
- *Format:* N/A
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* women who were assigned to this condition were told that therapy would be provided in 6 weeks and that an interviewer would call them every 2 weeks to ensure that they did not need emergency services. They were also encouraged to call if they wished to talk to a therapist who could provide client-centred telephone counselling.
- *Duration of intervention:* N/A

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: CAPS
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint and 12 months

Depression

- Outcome type: continuous outcome
- Scale used: BDI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint and 12 months

PTSD

- Outcome type: continuous outcome
- Scale used: PSS-SR
- Direction: lower is better
- Score range: 0 to 119
- Data value: endpoint and 12 months

Trauma-related beliefs

- Outcome type: continuous outcome
- Scale used: TRGI global guilt
- Direction: lower is better
- Score range: 0 to 4
- Data value: endpoint and 12 months

Treatment dropout

- Outcome type: dichotomous outcome

Identification

Sponsorship source: this work was supported by grant NIH-1 R01-MH51509 from the NIMH.

Country: USA

Setting: academic/clinical intervention setting; recruitment setting not reported

Authors name: Patricia Resick

Institution: Center for Trauma Recovery, Department of Psychology, University of Missouri-St. Louis

Email: resick@umsl.edu

Resick 2002 (Continued)

Year: 2002

Notes Data included are imputed rather than completer; 9-month data are assigned to our 1-year time point; 5-year to 10-year data are reported by [Wachen 2014](#).

Included in meta-analysis

Resick 2008a
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: October 2000 to August 2005 (data collection)

Ethics approvals: the study was conducted in compliance with the University of Missouri IRB

Location of study: St. Louis, Missouri, USA, metropolitan area

Randomisation method: not given

Participants

Baseline characteristics

CBT (CPT)

- *Participants (at randomisation):* 56
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given
- *Income:* 79% < USD 20,000
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 70.19 (15.5)
- *Partnered:* not given
- *Randomised (N):* 56
- *Completed post-treatment assessment (N):* 43
- *Dropped out or removed prior to analysis (N):* 11
- *Numbers analysed at final applicable time point (N):* 45
- *Number of sessions:* not given
- *Treatment completion:* 27 (48%)

CBT (cognitive therapy)

- *Participants (select at randomisation if available):* 51
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* not given

Resick 2008a (Continued)

- *Income*: 46% < USD 20,000
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 73.87 (21.04)
- *Partnered*: not given
- *Randomised (N)*: 51
- *Completed post-treatment assessment (N)*: 38
- *Dropped out or removed prior to analysis (N)*: 15
- *Numbers analysed at final applicable time point (N)*: 36
- *Number of sessions*: not given
- *Treatment completion*: 29 (57%)

CBT (written exposure)

- *Participants (at randomisation)*: 55
- *Gender*: 100% female participants
- *Age*: not given
- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: 42% < USD 20,000
- *Education*: not given
- *Employment*: not given
- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given
- *Baseline PTSD, M (SD)*: 70.38 (18.65)
- *Partnered*: not given
- *Randomised (N)*: 55
- *Completed post-treatment assessment (N)*: 38
- *Dropped out or removed prior to analysis (N)*: 15
- *Numbers analysed at final applicable time point (N)*: 40
- *Number of sessions*: not given
- *Treatment completion*: 30 (54%)

Overall

- *Participants (at randomisation)*: 162
- *Gender*: 100% female participants
- *Age, M (SD)*: 35.4 years (12.4 years)
- *Ethnicity*: 62% white, 34% African American, 4% other
- *Disability*: not given
- *Time since trauma, M (SD)*: 175 months (174 months)
- *Income*: not given
- *Education (% high school, college or apprentice, university or years of education)*: 13.8 years (2.8 years), 52% partial college or technical training
- *Employment*: not given
- *Sexual violence in adulthood*: 80.7% sexual violence in adulthood; 78% child sexual abuse; 60.7% domestic abuse; 84% adult physical assault
- *Comorbid conditions*: 50% current major depression; 20% panic disorder
- *Baseline PTSD*: not given
- *Partnered*: 20
- *Approached (N)*: 256

Resick 2008a (Continued)

- *Ineligible (N): 75*
- *Declined (N): 0*
- *Other (N): 19*
- *Randomised (N): 162*
- *Completed post-treatment assessment (N): 119*
- *Dropped out or removed prior to analysis (N): 41*
- *Numbers analysed at final applicable time point (N): 121*

Inclusion criteria

- Experienced sexual or physical assault in childhood or adulthood and met criteria for PTSD at the time of initial assessment
- At least 3 months post-trauma (no upper limit)
- If taking medication, is stabilised
- Had been abstinent from substance use for 6 months, if had substance dependence
- Current users had to agree to desist from substance use during treatment.

Exclusion criteria

- Illiteracy
- Current psychosis, suicidal intent, dependence on drugs or alcohol

Pretreatment: CPT group had a significantly lower income than other 2 groups (cognitive therapy and written exposure/accounts). Lowest-income participants were least likely to complete the full course of therapy.

Interventions

Intervention characteristics

CBT (CPT)

- *Planned number of intervention sessions: 12 (12 × 60-minute sessions)*
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation): face-to-face*
- *Format (group, individual, blend): individual*
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation): yes, therapists across arms were 8 women with either a doctorate or master's degree in clinical psychology and training in CBT. They were trained by Resick or another senior team member in the therapy required here; they had a manual, watched training videos and had practice sessions. They were supervised during the trial at weekly sessions.*
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation): yes, first author developed the therapy.*
- *Treatment fidelity (yes, no, unclear, with explanation): yes, trained independent raters conducted assessment of treatment adherence and therapist competence. All sessions were recorded and available for random selection for assessment of fidelity. Ninety per cent of unique and essential elements were included in all sessions, and there were no violations of the protocols regarding proscribed elements.*
- *Intervention aim and theoretical basis: CPT followed the manual as written by [Resick 1993](#). CPT is a highly structured protocol in which the client learns the skill of recognising and challenging dysfunctional cognitions, first about the worst traumatic event and then later with regard to the meaning of the events for current beliefs about self and others.*
- *Duration of intervention: 6 weeks*

CBT (cognitive therapy)

- *Planned number of intervention sessions: 12 (12 × 60-minute sessions)*
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation): face-to-face*
- *Format (group, individual, blend): individual*
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation): as previous*
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation): as previous*

Resick 2008a (Continued)

- *Treatment fidelity (yes, no, unclear, with explanation)*: as previous, and adherence for unique and essential elements was 90% adherence to the protocol across all sessions, and there were no protocol violations on proscribed elements.
- *Intervention aim and theoretical basis*: identical to CPT but without inclusion of the written account component
- *Duration of intervention*: 6 weeks

CBT (written exposure)

- *Planned number of intervention sessions*: 7 (2 × 60-minute sessions; 5 × 120 min)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: face-to-face
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: as previous
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: as previous
- *Treatment fidelity (yes, no, unclear, with explanation)*: as previous, and for unique and essential elements on written accounts adherence, there was 80% adherence to the protocol across all sessions, and there were 2 violations on proscribed elements.
- *Intervention aim and theoretical basis*: included only the writing account component, although this has been expanded considerably to fit into a similar amount of therapy time
- *Duration of intervention*: 6 weeks

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: CAPS
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint and 6 months

Adverse events

- Outcome type: adverse event
- Notes: the adverse event in the written accounts only arm was increased suicide ideation; 1 other adverse event was noted as being unrelated, and they did not report what it was or which group it had occurred in.

Treatment dropout

- Outcome type: dichotomous outcome

PTSD

- Outcome type: continuous outcome
- Scale used: PDS – Self-report
- Direction: lower is better
- Score range: 0 to 51
- Data value: endpoint and 6 months

Depression

- Outcome type: continuous outcome
- Scale used: BDI-II
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint and 6 months

Anxiety

- Outcome type: continuous outcome

Resick 2008a (Continued)

- Scale used: STAI-State
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint and 6 months

Trauma-related beliefs

- Outcome type: continuous outcome
- Scale used: PBRs
- Direction: higher is better
- Score range: 0 to 6
- Data value: endpoint and 6 months

Guilt

- Outcome type: continuous outcome
- Scale used: TRGI
- Direction: lower is better
- Score range: 0 to 4
- Data value: endpoint and 6 months

Shame

- Outcome type: continuous outcome
- Scale used: Epworth Sleepiness Scale
- Direction: lower is better
- Score range: 25 to 100
- Data value: endpoint and 6 months

Identification

Sponsorship source: NIMH grant 2-R01-MH51509

Country: USA

Setting: community sample identified through victim assistance agencies, community therapists and self-referral; interventions delivered in academic centre

Authors name: Patricia Resick

Institution: Boston University

Email: Patricia.Resick@va.gov

Year: 2008

Notes

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Rothbaum 1997

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: 4 months

Ethics approvals: not given

Rothbaum 1997 (Continued)

Location of study: Atlanta, Georgia, USA

Randomisation method: not given

Participants

Baseline characteristics

Behavioural (EMDR)

- *Participants (select at randomisation if available):* 11
- *Gender:* 100% female participants
- *Age, M (SD):* 31.6 years (9.8 years)
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma, M (SD):* 62.2 months (53.3 months)
- *Income:* 27% < USD 10,000
- *Education (% high school, college or apprentice, university or years of education):* 50% high school, 50% college
- *Employment (% employed; unemployed, other):* 70% employed; 10% unemployed; 20% student
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 33.3 (8.7)
- *Partnered:* 30%
- *Randomised (N):* 11
- *Completed post-treatment assessment (N):* 10
- *Dropped out or removed prior to analysis (N):* 1
- *Numbers analysed at final applicable time point (N):* 10
- *Number of sessions, M:* 4
- *Treatment completion:* 10 (91%)

Wait-list

- *Participants (at randomisation):* 10
- *Gender:* 100% female participants
- *Age, M (SD):* 37.5 years (11.1 years)
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma, M (SD):* 155.8 months (106.6 months)
- *Income:* 10% < USD 10,000
- *Education (% high school, college or apprentice, university or years of education):* 50% high school, 50% college
- *Employment (% employed, unemployed, other):* 62.5% employed, 37.5% unemployed
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* not given
- *Baseline PTSD, M (SD):* 39 (8.2)
- *Partnered:* 25%
- *Randomised (N):* 10
- *Completed post-treatment assessment (N):* 8
- *Dropped out or removed prior to analysis (N):* 2
- *Numbers analysed at final applicable time point (N):* 8

Overall

- *Participants (at randomisation):* 21
- *Gender:* 100% female participants
- *Age:* not given

Rothbaum 1997 (Continued)

- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: 22% < USD 10,000
- *Education (% high school, college or apprentice, university or years of education)*: 50% high school, 50% college
- *Employment (% employed; unemployed, other)*: 55.5% employed, 22.2% unemployed; 11.1% student
- *Sexual violence in adulthood*: 100%
- *Comorbid conditions*: not given
- *Baseline PTSD*: not given
- *Partnered*: 28%
- *Approached (N)*: not given
- *Ineligible (N)*: not given
- *Declined (N)*: not given
- *Other (N)*: not given
- *Randomised (N)*: 21
- *Completed post-treatment assessment (N)*: 18
- *Dropped out or removed prior to analysis (N)*: 3
- *Numbers analysed at final applicable time point (N)*: 18

Inclusion criteria

- Adult females
- Victim of rape
- Rape occurred at least 3 months prior to allow for the natural decline in PTSD symptoms
- Participants met the criteria for DSM-III-R PTSD

Exclusion criteria

- Alcohol or drug dependence
- Had used cocaine in last 60 d

Pretreatment: none reported

Interventions
Intervention characteristics

Behavioural (EMDR)

- *Planned number of intervention sessions*: 4
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: face-to-face
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: yes, the author was the therapist for all participants in the EMDR condition. She was trained by Francine Shapiro, PhD, at levels I and II. The therapists for the participants receiving EMDR following completion of the wait-list condition, in addition to the author, included another female psychologist and a female psychiatrist, both also having received training at levels I and II.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: yes, the author was the therapist, and the treatment integrity was assessed by those aligned with the therapy developer.
- *Treatment fidelity (yes, no, unclear, with explanation)*: unclear, videotapes of 1 session for each EMDR participant were randomly selected and reviewed by someone from the therapy developers team, but outcomes of that were not reported.
- *Intervention aim and theoretical basis*: EMDR is based around the idea that PTSD is caused by unprocessed emotions and memory from the traumatic event. The therapy allows the person to process the trauma and retrains the person's emotional response to stimuli that have become associated with the trauma but that are in fact generally safe, leading to reduced symptoms of PTSD.

Rothbaum 1997 (Continued)

- Duration of intervention: 4 weeks

Wait-list

- Planned number of intervention sessions: N/A
- Mode of delivery: N/A
- Format: N/A
- Therapist qualifications and training appropriate: N/A
- Research allegiance or conflict of interest: N/A
- Treatment fidelity: N/A
- Intervention aim and theoretical basis: N/A
- Duration of intervention: N/A

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: PSS-I
- Direction: lower is better
- Score range: 0 to 51
- Data value: endpoint and 3 months

Depression

- Outcome type: continuous outcome
- Scale used: BDI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint and 3 months

PTSD

- Outcome type: continuous outcome
- Scale used: IES-R Intrusion
- Direction: lower is better
- Score range: 0 to 4
- Data value: endpoint and 3 months

PTSD

- Outcome type: continuous outcome
- Scale used: IES-R Avoidance
- Direction: lower is better
- Score range: 0 to 4
- Data value: endpoint and 3 months

PTSD

- Outcome type: continuous outcome
- Scale used: IES-R total
- Direction: lower is better
- Score range: 0 to 12
- Data value: endpoint and 3 months

Treatment dropout

- Outcome type: dichotomous outcome

Global mental health (RAST)

Rothbaum 1997 (Continued)

- Outcome type: continuous outcome
- Scale used: RAST
- Direction: lower is better
- Score range: 0 to 280
- Data value: endpoint and 3 months

Anxiety (STAI-State)

- Outcome type: continuous outcome
- Scale used: STAI-State
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint and 3 months

Anxiety (STAI-Trait)

- Outcome type: continuous outcome
- Scale used: STAI-Trait
- Direction: lower is better
- Score range: 20 to 80
- Data value: endpoint and 3 months

Identification	<p>Sponsorship source: University Research Committee of Emory University</p> <p>Country: USA</p> <p>Setting: academic setting with community sample</p> <p>Authors name: Barbara O Rothbaum</p> <p>Institution: Emory University</p> <p>Email: brothba@emory.edu</p> <p>Year: 1997</p>
Notes	<p>Wait-list group received intervention after post-treatment measures, so no 3-month follow-up data included for them. Follow-up data for the wait-list group are not included at all for PTSD (PSS-I) as a total score, although the subscale data are provided.</p>

Rothbaum 2005

Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Duration of study: not given</p> <p>Ethics approvals: the informed consent form and this study were approved by an IRB (Emory).</p> <p>Location of study: Atlanta, Georgia, USA</p> <p>Randomisation method: not given</p>
Participants	<p>Baseline characteristics</p> <p>Behavioural (EMDR)</p>

Rothbaum 2005 (Continued)

- *Participants (completers):* 20
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma, M (SD):* 145.9 months (146.8 months)
- *Income:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M:* 80
- *Partnered:* not given
- *Randomised (N):* 25
- *Completed post-treatment assessment (N):* 20
- *Dropped out or removed prior to analysis (N):* 5
- *Numbers analysed at final applicable time point (N):* 19
- *Number of sessions:* not given
- *Treatment completion:* 20 (80%)

CBT (PE)

- *Participants (completers):* 20
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma, M (SD):* 120.9 months (94.1 months)
- *Income:* not given
- *Education:* not given
- *Employment:* not given
- *Sexual violence in adulthood:* not given
- *Comorbid conditions:* not given
- *Baseline PTSD, M:* 61
- *Partnered:* not given
- *Randomised (N):* 23
- *Completed post-treatment assessment (N):* 20
- *Dropped out or removed prior to analysis (N):* 5
- *Numbers analysed at final applicable time point (N):* 18
- *Number of sessions:* not given
- *Treatment completion:* 20 (87%)

Wait-list

- *Participants (completers):* 20
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma, M (SD):* 162.9 months (136.9 months)
- *Income:* not given
- *Education:* not given
- *Employment:* not given

Rothbaum 2005 (Continued)

- *Sexual violence in adulthood*: not given
- *Comorbid conditions*: not given
- *Baseline PTSD, M*: 78
- *Partnered*: not given
- *Randomised (N)*: 24
- *Completed post-treatment assessment (N)*: 20
- *Dropped out or removed prior to analysis (N)*: 20
- *Numbers analysed at final applicable time point (N)*: 0

Overall

- *Participants (select at randomisation if available)*: 60
- *Gender*: 100% female participants
- *Age, M (SD)*: 33.8 years (11.0 years)
- *Ethnicity*: 68% white
- *Disability*: not given
- *Time since trauma*: not given
- *Income*: 30% household income USD 40,000 or higher
- *Education (% high school, college or apprentice, university or years of education)*: 48% college degree or higher
- *Employment (% employed; unemployed, other)*: 77% employed or full-time students
- *Sexual violence in adulthood*: 100% sexual violence > 12 years; including the index assault, participants experienced a mean of 6.0 traumas (SD = 4.1) prior to study entry
- *Comorbid conditions*: 65% had 1 or more comorbid mental health diagnosis.
- *Baseline PTSD*: not given
- *Partnered*: 26.7%
- *Approached (N)*: not given
- *Ineligible (N)*: 1
- *Declined (N)*: not given
- *Other (N)*: 1
- *Randomised (N)*: 72
- *Completed post-treatment assessment (N)*: 60
- *Dropped out or removed prior to analysis (N)*: 35
- *Numbers analysed at final applicable time point (N)*: 37

Inclusion criteria

- A rape or attempted rape in adulthood (age 12 years or older) or a single incident of rape in childhood (age 0 years to 11 years) by either a family or a non-family member
- If taking psychotropic medication, participants were required to be stable on the medication at the same dosage for 30 d prior to study entry and to agree not to change medication or dosage for duration of the study.

Exclusion criteria

- History of schizophrenia or other psychoses
- Current suicidal risk or practised self-mutilation
- Illiterate and thus unable to complete self-reports
- Current alcohol or drug dependence as determined by the Structured Clinical Interview for the DSM-IV
- Blind or had a history of serious eye disease (e.g. detached retina) that would cause risk with rapid eye movement
- Use of cocaine in any form within 60 d of treatment administration
- In an ongoing threatening situation (e.g. domestic violence)

Rothbaum 2005 (Continued)

Pretreatment: participants in the EMDR condition exhibited significantly higher overall PTSD symptoms; higher levels of intrusive symptoms on the PSS; and higher levels of depression, dissociation and trait anxiety than the PE group.

Interventions

Intervention characteristics

Behavioural (EMDR)

- *Planned number of intervention sessions:* 9 (× 90 min)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* unclear, there was not much information other than that participants were assigned to 1 of 3 doctoral-level psychologists who were trained in both therapies.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, 92.09% of sessions adherent for essential and unique items; therapist skill was rated 6.04 (SD 0.58)
- *Intervention aim and theoretical basis:* EMDR involves having the patient imagine a scene that represents the worst part of the trauma, focusing on the sensations of distress in her body, and rehearsing negative thoughts that match the picture. The patient simultaneously follows the therapist's fingers moving back and forth approximately 18 inches in front of her, a minimum of 20 times each repetition. Distress ratings are gathered using a SUDs from 0 to 10. 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.
- *Duration of intervention:* 5 weeks

CBT (PE)

- *Planned number of intervention sessions:* 9 (× 90 min)
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* as previous
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* unclear
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, 90.46% of sessions adherent for essential and unique items; therapist skill was rated 5.80 (SD = 0.66)
- *Intervention aim and theoretical basis:* PE treatment (Foa 1998; Foa 1991) – a hierarchy of avoided situations is constructed for in vivo exposure homework. The next 7 sessions are devoted to reliving the rape scene in imagination. Participants 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 to 100) are monitored every 5 min during exposure. Participants are encouraged to describe the rape in its entirety, repeating it several times for 45 min to 60 min per session. Following exposure, the participant's reaction to the exposure situation is discussed, and a homework assignment is assigned. Participants' narratives are tape-recorded, and they are instructed to listen to the tapes at home at least once daily.
- *Duration of intervention:* 5 weeks

Wait-list

- *Planned number of intervention sessions:* N/A
- *Mode of delivery:* N/A
- *Format:* N/A
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* N/A
- *Duration of intervention:* N/A

Rothbaum 2005 (Continued)

Outcomes

Depression

- Outcome type: continuous outcome
- Scale used: BDI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint and 6 months

Treatment dropout

- Outcome type: dichotomous outcome

Anxiety

- Outcome type: continuous outcome
- Scale used: STAI-State
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint and 6 months

Dissociation

- Outcome type: continuous outcome
- Scale used: Dissociative Experiences Scale-II
- Direction: lower is better
- Score range: 0 to 100
- Data value: endpoint and 6 months

Identification

Sponsorship source: NIMH grant 1 R01 MH56351-01A1

Country: USA

Setting: women with rape-related PTSD; interventions delivered in clinical academic setting

Authors name: Barbara O Rothbaum

Institution: Emory University

Email: brothba@emory.edu

Year: 2005

Notes

No explanation on where sample was derived from. The 60 in the population characteristics is the intervention completer sample. Final time point is 6 months with 18 PE and 19 EMDR participants and no control.

Schnurr 2007

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: August 2002 to October 2005

Ethics approvals: IRB at each recruitment site approved the protocol.

Location of study: Vermont, USA

Psychosocial interventions for survivors of rape and sexual assault experienced during adulthood (Review)

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Schnurr 2007 (Continued)

Randomisation method: study staff called a computerised voice information system at the study co-ordinating centre to obtain the treatment assignment for participants. The voice information system first verified entry criteria to ensure accuracy and reduce errors. Verified eligible participants were randomised within each site to PE or PCT using permuted blocks with random block sizes of 4 or 6.

Participants

Baseline characteristics

CBT (PE)

- *Participants (at randomisation):* 141
- *Gender:* 100% female participants
- *Age, M (95% CI):* 44.6 years (43.1 years to 46.2 years)
- *Ethnicity:* 56% white, 33.3% Black, Hispanic 5.7%, other 5%
- *Disability (%):* 19.9% (based on PTSD disability status approved)
- *Time since trauma:* not given
- *Income:* not given
- *Education (% high school, college or apprentice, university or years of education):* 91.5% post high-school education
- *Employment (% employed; unemployed, other):* 37.6% unemployed
- *Sexual violence in adulthood:* 69.5%
- *Comorbid conditions:* 75.2%
- *Baseline PTSD, M (95% CI):* 77.6 (74.8 to 80.4)
- *Partnered:* 31.9%
- *Randomised (N):* 141
- *Completed post-treatment assessment (N):* 141
- *Dropped out or removed prior to analysis (N):* 21
- *Numbers analysed at final applicable time point (N):* 141
- *Number of sessions, M:* 8
- *Treatment completion:* 88 (62%)

Other psychologically oriented interventions (PCT)

- *Participants (at randomisation):* 143
- *Gender:* 100% female participants
- *Age, M (95% CI):* 44.9 years (43.4 years to 46.5 years)
- *Ethnicity:* 53.1% white, 32.2% Black, Hispanic 6.3%, other 8.4%
- *Disability:* 23.8% (based on PTSD disability status approved)
- *Time since trauma:* not given
- *Income:* not given
- *Education (% high school, college or apprentice, university or years of education):* 86.7% post-high school education
- *Employment (% employed, unemployed, other):* 39.2% unemployed
- *Sexual violence in adulthood:* 76.2%
- *Comorbid conditions:* 80.4%
- *Baseline PTSD, M (95% CI):* 77.9 (75.1 to 80.6)
- *Partnered:* 31.5%
- *Randomised (N):* 143
- *Completed post-treatment assessment (N):* 143
- *Dropped out or removed prior to analysis (N):* 17
- *Numbers analysed at final applicable time point (N):* 143
- *Number of sessions, M:* 9.3
- *Treatment completion:* 113 (79%)

Overall

Schnurr 2007 (Continued)

- *Participants (select at randomisation if available):* 284
- *Gender:* 100% female participants
- *Age:* not given
- *Ethnicity:* 55% white, 33% Black, 6% Hispanic, 6% other
- *Disability:* 21.8% (based on PTSD disability status approved)
- *Time since trauma:* not given
- *Income:* not given
- *Education (% high school, college or apprentice, university or years of education):* 89% post-high school
- *Employment (% employed; unemployed, other):* 38% unemployed
- *Sexual violence in adulthood:* 73%
- *Comorbid conditions:* 78%
- *Baseline PTSD:* not given
- *Partnered:* 31%
- *Approached (N):* 396
- *Ineligible (N):* 48
- *Declined (N):* 5
- *Other (N):* 59
- *Randomised (N):* 284
- *Completed post-treatment assessment (N):* 284
- *Dropped out or removed prior to analysis (N):* 38
- *Numbers analysed at final applicable time point (N):* 284

Inclusion criteria

- Adult females
- Current PTSD – assessed using CAPS – symptom severity of 45 or higher
- 3 or more months since experiencing trauma
- Clear memory of the trauma that caused the PTSD
- Agreement to not receive other psychotherapy for PTSD during study
- If taking psychoactive medication, stable regimen for last 2 months

Exclusion criteria

- Substance dependence not in remission for at least 3 months
- Current psychotic symptoms, mania or bipolar disorder
- Prominent current suicidal or homicidal ideation
- Cognitive impairment
- Current involvement in a violent relationship
- Self-mutilation within the past 6 months

Pretreatment: none reported

Interventions

Intervention characteristics

CBT (PE)

- *Planned number of intervention sessions:* 10
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, master's- or doctorate-level qualifications among 52 female therapists all receiving bespoke training and supervision of practice
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* yes, developers of therapy are co-authors of the study.

Schnurr 2007 (Continued)

- *Treatment fidelity (yes, no, unclear, with explanation)*: yes, 11.7% of sessions were reviewed by someone independent of therapy delivery and rated as very good to excellent on average on competence and completeness.
- *Intervention aim and theoretical basis*: PE included education about common reactions to trauma; breathing retraining; prolonged (repeated) recounting (imaginal exposure) of trauma memories during sessions; homework (listening to a recording of the recounting made during the therapy session and repeated in vivo exposure to safe situations the participant avoids because of trauma-related fear); and discussion of thoughts and feelings related to exposure exercises. Sessions 1 and 2 were introductory and included provision of the treatment rationale and education about PTSD. Imaginal exposure occurred in Sessions 3 through 10.
- *Duration of intervention*: 10 weeks

Other psychologically oriented interventions (PCT)

- *Planned number of intervention sessions*: 10
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation)*: face-to-face
- *Format (group, individual, blend)*: individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation)*: yes, as before
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation)*: yes, developers of therapy are co-authors of the study.
- *Treatment fidelity (yes, no, unclear, with explanation)*: yes, as before
- *Intervention aim and theoretical basis*: instead of focusing on trauma, PCT focuses on current life problems as manifestations of PTSD. The aim of using PCT in this study was to provide a credible therapeutic alternative to control for nonspecific therapeutic factors so that observed effects of PE could be attributed to its specific effects beyond the benefits of good therapy. Treatment followed the same format as PE, although the content differed. Sessions 1 and 2 were introductory and included provision of the treatment rationale and education about PTSD. Sessions 3 through 9 focused on discussing and reviewing general daily difficulties. Session 10 focused on reviewing accomplishments made during therapy and plans for the future.
- *Duration of intervention*: 10 weeks

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: CAPS
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, 3 months and 6 months

Depression

- Outcome type: continuous outcome
- Scale used: BDI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint, 3 months and 6 months

Adverse events

- Outcome type: adverse event

Treatment dropout

- Outcome type: dichotomous outcome

PTSD

- Outcome type: continuous outcome
- Scale used: PCL-C

Schnurr 2007 (Continued)

- Direction: lower is better
- Score range: 17 to 85
- Data value: endpoint, 3 months and 6 months

Anxiety

- Outcome type: continuous outcome
- Scale used: STAI-State
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, 3 months and 6 months

Quality of life

- Outcome type: continuous outcome
- Scale used: Quality of Life Inventory
- Direction: higher is better
- Score range: -6 to 6
- Data value: endpoint, 3 months and 6 months

Global mental health

- Outcome type: continuous outcome
- Scale used: SF-36 Mental
- Direction: higher is better
- Score range: 0 to 100
- Data value: endpoint, 3 months and 6 months

Quality of life

- Outcome type: continuous outcome
- Scale used: SF-36 Physical
- Direction: higher is better
- Score range: 0 to 100
- Data value: endpoint, 3 months and 6 months

Substance use

- Outcome type: continuous outcome
- Scale used: ASI Alcohol
- Direction: lower is better
- Score range: 0 to 9
- Data value: endpoint, 3 months and 6 months

Substance use

- Outcome type: continuous outcome
- Scale used: ASI Drug
- Direction: lower is better
- Score range: 0 to 9
- Data value: endpoint, 3 months and 6 months

Identification

Sponsorship source: VA Cooperative Studies Program and the Department of Defense

Country: USA

Setting: VA medical centres, counselling centres and a military hospital

Authors name: Paula Schnurr

Schnurr 2007 (Continued)

Institution: Dartmouth Medical School

Email: Paula.Schnurr@Dartmouth.edu

Year: 2007

Notes Included in meta-analysis

Sikkema 2018
Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: March 2016 to July 2017

Ethics approvals: all procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards (Duke C0147, UCT 071/2014).

Location of study: Cape Town, South Africa

Randomisation method: Participants were randomly assigned (1:1) to the SoC control condition (SoC: 3 adherence 'readiness' sessions) or the experimental intervention condition (SoC, plus ImpACT) using a small block (size 8 or 10) randomisation procedure. Condition assignments were placed in sealed envelopes, blinded to study staff until assignment. Due to the nature of the intervention conditions, neither participants nor staff could be blinded to condition assignment.

Participants

Baseline characteristics

Other psychosocial interventions (ImpACT)

- *Participants (at randomisation):* 32
- *Gender:* 100% female participants
- *Age, M (SD):* 29.2 years (6.6 years)
- *Ethnicity:* not given
- *Disability:* not given
- *Time since trauma:* 43.8% in last 3 months
- *Income:* not given
- *Education (% high school, college or apprentice, university or years of education):* 81.3% some high school or less, 15.6% completed high school, 3.1% some university or more
- *Employment (% employed; unemployed, other):* 31.2% employed, 6.3% casual or sometimes working, 62.5% unemployed
- *Sexual violence in adulthood:* 75.0%
- *Comorbid conditions:* 100% HIV-infected; 93.8% lifetime physical partner abuse; 46.9% hazardous drinking
- *Baseline PTSD, M (SD):* 43.28 (3.88)
- *Partnered:* 93.7%
- *Randomised (N):* 32
- *Completed post-treatment assessment (N):* 19
- *Dropped out or removed prior to analysis (N):* 9
- *Numbers analysed at final applicable time point (N):* 23
- *Number of sessions, M (SD):* individual sessions, 3.1 (1.3); group sessions, no mean given but attendance was poor

Sikkema 2018 (Continued)

- *Treatment completion*: 21 (66%)

Usual care

- *Participants (at randomisation)*: 32
- *Gender*: 100% female participants
- *Age, M (SD)*: 29.0 years (8.4 years)
- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: 37.5% in last 3 months
- *Income*: not given
- *Education (% high school, college or apprentice, university or years of education)*: 75% some high school or less, 15.6% completed high school, 9.4% some university or more
- *Employment (% employed, unemployed, other)*: 18.7% employed, 6.3% casual or sometimes working, 75% unemployed
- *Sexual violence in adulthood*: 78.1%
- *Comorbid conditions*: 100% HIV infected; 75% lifetime physical partner abuse; 40.6% hazardous drinking
- *Baseline PTSD, M (SD)*: 30.72 (3.58)
- *Partnered*: 81.2%
- *Randomised (N)*: 32
- *Completed post-treatment assessment (N)*: 26
- *Dropped out or removed prior to analysis (N)*: 4
- *Numbers analysed at final applicable time point (N)*: 28

Overall

- *Participants (at randomisation)*: 64
- *Gender*: 100% female participants
- *Age, M (SD)*: 29.1 years (7.5 years)
- *Ethnicity*: not given
- *Disability*: not given
- *Time since trauma*: 40.6% in last 3 months
- *Income*: not given
- *Education (% high school, college or apprentice, university or years of education)*: 78.1% some high school or less, 15.6% completed high school, 6.3% some university or more
- *Employment (% employed, unemployed, other)*: 25% employed, 6.3% casual or sometimes working, 68.7% unemployed
- *Sexual violence in adulthood*: 76.6%
- *Comorbid conditions*: 100% HIV infected; 84.4% lifetime physical partner abuse; 43.8% hazardous drinking
- *Baseline PTSD*: not given
- *Partnered*: 87.5%
- *Approached (N)*: 141
- *Ineligible (N)*: 59
- *Declined (N)*: 10
- *Other (N)*: 8
- *Randomised (N)*: 64
- *Completed post-treatment assessment (N)*: 45
- *Dropped out or removed prior to analysis (N)*: 13
- *Numbers analysed at final applicable time point (N)*: 51

Inclusion criteria

- Women who were HIV-infected and met ART initiation criteria

Sikkema 2018 (Continued)

- History of sexual abuse, defined as sexual abuse or assault that occurred during childhood, adolescence or adulthood, based on the WHO Composite International Diagnostic Interview and the Childhood Trauma Questionnaire
- 18 years or older
- Xhosa-speaking
- Accessing HIV care services at the study clinic

Exclusion criteria

- Women with current suicidal intent were excluded and referred for psychiatric treatment

Pretreatment: no significant differences were identified between groups on sample characteristics recorded, although there was a difference on the baseline scores for PTSD (PCL-5).

Interventions
Intervention characteristics

Other psychosocial interventions (ImpACT)

- *Planned number of intervention sessions:* 10
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* blend
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* unclear, the provider was trained by the study PI and co-ordinator to facilitate ImpACT using an intervention manual, participant workbook and culturally tailored visual aids. There was individual supervision from a clinical psychologist weekly.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* yes, PI developed the intervention.
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, quality assurance data collected after each session and checked and reviewed by study co-ordinator with supervisory meetings. Assessment of fidelity for individual sessions high at 97.8%. Fidelity for group sessions also reported as high
- *Intervention aim and theoretical basis:* designed to reduce traumatic stress and improve HIV care engagement by developing effective strategies for coping with HIV and trauma and by enhancing adherence to ART (not singularly intended to treat PTSD). It addressed commonalities of stressors in trauma and HIV also included elements of CPT and adaptive coping strategies.
- *Duration of intervention:* 10 weeks

Usual care

- *Planned number of intervention sessions:* 3
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* SoC counselling designed to support adherence to ART for HIV but not to tackle trauma from abuse
- *Duration of intervention:* 3 weeks

Outcomes
PTSD

- Outcome type: continuous outcome
- Scale used: PCL-5
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint and 3 months

Treatment dropout (intervention only)

Sikkema 2018 (Continued)

- Outcome type: dichotomous outcome

Identification

Sponsorship source: Duke University, NIMH and University of Cape Town

Country: South Africa

Setting: HIV-infected women initiating ART recruited (and received intervention) at a primary healthcare clinic

Authors name: Kathleen Sikkema

Institution: Duke University and University of Cape Town

Email: kathleen.sikkema@duke.edu

Year: 2018

Notes

ClinicalTrials.gov NCT02223390

Review team counted the data in the paper that describe 3-month follow-up as post-treatment because the intervention itself lasted for 10 weeks and these data are the first post-treatment assessment of outcome. Likewise, the 6-month follow-up was treated as 3-month post-treatment follow-up for our purposes.

Included in meta-analysis

Surís 2013

Study characteristics

Methods

Study design: randomised controlled trial

Study grouping: parallel group

Duration of study: not given

Location of study: Dallas, Texas, USA

Randomisation method: for the purpose of randomisation, participants were assigned sequential PIN numbers as they entered the study. Blocks of random numbers were generated for each therapist and were allocated to either CPT or PCT using a conditional statement. The random number sequence was maintained on an Excel spreadsheet, and as participants' PINs were entered into the spreadsheet, the preassigned condition was revealed. Assignment to therapist was based on therapist availability.

Ethics approvals: all study-related procedures were conducted in compliance with the IRB of the VA North Texas Health Care System, Dallas VA Medical Center.

Participants

Baseline characteristics

CBT (CPT)

- *Participants (completers):* 52
- *Gender:* 83% female participants; 17% (9) male participants
- *Age, M (SD):* 44.6 years (10.5 years)
- *Ethnicity:* 44% white, non-Hispanic, 39% Black, 17% other
- *Disability:* 61% (based on disability status approved), 20% (based on PTSD disability status approved)
- *Time since trauma:* not given
- *Income:* not given

Suris 2013 (Continued)

- *Education (% high school, college or apprentice, university or years of education):* 17% high school, 67% college, 16% post-college
- *Employment (% employed, unemployed, other):* 44% employed, 35% unemployed, 21% other
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* 61% VA disability status
- *Baseline PTSD, M (SD):* 85.07 (2.69)
- *Partnered:* 29%
- *Randomised (N):* 72
- *Completed post-treatment assessment (N):* 45
- *Dropped out or removed prior to analysis (N):* 20
- *Numbers analysed at final applicable time point (N):* 52
- *Number of sessions, M (SD):* 9.7 (3.5)
- *Treatment completion:* 34 (47%)

Other psychologically orientated interventions (PCT)

- *Participants (completers):* 34
- *Gender:* 88% female participants, 12% (4) male participants
- *Age, M (SD):* 48.4 years (8.2 years)
- *Ethnicity:* 44% white, non-Hispanic, 44% Black, 12% other
- *Disability:* 65% (based on disability status approved), 24% (based on PTSD disability status approved)
- *Time since trauma:* not given
- *Income:* not given
- *Education (% high school, college or apprentice, university or years of education):* 26% high school, 62% college, 12% post-college
- *Employment (% employed, unemployed, other):* 32% employed, 41% unemployed, 27% other
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* 65% VA disability status
- *Baseline PTSD, M (SD):* 83.81 (3.29)
- *Partnered:* 32%
- *Randomised (N):* 57
- *Completed post-treatment assessment (N):* 44
- *Dropped out or removed prior to analysis (N):* 23
- *Numbers analysed at final applicable time point (N):* 34
- *Number of sessions, M (SD):* 10.7 (3.1)
- *Treatment completion:* 28 (49%)

Overall

- *Participants (select at randomisation if available):* 86
- *Gender:* 85% female participants, 15% male participants
- *Age, M (SD):* 46.1 years (9.8 years)
- *Ethnicity:* 44% white, non-Hispanic; 41% Black; 15% other
- *Disability:* 62% (based on disability status approved), 21% (based on PTSD disability status approved)
- *Time since trauma:* not given
- *Income:* not given
- *Education (% high school, college or apprentice, university or years of education):* 21% high school, 65% college, 14% post-college
- *Employment (% employed, unemployed, other):* 39% employed, 37% unemployed, 24% other
- *Sexual violence in adulthood:* 100%
- *Comorbid conditions:* 62% VA disability status
- *Baseline PTSD:* not given

Suris 2013 (Continued)

- Partnered: 30%
- Approached (N): 481
- Ineligible (N): 147
- Declined (N): 119
- Other (N): 86
- Randomised (N): 129
- Completed post-treatment assessment (N): 89
- Dropped out or removed prior to analysis (N): 43
- Numbers analysed at final applicable time point (N): 86

Inclusion criteria

- Veteran status with a current diagnosis of PTSD related to MST
- MST event occurred ≥ 3 months prior to study entry
- MST was the veteran's lifetime trauma associated with the most severe current distress
- Veteran had > 1 clear memory of the trauma
- Any psychiatric medication regimen was stable for ≥ 6 weeks

Exclusion criteria

- Active substance dependence within the last 3 months
- Current psychotic symptoms
- Current unstable bipolar disorder
- Current prominent suicidal or homicidal intent
- Severe cognitive impairment
- Currently receiving other psychotherapy specifically for PTSD
- Current involvement in a violent relationship

Pretreatment: although the 2 treatment groups did not significantly differ in any demographic characteristics, the baseline CAPS re-experiencing subscale (CAPS B) was significantly higher for the CPT than for the PCT group. This difference was addressed in relevant statistical analyses.

Interventions

Intervention characteristics

CBT (CPT)

- *Planned number of intervention sessions:* 12
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, 4 master's- or doctoral-level mental health providers were trained in both the CPT and PCT protocols.
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* unclear, as Chard, a co-author of the current paper, is one of the authors of the adapted CPT tested in this randomised controlled trial. Thus, there may have been an incentive to see the therapy work. On the other hand, Alina Suris led the current paper and is based at different institution, and there were good efforts to monitor fidelity.
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, all therapy sessions were videotaped after obtaining informed consent. A minimum of 2 practice cases were required for each treatment modality. Therapists received weekly supervision, including videotape review. Twelve per cent of therapy tapes from each condition were randomly selected for rating by an independent expert. Ratings were made on a scale of 1 = poor to 7 = excellent, with 4 = satisfactory. Ratings were made for unique and essential elements specific to each session of each therapy approach, as well as essential but not unique elements (i.e. rapport-related) that were the same for every session across both approaches. Ratings were averaged across sessions for each therapist, for each condition. Treatment fidelity analysis indicated a below-satisfactory competency rating in the CPT condition for 1 therapist. This therapist's data were excluded from study analyses (129 to 86).
- *Intervention aim and theoretical basis:* CPT is a manualised CBT developed by [Resick 1993](#) for the treatment of rape-related PTSD and further adapted for the treatment of PTSD in veterans and

Suris 2013 (Continued)

military personnel (Resick 2008b). CPT provides a framework for conceptualising PTSD as a disorder of nonrecovery from trauma. Interventions include education, CR and writing trauma narratives. The first 7 sessions address education, examination of thoughts through Socratic dialogue and skill building; the remaining 5 sessions challenge beliefs surrounding themes of safety, trust, power, self-esteem and intimacy.

- *Duration of intervention:* 6 weeks to 12 weeks

Other psychologically orientated interventions (PCT)

- *Planned number of intervention sessions:* 12
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* face-to-face
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate (yes, no, unclear, with explanation):* yes, as previous
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, as previous
- *Intervention aim and theoretical basis:* PCT is a manualised therapy for the treatment of PTSD, but without the cognitive-behavioural or trauma-focused components of CPT. In PCT, therapeutic focus is deliberately redirected away from discussion of traumatic events. PCT provides general support and education focused on current issues in the participant's life. Emphasis is on problem-solving and improving relationships, with connections made between current problems and PTSD symptoms. Like CPT, PCT utilises a written component, but in the form of daily journaling as opposed to written trauma accounts. In the current study, the number of sessions of PCT was extended from 10 to 12 to match the time and attention components of CPT. The PCT manual has not been published.
- *Duration of intervention:* 6 weeks to 12 weeks

Outcomes

PTSD (PCL-C)

- Outcome type: continuous outcome
- Scale: PCL-C
- Direction: lower is better
- Score range: 17 to 85
- Data value: endpoint, 3 months and 6 months

PTSD

- Outcome type: continuous outcome
- Scale: CAPS
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, 3 months and 6 months

Depression

- Outcome type: continuous outcome
- Scale: Quick Inventory of Depressive Symptomology
- Direction: lower is better
- Score range: 0 to 27
- Data value: endpoint, 3 months and 6 months

PTSD

- Outcome type: continuous outcome
- Scale: PCL-5
- Direction: lower is better
- Score range: 0 to 80
- Data value: endpoint, 3 months and 6 months

Suris 2013 (Continued)**PTSD**

- Outcome type: continuous outcome
- Scale: PSS-I
- Direction: lower is better
- Score range: 0 to 51
- Data value: endpoint, 3 months and 6 months

PTSD

- Outcome type: continuous outcome
- Scale: PSS-SR
- Direction: lower is better
- Score range: 0 to 119
- Data value: endpoint, 3 months and 6 months

Depression

- Outcome type: continuous outcome
- Scale: BDI
- Direction: lower is better
- Score range: 0 to 63
- Data value: endpoint, 3 months and 6 months

PTSD

- Outcome type: continuous outcome
- Scale: IES-R Intrusion
- Direction: lower is better
- Score range: 0 to 4
- Data value: endpoint, 3 months and 6 months

PTSD

- Outcome type: continuous outcome
- Scale: IES-R Avoidance
- Direction: lower is better
- Score range: 0 to 4
- Data value: endpoint, 3 months and 6 months

PTSD

- Outcome type: continuous outcome
- Scale: IES-R Hyperarousal
- Direction: lower is better
- Score range: 0 to 4
- Data value: endpoint, 3 months and 6 months

PTSD

- Outcome type: continuous outcome
- Scale: MPSS-SR
- Direction: lower is better
- Score range: 0 to 119
- Data value: endpoint, 3 months and 6 months

Adverse events

- Outcome type: adverse event

Suris 2013 (Continued)

- Notes: during the course of the study, there were 3 adverse events in the CPT condition (1 suicide attempt by overdose and 2 psychiatric hospitalisations) and 2 adverse events in the PCT condition (1 suicide attempt by overdose and 1 psychiatric hospitalisation). No events were deemed definitely study-related; however, 1 psychiatric hospitalisation in the CPT condition was deemed possibly related. "Although we did not collect data on causes of dropout, we hypothesize that this is related to the fact that participants write their trauma narratives as homework for sessions 3 and 4. The writing of trauma narratives can be an especially challenging component of this therapy approach in terms of the emotional demands involved. Dropping out of therapy is one method of avoidance coping when faced with distressing emotions, or even the possibility of distressing emotions. In addition to the emotional demands of directly confronting one's trauma, CPT is also more demanding in terms of the mental focus and the homework required (as opposed to the trauma-free journaling of PCT), which may have also contributed to the differential dropout between the treatment groups." (Discussion, p. 35)

Treatment dropout

- Outcome type: dichotomous outcome

Identification	<p>Sponsorship source: Veterans Administration Rehabilitation Research & Development Service (US government)</p> <p>Country: USA</p> <p>Setting: outpatients clinic at a VA Medical Centre</p> <p>Comments: Clinical trial NCT00371644 at http://clinicaltrials.gov/. There were 13 male participants in this study. We included the 4-month outcome data as our 3-month time point. There were no significant differences between the randomised sample of 129 and the final sample of 86 on demographic or baseline measures, and the study only reported the latter group.</p> <p>Authors name: Alina Suris</p> <p>Institution: VA North Texas Health Care System</p> <p>Email: alina.suris@va.gov</p> <p>Year: 2013</p>
Notes	Included in meta-analysis

Walsh 2017
Study characteristics

Methods	<p>Study design: randomised controlled trial</p> <p>Study grouping: parallel group</p> <p>Duration of study: recruitment May 2009 to December 2013</p> <p>Ethics approvals: all procedures were approved by 2 university and 2 affiliated hospital IRBs</p> <p>Location of study: Midwestern USA</p> <p>Randomisation method: the study was designed as a parallel trial with an allocation ratio of 1:1:1. A computerised random numbers generator was used to randomly assign participants to 1 of 3 conditions via a stratified blocked randomisation procedure with variable block sizes of 9 or 12. Nurses who enrolled participants immediately after the study commenced (phase 1) accessed videos for participants via a secure internet link and administered videos prior to the medical examination. Following an approved change of scope, those enrolled in phase 2 (n = 126) were administered videos on CDs following the medical examination that were stored in envelopes pre-</p>
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Walsh 2017 (Continued)

pared by a study coordinator and labelled only with a participant number until opened by the nurse, who was blind to study condition to that point.

Participants

Baseline characteristics

Other psychosocial interventions (prevention of post-rape stress video)

- *Participants (completers/assessed):* 54
- *Gender:* 100% female participants
- *Age, M (SD):* 26.79 years (8.22 years)
- *Ethnicity:* 66.7% minority status
- *Disability:* not given
- *Time since trauma, M:* < 7 d
- *Income:* 84.8% < USD 25,000; 10.9% USD 25,000 to USD 50,000; 4.3% > USD 50,000
- *Education (% high school, college or apprentice, university or years of education):* 27.8% less than high school; 59.3% high school diploma, some college or both; 13% college degree
- *Employment (% employed, unemployed, other):* 33.3% employed; 11.1% student
- *Sexual violence in adulthood:* 96.1%
- *Comorbid conditions:* 50% past-year binge-drinking; 42.6% past-year marijuana use
- *Baseline PTSD:* not given
- *Partnered:* 16.7%
- *Randomised (N):* 82
- *Completed post-treatment assessment (N):* 54
- *Dropped out or removed prior to analysis (N):* 44
- *Numbers analysed at final applicable time point (N):* 38
- *Number of sessions, M:* 1
- *Treatment completion:* 77 (94%)

Behavioural (relaxation video)

- *Participants (completers/assessed):* 48
- *Gender:* 100% female participants
- *Age, M (SD):* 27.99 years (10.77 years)
- *Ethnicity:* 53.8% minority status
- *Disability:* not given
- *Time since trauma, M:* < 7 d
- *Income:* 78.3% < USD 25,000; 19.6% USD 25,000 to USD 50,000; 2.2% > USD 50,000
- *Education (% high school, college or apprentice, university or years of education):* 22.9% less than high school; 66.7% high school diploma, some college or both; 10.4% college degree
- *Employment (% employed; unemployed, other):* 34.4% employed; 10.4% student
- *Sexual violence in adulthood:* 93.5%
- *Comorbid conditions:* 48.1% past-year binge-drinking; 51.9% past-year marijuana use
- *Baseline PTSD:* not given
- *Partnered:* 10.4%
- *Randomised (N):* 82
- *Completed post-treatment assessment (N):* 48
- *Dropped out or removed prior to analysis (N):* 41
- *Numbers analysed at final applicable time point (N):* 41
- *Number of sessions, M:* 1
- *Treatment completion:* 77 (94%)

Usual care

- *Participants (completers/assessed):* 52
- *Gender:* 100% female participants

Walsh 2017 (Continued)

- *Age, M (SD):* 27.52 years (10.01 years)
- *Ethnicity:* 50.0% minority status
- *Disability:* not given
- *Time since trauma, M:* < 7 d
- *Income:* 88.9% < USD 25,000; 6.7% USD 25,000 to USD 50,000; 4.4% > USD 50,000
- *Education (% high school, college or apprentice, university or years of education):* 17.3% less than high school; 78.8% high school diploma, some college or both; 3.8% college degree
- *Employment (% employed, unemployed, other):* 34.6% employed; 19.2% student
- *Sexual violence in adulthood:* 97.5%
- *Comorbid conditions:* 33.3% past-year binge-drinking; 45.8% past-year marijuana
- *Baseline PTSD:* not given
- *Partnered:* 13.5%
- *Randomised (N):* 81
- *Completed post-treatment assessment (N):* 52
- *Dropped out or removed prior to analysis (N):* 39
- *Numbers analysed at final applicable time point (N):* 42

Overall

- *Participants (completers/assessed):* 154
- *Gender:* 100% female participants
- *Age, M (SD):* 27.53 years (9.7 years)
- *Ethnicity:* 42.9% white; 29.2% Black/African American; 11% Hispanic/Latina, 9.7% multiracial; 7.1% Native American
- *Disability:* not given
- *Time since trauma, M:* < 7 d
- *Income:* 83.9% < USD 25,000; 12.4% USD 25,000 to USD 50,000; 3.6% > USD 50,000
- *Education (% high school, college or apprentice, university or years of education):* 22.7% less than high school; 68.2% high school diploma, some college or both; 9.1% college degree
- *Employment (% employed, unemployed, other):* 34.4% employed; 13.6% student
- *Sexual violence in adulthood:* 95.7% sexual violence in adulthood and 62% had a prior sexual assault
- *Comorbid conditions:* 44.2% past-year binge-drinking; 46.8% past-year marijuana use
- *Baseline PTSD:* not given
- *Partnered:* 13.6%
- *Approached (N):* 711
- *Ineligible (N):* 231
- *Declined (N):* 209
- *Other (N):* 26
- *Randomised (N):* 245
- *Completed post-treatment assessment (N):* 154
- *Dropout/removed prior to analysis (N):* 124
- *Numbers analysed at final applicable time point (N):* 121

Inclusion criteria

- Girls and women 15 years or older who were recent victims of sexual assault (rape, suspected rape or attempted rape)
- Had a sexual assault medical and forensic examination within 7 d of assault

Exclusion criteria

- Non-English-speaking
- Presented with serious injuries or medical issues, psychological distress, acute intoxication or other factors that would preclude participating in informed consent procedures

Walsh 2017 (Continued)

Pretreatment: none reported

Interventions

Intervention characteristics

Other psychosocial interventions (prevention of post-rape stress video)

- *Planned number of intervention sessions:* 1
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* video
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* unclear, authors seem to have developed the video.
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, video consistently delivers same content.
- *Intervention aim and theoretical basis:* this 9-minute video entitled Steps to Recovery included a female narrator providing information that could be used by victims to prevent future emotional problems and substance abuse, such as instructions for proper implementation of self-directed exposure exercises, methods to recognise and terminate inappropriate avoidance, and strategies to engage in activities that specifically did not involve alcohol or drug use and avoid situations or cues that have been triggers for use. Video included information, psychoeducation and modelling of adaptive behavioural coping strategies for use post-assault.
- *Duration of intervention:* 1 session in the ED

Behavioural (relaxation video)

- *Planned number of intervention sessions:* 1
- *Mode of delivery (face-to-face, online, video, telephone, blend, with explanation):* video
- *Format (group, individual, blend):* individual
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest (yes, no, unclear, with explanation):* no
- *Treatment fidelity (yes, no, unclear, with explanation):* yes, video consistently delivers same content
- *Intervention aim and theoretical basis:* this active control is a 9-minute video that included a female narrator providing instructions in diaphragmatic breathing, use of words such as 'relax' paired with exhalation, instructions regarding muscle relaxation, and pleasant nature-related imagery and sounds. The original DVD was a commercial product entitled Relax© (David Garrigus Productions) that was edited for content and length.
- *Duration of intervention:* 1 session in the ED

Usual care

- *Planned number of intervention sessions:* N/A
- *Mode of delivery:* N/A
- *Format:* N/A
- *Therapist qualifications and training appropriate:* N/A
- *Research allegiance or conflict of interest:* N/A
- *Treatment fidelity:* N/A
- *Intervention aim and theoretical basis:* N/A
- *Duration of intervention:* N/A

Outcomes

PTSD

- Outcome type: continuous outcome
- Scale used: PSS-SR
- Direction: lower is better
- Score range: 0 to 119
- Data value: endpoint

Walsh 2017 (Continued)

Substance use

- Outcome type: continuous outcome
- Scale used: DAST
- Direction: lower is better
- Score range: 0 to 28
- Data value: endpoint

Substance use

- Outcome type: continuous outcome
- Scale used: AUDIT
- Direction: lower is better
- Score range: 0 to 40
- Data value: endpoint

Adverse events

- Outcome type: adverse event

Treatment dropout

- Outcome type: dichotomous outcome

Identification

Sponsorship source: the study was conducted with support from National Institute on Drug Abuse grant DA023099. Manuscript preparation was supported by National Institutes of Health grants MH107641, MH107641-02S1, DA036213 and T32-MH018869. Trial registered at clinicaltrials.gov under the registration number NCT01430624

Country: USA

Setting: 2 medical centres (acute) providing post-sexual assault medical forensic examinations

Authors name: Kate Walsh

Institution: Yeshiva University

Email: kate.walsh@einstein.yu.edu

Year: 2017

Notes

No baseline data, and we treated the 6-week data as post-treatment; population characteristics by the groups N included in final analysis (n = 154). PTSD data taken from trial registry <https://clinicaltrials.gov/ct2/show/results/NCT01430624>

Included in meta-analysis

Communicated with the author(s) for purposes of the research

AC: Assessment Control; ADIS-R: Anxiety Disorders Interview Schedule-Revised; ART: antiretroviral therapy; ASI: Addiction Severity Index; AUD: Australian dollar; AUDIT: Alcohol Use Disorders Identification Test; BA: Bachelor of Arts degree; BAI: Beck Anxiety Inventory; BDI: Beck Depression Inventory; BS: Bachelor of Science degree; BSI: Brief Symptom Inventory; CAPS: Clinician-Administered PTSD Scale; CAPS-5: Clinician-Administered PTSD Scale for DSM-5; CBT: cognitive behavioural therapy; CES-D: Center for Epidemiologic Studies Depression Scale; CI: confidence interval; CPT: cognitive processing therapy; CR: cognitive restructuring; CTSA: Center for the Treatment and Study of Anxiety; DAST: Drug Abuse Screening Test; DSM-III-R: *Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised*; DSM-IV: *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*; DSM-5: *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*; ED: emergency department; EMDR: eye movement desensitisation and reprocessing; HADS: Hospital Anxiety and Depression Scale; HBT: home-based telemedicine; HIPAA: Health Insurance Portability and Accountability Act; HRV: heart rate variability; HRVB: heart rate variability biofeedback; IES-R: Impact of Event Scale – Revised; ImpACT: improving AIDS care after trauma IRB: institutional review board; IRC: International Rescue Committee; IRT: image rehearsal therapy; ITT: intention-to-treat; KTA: Karolinska Trial Alliance; LI: Lifespan Integration; LZNF: low-resolution electromagnetic tomography Z score neurofeedback; M: mean; M-CET: multiple-channel exposure

therapy; MLI: Modified Lifespan Integration; MPSS-SR: Modified PTSD Symptom Scale – Self-Report; MST: military sexual trauma; N/A: not applicable; NEIRB: New England Independent Review Board; NET: narrative exposure therapy; NIMH: National Institute of Mental Health; PAOS: Postacademisch Onderwijs in de Sociale Wetenschappen; PBRS: Pediatric Behavior Rating Scale; PCL-5: Post-traumatic Stress Disorder Checklist for DSM-5 criteria; PCL-C: Post-traumatic Stress Disorder Checklist for DSM-5 criteria – Civilian version; PCT: present-centred therapy; PDS-I: Posttraumatic Diagnostic Scale; PDS-I: Posttraumatic Diagnostic Scale – Interview; PE: prolonged exposure; PEP: postexposure prophylaxis; PI: principal investigator; PhD: Doctor of Philosophy; PSS-I: PTSD Symptom Scale – Interview; PSS-SR: PTSD Symptom Scale – Self-Report; PTCL: Post-traumatic Cognitions Inventory; PTSD: post-traumatic stress disorder; QOLI: Quality of Life Inventory; RAST: Rape Aftermath Symptom Test; REDCap: Research Electronic Data Capture; RTM: reconsolidation of traumatic memories; SANE: sexual assault nurse examiner; SC: supportive counselling; SD: standard deviation; SF-36: 36-item Short-Form Health Survey; SHE: Safe and Healthy Experiences programme; SIT: stress inoculation therapy; SoC: standard of care; ssmCPT: sleep and symptom monitoring; SSS: Symptom Severity Score; STAI: State-Trait Anxiety Inventory; SUDs: subjective units of discomfort scale; TAU: treatment as usual; TCTSY: trauma centre trauma-sensitive yoga; TRGI: Trauma-Related Guilt Inventory; USD: US dollar; VA: Veterans Affairs; VSLA: Village Savings and Loans Associations; WHO: World Health Organization; WOAR: Women Organized Against Rape; WONSA: World of No Sexual Abuse

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Annan 2017	Ineligible population: focus on IPV survivors ^b
Arntz 2007	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Boals 2016	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Bragesjö 2021	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Bryant 2017	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Cheung 2019	Ineligible population: focus was on IPV survivors ^b
Coffey 2016	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Crespo 2010	Ineligible population: focus was on IPV survivors ^b
Deville 1999	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Echeburúa 1997	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Graham-Bermann 2015	Ineligible population: focus was on IPV survivors ^b
Ha 2019	Ineligible population: childhood trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Jalal 2020	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Johnson 2020	Ineligible population: focus was on IPV survivors ^b

Study	Reason for exclusion
Kanady 2018	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Kip 2013	Ineligible population: combat trauma population and did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Krupnick 2008	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Kubany 2004	Ineligible population: focus was on IPV survivors ^b
Latif 2017	Ineligible population: focus was on IPV survivors ^b
Lee 2021	Ineligible population: childhood trauma population and did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Meffert 2021	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Patel 2019	Ineligible population: focus was on IPV survivors ^b
Rothbaum 2012	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Sack 2016	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Saftlas 2014	Ineligible population: focus was on IPV survivors ^b
Scheck 1998	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a
Sharma 2018	Ineligible population: focus was on IPV survivors ^b
Tiwari 2012	Ineligible population: focus was on IPV survivors ^b
Tiwari 2017	Ineligible population: focus was on IPV survivors ^b
Wagman 2015	Ineligible population: focus was on IPV survivors and HIV population ^b
Wells 2019	Ineligible population: trauma population but did not meet our inclusion criterion that 50% of those randomised had been subjected to adulthood sexual violence and abuse ^a

^aFor trials delivered in PTSD and trauma populations, we searched for proportions affected by rape, sexual assault or abuse in adulthood. If these were missing, we contacted authors and requested disaggregated data. Where the proportion of randomised participants affected by sexual violence and abuse in adulthood was > 50%, we excluded trials.

^bWhilst we recognise that a substantial proportion of victims of IPV are subjected to sexual abuse, we excluded IPV trials as it is the topic of another Cochrane Review.

Abbreviations

IPV: intimate partner violence; PTSD: post-traumatic stress disorder

Characteristics of studies awaiting classification [ordered by study ID]

Dutton 2021

Methods	Scientific title: The holistic healing arts retreat: an intensive, experiential intervention for survivors of interpersonal trauma
Participants	<p>Sample size: 109 (49 retreat now; 60 retreat later)</p> <p>Location/setting: USA</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • Identification as female • Self-reported history of interpersonal trauma (child abuse, sexual assault or domestic violence) • Being at least 18 years of age • Having previously received clinical or support services related to trauma <p>Exclusion criteria</p> <ul style="list-style-type: none"> • Currently living in a violent or abusive relationship • Current pregnancy • Current alcohol or drug abuse • Hospitalisation for emotional distress or suicidal attempts within the past 6 months • Inability to speak and write in English
Interventions	<p>Allocation using 1:1 ratio to re-treat now and re-treat later conditions</p> <p>Experimental 1: re-treat now (5-day residential retreat to promote healing for women)</p> <p>Comparator: re-treat later</p>
Outcomes	<ol style="list-style-type: none"> 1. PTSD symptoms (using PCL-5) 2. Depressive symptoms (using PHQ-9) 3. Perceived stress (using PSS)
Notes	<p>Trial registry: not declared</p> <p>Trial registration number: not declared</p> <p>Funding source: the Joyful Heart Foundation, the Blue Shield of California Foundation, Sukey Novogratz, the Nathan Cummings Foundation, Jenny Lorant-Grouf, Bloomingdale's, the Verizon Foundation, the Annenberg Foundation, and the Dreiseszun Family Foundation</p>

PCL-5: Post-Traumatic Stress Disorder Checklist for DSM-5; PHQ-9: Physician Health Questionnaire-9; PSS: Perceived Stress Scale; PTSD: post-traumatic stress disorder

Characteristics of ongoing studies [ordered by study ID]

IRCT20120619010063N8

Study name	<p>Public title: The effectiveness of mindfulness-based group art therapy (MBAT) on improving psychological symptoms in sexual assault victims</p> <p>Scientific title: The effectiveness of mindfulness-based group art therapy (MBAT) on depression, anxiety, intrusive thoughts and shame in sexual assault victims</p>
Methods	<p>Design: randomised trial</p> <p>Location or setting: Hamedan, Iran</p>
Participants	Sample size: 24 (target)

IRCT20120619010063N8 (Continued)

Inclusion criteria

- Being female
- Having been sexually assaulted
- Experiencing the trauma with a slight intensity (having a score between 24 and 32 on Weiss and Marmar's IES-R)
- Having the doctor's permission for taking drugs (if taken any) in a fixed dosage during the treatment sessions
- Age range from 18 years to 65 years
- Signing the informed consent
- Having been educated for at least 8 years

Exclusion criteria

- Diagnosis of schizophrenia, bipolar type I, being delusional, having active suicidal thoughts, substance abuse
- Possibility of getting uncontrollably anxious or aggressive or having uncontrollable impulses
- The existence of potential harm for participants
- Being diagnosed with full criteria of personality disorders
- Being diagnosed with panic disorder

Recruitment status: completed

Interventions	Experimental group: received 8 sessions of mindfulness-based art therapy Comparator: wait-list
Outcomes	<ol style="list-style-type: none"> 1. Depression score on short form of Depression Anxiety Stress Scales (timing of assessment: end of the study and 2 months after the end of study) 2. Anxiety score on short form of Depression Anxiety Stress Scales (timing of assessment: end of the study and 2 months after the end of study) 3. Intrusive thoughts score on the IES-R (timing of assessment: end of the study and 2 months after the end of study) 4. Shame score on Personal Feelings Questionnaire (timing of assessment: end of the study and 2 months after the end of study)
Starting date	Study start date: 23 July 2019 Study end date: 23 August 2019
Contact information	Name(s): Kheirollah Sadeghi E-mail: khsadeghi@kums.ac.ir
Notes	Trial registry: Iranian Registry of Clinical Trials Trial registration number: IRCT20120619010063N8 Funding source: Kermanshah University of Medical Sciences

ISRCTN16806208

Study name	Public title: A randomised controlled trial of therapist-assisted online psychological therapies for post-traumatic stress disorder Scientific title: A randomised controlled trial of therapist-assisted online psychological therapies for post-traumatic stress disorder
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ISRCTN16806208 (Continued)

Methods	<p>Design: single-blind, randomised controlled trial, with an embedded process study</p> <p>Location or setting: UK</p>
Participants	<p>Sample size: 217 participants (target)</p> <p>Inclusion criteria</p> <ol style="list-style-type: none"> 1. Aged 18 years and above 2. Diagnosis of PTSD (as assessed with the Structured Clinical Interview for DSM-5) 3. Their current re-experienced symptoms are linked to 1 or 2 discrete traumatic events that they experienced in adulthood or adolescence, or several traumatic episodes during a longer period of high threat (e.g. domestic abuse, war zone experiences). 4. PTSD is the main psychological problem needing treatment. 5. Willing and able to provide informed consent 6. Able to read and write in English 7. Access to internet 8. Willing to be randomly allocated to one of the psychological treatments or wait 9. If taking psychotropic medication, the dose must be stable for at least 1 month before randomisation. 10. If currently receiving psychological therapy for PTSD, this treatment must have ended before randomisation. <p>Exclusion criteria</p> <ol style="list-style-type: none"> 1. History of psychosis 2. Current substance dependence 3. Current borderline personality disorder 4. Acute serious suicide risk <p>Recruitment: completed</p>
Interventions	<p>Allocation using a 3:3:1 ratio</p> <p>Experimental 1: internet-delivered cognitive therapy (iCT-PTSD)</p> <p>Experimental 2: internet-delivered stress-management (iStress-PTSD)</p> <p>Comparator: wait-list</p>
Outcomes	<ol style="list-style-type: none"> 1. PTSD (PCL-5, CAPS-5, IES-R) (timing of assessment: 6 weeks, 13 weeks, 26 weeks, 39 weeks, 65 weeks) 2. Depression (PHQ-9) (timing of assessment: 6 weeks, 13 weeks, 26 weeks, 39 weeks, 65 weeks) 3. Anxiety (GAD-7) (timing of assessment: 6 weeks, 13 weeks, 26 weeks, 39 weeks, 65 weeks) 4. Disability (Work and Social Adjustment Scale) (timing of assessment: 6 weeks, 13 weeks, 26 weeks, 39 weeks, 65 weeks) 5. Sleep problems (Insomnia Sleep Index) (timing of assessment: 6 weeks, 13 weeks, 26 weeks, 39 weeks, 65 weeks) 6. Wellbeing (WHO Five Well-being Index) (timing of assessment: 6 weeks, 13 weeks, 26 weeks, 39 weeks, 65 weeks) 7. QoL (Endicott QoL Scale) (timing of assessment: 6 weeks, 13 weeks, 26 weeks, 39 weeks, 65 weeks) 8. Health economics (timing of assessment: 6 weeks, 13 weeks, 26 weeks, 39 weeks, 65 weeks) 9. Process measures (timing of assessment: 6 weeks, 13 weeks, 26 weeks, 39 weeks, 65 weeks) 10. Therapeutic alliance (timing of assessment: 2 and 6 weeks) 11. Satisfaction (timing of assessment: 13 weeks) <p>Primary endpoint at 13 weeks</p>

ISRCTN16806208 (Continued)

Starting date	Study start date: 15 December 2017 Study end date: 31 December 2021 (estimated)
Contact information	Name(s): Prof Anke Ehlers, University of Oxford E-mail: anke.ehlers@psy.ox.ac.uk
Notes	Trial registry: ISRCTN Registry Trial registration number: ISRCTN16806208 Funding source: Wellcome Trust

NCT02808468

Study name	Public title: Brief restructuring intervention following trauma exposure (BRITE) Scientific title: Developing a brief early cognitive intervention for PTSD and alcohol misuse
Methods	Study design: randomised trial Location/setting: USA
Participants	Sample size: 63 participants who self-identify as female (actual) Inclusion criteria <ul style="list-style-type: none"> • Identifies as female • Age > 18 years • 2 weeks to 10 weeks post-sexual assault • PTSD symptoms related to recent sexual assault, specifically defined as a minimum of 1 re-experiencing, 1 avoidance, 2 negative alterations in mood/cognition, or 2 hyperarousal symptoms • Drinking > 3 drinks on 1 occasion in the past month and at least 2 reported negative consequences of alcohol use • Capacity to provide informed consent • English fluency • No planned absences that they would be unable to complete 5 weeks of assessments and coaching calls • Access to a telephone Exclusion criteria <ul style="list-style-type: none"> • Acutely suicidal with intent, plan or both • Exhibit current psychosis • Previous nonresponse to an adequate trial (8 or more sessions) of CPT Recruitment status: completed
Interventions	Active comparator: brief cognitive therapy Control: assessment only
Outcomes	<ol style="list-style-type: none"> 1. PTSD (timing of assessment: 12 weeks) 2. Drinking frequency and quantity (timing of assessment: 12 weeks) 3. Alcohol use consequences (timing of assessment: 12 weeks)

NCT02808468 (Continued)

Starting date	Study start date: 1 March 2015 Study end date: February 2020 (actual)
Contact information	Name(s): Michele Bedard-Gilligan, PhD E-mail: not reported
Notes	Trial registry: ClinicalTrials.Gov Trial registration number: NCT02808468 Funding source: National Institute on Alcohol Abuse and Alcoholism (NIAAA)

NCT03019497

Study name	Public title: Cognitive-behavioral therapy for treatment of post-traumatic stress disorder and related problems (CBT-PTSD-RP) Scientific title: Towards optimization of traumatic cognitive-behavioral therapy for treatment of post-traumatic stress disorder and related problems
Methods	Study design: randomised trial Location/setting: Canada
Participants	Sample size: 134 participants (actual) Inclusion criteria <ul style="list-style-type: none"> • Exposed to a traumatic event at an adult age • Primary PTSD diagnosis according to the DSM-5 criteria • At least 1 PTSD-related problem (depressive, anxiety or sleep disorders, pain, psychosocial stressors, inadequate social support, substance use disorder) • Fluent in French Exclusion criteria <ul style="list-style-type: none"> • Schizophrenia diagnostic, current or past psychotic episodes, bipolar disorder, organic cerebral disorder or intellectual deficiency • Presence of a trouble linked to a substance developed prior to the traumatic event • Physical condition preventing participation in the study (e.g. cerebral trauma) • Presence of active suicide ideas Recruitment status: completed
Interventions	Experimental: CBT with specific modules about a specific related problem Active comparator: CBT without specific modules
Outcomes	<ol style="list-style-type: none"> 1. PTSD (timing of assessment: 1 week, 3 months and 6 months) 2. Depression (timing of assessment: 1 week, 3 months and 6 months) 3. Anxiety (timing of assessment: 1 week, 3 months and 6 months) 4. QoL (timing of assessment: 1 week, 3 months and 6 months) 5. Social support in anxious situations (timing of assessment: 1 week, 3 months and 6 months) 6. Sleep quality (timing of assessment: 1 week, 3 months and 6 months) 7. Life events (timing of assessment: 1 week, 3 months and 6 months)

NCT03019497 (Continued)

8. Pain (timing of assessment: 1 week, 3 months and 6 months)
9. Health cost (timing of assessment: 3 months)
10. Social provisions (timing of assessment: 1 week, 3 months and 6 months)

Starting date	Study start date: January 2017 Study end date: June 2021 (actual)
Contact information	Name(s): Stéphane Guay, PhD E-mail: not reported
Notes	Trial registry: ClinicalTrials.Gov Trial registration number: NCT03019497 Funding source: Université de Montréal

NCT03429166

Study name	Public title: Connecting women to care: home-based psychotherapy for women with MST living in rural areas (CWC) Scientific title: Connecting women to care: home-based psychotherapy for women with MST living in rural areas
Methods	Study design: randomised trial Location/setting: USA
Participants	Sample size: 170 female veterans (target) Inclusion criteria <ul style="list-style-type: none"> • Veteran • A positive screen for MST • A positive PTSD screen defined as PC-PTSD cutoff of > 3 Exclusion criteria <ul style="list-style-type: none"> • Substance abuse not in remission for at least 3 months • Current psychotic symptoms <ul style="list-style-type: none"> ◦ Unmedicated mania or bipolar disorder ◦ Prominent current suicidal or homicidal ideation • Cognitive impairment indicated by chart diagnoses or observable cognitive difficulties • Current involvement in a violent relationship defined as more than casual contact (e.g. dating or living with an abusive partner) Recruitment status: recruiting
Interventions	Experimental: Non-trauma-focused treatment (skills training in affective and interpersonal regulation) Active comparator: Non-trauma-focused treatment (present centred-therapy)
Outcomes	<ol style="list-style-type: none"> 1. PTSD (timing of assessment: 26 weeks) 2. Interpersonal support (timing of assessment: 26 weeks) 3. Interpersonal problems (timing of assessment: 26 weeks)

NCT03429166 (Continued)

4. Difficulties in emotion regulation (timing of assessment: 26 weeks)
5. Depression (timing of assessment: 26 weeks)
6. Anxiety (timing of assessment: 26 weeks)

Starting date	Study start date: 3 September 2018 Study end date: 31 March 2022 (estimated)
Contact information	Name(s): Marylene Cloitre, PhD E-mail: not reported
Notes	Trial registry: ClinicalTrials.Gov Trial registration number: NCT03429166 Funding source: VA Office of Research and Development

NCT03703258

Study name	Public title: Tools for health and resilience implemented after violence exposure (Project THRIVE) Scientific title: Preventing risky drinking and PTSD after sexual assault: a web-based intervention
Methods	Study design: randomised trial Location/setting: USA
Participants	Sample size: 40 participants who self-identify as female (target) Inclusion criteria <ul style="list-style-type: none"> • Informed consent • Self-identification as female • Sexual assault, defined as endorsement of unwanted, attempted or completed sexual contact in the past 10 weeks • Age > 18 years • English fluency • Smartphone and internet access at least daily for 3 weeks and at least weekly for 3 months • Consumption of > 1 alcoholic drink in the past month • > 1 episode of high-risk drinking in past 6 months, defined as either > 3 drinks on a given day or > 7 drinks in a given week • At least 3 symptom clusters endorsed on the PTSD Checklist Exclusion criteria <ul style="list-style-type: none"> • Active suicidality • Psychosis Recruitment status: recruiting
Interventions	Experimental: app-based cognitive-behavioural intervention Control: assessment-only (app use but restricted to daily surveys and symptom tracker)
Outcomes	<ol style="list-style-type: none"> 1. Problem drinking (timing of assessment: 3 weeks and 3 months) 2. PTSD (timing of assessment: 3 weeks and 3 months)

NCT03703258 (Continued)

3. Anxiety (timing of assessment: 3 weeks and 3 months)
4. Coping self-efficacy (timing of assessment: 3 weeks and 3 months)
5. Depression (timing of assessment: 3 weeks and 3 months)
6. Alcohol consumption (timing of assessment: 3 weeks and 3 months)

Starting date	Study start date: 13 January 2021 Study end date: 1 September 2023 (estimated)
Contact information	Name(s): Emily Dworkin, PhD; Christine Lee E-mail: edworkin@uw.edu; leecm@uw.edu
Notes	Trial registry: ClinicalTrials.Gov Trial registration number: NCT03703258 Funding source: University of Washington

NCT03794986

Study name	Public title: Peer online motivational interviewing for sexual and gender minority male survivors Scientific title: Peer online motivational interviewing for sexual and gender minority male survivors
Methods	Study design: randomised trial Location/setting: USA
Participants	Sample size: 344 SGM survivors (actual) Inclusion criteria <ul style="list-style-type: none"> • 18 years or older • English-speaking men who have sex with men or individuals identifying as SGM males • Individuals who report a history of sexual abuse and individuals who self-report a minimum cutoff score of 3.0 or higher on emotional distress, using a 4-question symptom inventory Exclusion criteria <ul style="list-style-type: none"> • Individuals who endorse active psychosis • Individuals who have a cognitive dysfunction • SGM men who report that they are currently in formal mental health counselling Recruitment status: active, not recruiting
Interventions	6-week duration Experimental: motivational interviewing Active comparator: motivational interviewing with trauma-informed SGM affirmative care
Outcomes	<ol style="list-style-type: none"> 1. Number of participants who engage in treatment (timing of assessment: within 120 d of last online group) 2. Depression (timing of assessment: 14 d, 60 d and 120 d) 3. PTSD (timing of assessment: 14 d, 60 d and 120 d) 4. Substance abuse (timing of assessment: 14 d, 60 d and 120 d)

NCT03794986 (Continued)

5. Psychosocial functioning (timing of assessment: 14 d, 60 d and 120 d)
6. Service utilisation (timing of assessment: 14 d, 60 d and 120 d)

Starting date	Study start date: 1 April 2019 Study end date: 31 March 2023 (estimated)
Contact information	Name(s): Joan Cook, PhD E-mail: not reported
Notes	Trial registry: ClinicalTrials.gov Trial registration number: NCT03794986 Funding source: Yale University

NCT04124380

Study name	Public title: Understanding and testing recovery processes for PTSD and alcohol use following sexual assault Scientific title: Understanding and testing recovery processes for PTSD and alcohol use following sexual assault
Methods	Study design: randomised trial Location/setting: USA
Participants	Sample size: 180 participants (target) Inclusion criteria <ol style="list-style-type: none"> 1. Identifies as female 2. Between the ages of 18 years and 65 years 3. Reports a sexual assault in the last 4 weeks to 1 year 4. Current PTSD severity of ≥ 23 on the PSS-I-5 5. Current heavy alcohol use (≥ 2 heavy episodic drinking occasions (≥ 4 drinks on 1 occasion) in past month) 6. Access to the internet and a device with a webcam Exclusion criteria <ol style="list-style-type: none"> 1. Current diagnosis of schizophrenia, delusional disorder or organic mental disorder as defined by the DSM-5 2. Current diagnosis of bipolar disorder, depression with psychotic features or depression severe enough to require immediate psychiatric treatment (i.e. serious suicide risk with intent and plan) 3. Unwilling or unable to discontinue current trauma-focused psychotherapy or current substance use psychotherapy 4. Unstable dose of psychotropic medications in the prior 3 months 5. Ongoing intimate relationship with the perpetrator of most recent assault 6. Current diagnosis of a severe substance use disorder according to DSM-5, other than alcohol in the last month 7. No clear trauma memory 8. Current higher dose use of benzodiazepines (greater than the equivalent of 4 mg of lorazepam, 2 mg of alprazolam, 1.5 mg of clonazepam or 20 mg of diazepam)

NCT04124380 (Continued)

	Recruitment status: recruiting
Interventions	<p>Experimental 1: imaginal exposure, then alcohol skills training</p> <p>Experimental 2: alcohol skills training, then imaginal exposure</p> <p>Experimental 3: alcohol skills training, no additional treatment</p> <p>Experimental 4: imaginal exposure, no additional treatment</p> <p>Active comparator: supportive counselling/telehealth</p>
Outcomes	<ol style="list-style-type: none"> 1. Alcohol use (timing of assessment: unknown) 2. PTSD (timing of assessment: unknown) 3. Psychosocial functioning (timing of assessment: unknown) 4. QoL (timing of assessment: unknown) 5. Alcohol cravings (timing of assessment: unknown) 6. Alcohol consequences (timing of assessment: unknown) 7. Depression (timing of assessment: unknown) 8. Reward (timing of assessment: unknown) 9. Fear (timing of assessment: unknown)
Starting date	<p>Study start date: 22 March 2021</p> <p>Study end date: 31 August 2024 (estimated)</p>
Contact information	<p>Name(s): Michele Bedard-Gilligan, PhD</p> <p>E-mail: mab29@uw.edu</p>
Notes	<p>Trial registry: ClinicalTrials.Gov</p> <p>Trial registration number: NCT04124380</p> <p>Funding source: University of Washington</p>

NCT04582695

Study name	<p>Public title: Early intervention following sexual assault</p> <p>Scientific title: Integrated early intervention for alcohol use disorder and posttraumatic stress disorder following sexual assault</p>
Methods	<p>Study design: randomised trial</p> <p>Location/setting: USA</p>
Participants	<p>Sample size: 64 participants (target)</p> <p>Inclusion criteria</p> <ul style="list-style-type: none"> • Female; any race or ethnicity; age 18 years to 65 years • Sexual assault that occurred within the past 6 weeks • Participants must be able to comprehend English • A score of 3 or greater on the AUDIT-C screen • A score of 33 or greater on the PCL-5. Participants may also meet criteria for an alcohol use disorder, previous history of PTSD, mood disorder (except bipolar affective disorder, see Exclusion Criteria) or other anxiety disorders (panic disorder, agoraphobia, social phobia, generalised anxiety

Psychosocial interventions for survivors of rape and sexual assault experienced during adulthood (Review)

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NCT04582695 (Continued)

disorder or obsessive-compulsive disorder). The inclusion of participants with affective and other anxiety disorders is essential because of the marked frequency of the co-existence of mood and other anxiety disorders among participants with alcohol use disorder and PTSD (Norman 2018; Zinzow 2012). Participants may meet the DSM-5 criteria for another substance use disorder if alcohol is the primary substance of choice.

- Must consent to complete all treatment and follow-up visits

Exclusion criteria

- Lack of any memory of the sexual assault
- Participants meeting the DSM-5 criteria for a history of or current psychotic, bipolar or dissociative identify disorder or a current eating disorder, as the study protocol may be therapeutically insufficient
- Participants experiencing significant withdrawal symptoms, as evidence by a score of 10 or more on the CIWA. These participants will be referred for clinical detoxification and may be reassessed for study eligibility after medically supervised detoxification has been completed.
- Individuals considered an immediate suicide risk, with current suicidal ideation and intent. These individuals will be referred directly for treatment
- Individuals on psychotropic medications must be stabilised on it for at least 2 weeks prior to beginning the study.
- Any other medical or psychiatric conditions that the investigators believe may compromise the individual's ability to safely participate in the study

Recruitment status: recruiting

Interventions	<p>Experimental: written exposure therapy integrated with CBT</p> <p>Active comparator: written exposure therapy</p>
Outcomes	<ol style="list-style-type: none"> 1. Alcohol use disorder symptoms (timing of assessment: 6 weeks) 2. Per cent drinking days (timing of assessment: 6 weeks) 3. PTSD (timing of assessment: 6 weeks) 4. Depression (timing of assessment: 6 weeks) 5. Anxiety (timing of assessment: 6 weeks)
Starting date	<p>Study start date: 15 December 2020</p> <p>Study end date: 31 July 2025 (estimated)</p>
Contact information	<p>Name(s): Christine K Hahn, PhD; Sudie Back, PhD</p> <p>E-mail: hahnc@musc.edu; backs@musc.edu</p>
Notes	<p>Trial registry: ClinicalTrials.Gov</p> <p>Trial registration number: NCT04582695</p> <p>Funding source: Medical University of South Carolina</p>

AUDIT-C: Alcohol Use Disorders Identification Test; CAPS-5: Clinician-Administered PTSD Checklist for DSM-5; CBT: cognitive behavioural therapy; CIWA: Clinical Institute Withdrawal Assessment of Alcohol; CPT: cognitive processing therapy; DSM-5: *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*; GAD-7: Generalised Anxiety Disorder-7; IES-R: Impact of Event Scale-Revised; IPV: intimate partner violence; ISRCTN: International Standard Randomised Controlled Trial Number; MST: military sexual trauma; PCL-5: PTSD Checklist for DSM-5 criteria; PC-PTSD: Primary Care Posttraumatic Stress Disorder; PHQ: Patient Health Questionnaire; PSS-I: PTSD Symptom Scale-Interview, for DSM-5; PTSD: post-traumatic stress disorder; QoL: quality of life; SGM: sexual- or gender-minority male; WHO: World Health Organization; VA: Veterans Affairs

RISK OF BIAS

Legend:  Low risk of bias  High risk of bias  Some concerns

Risk of bias for analysis 1.1 Psychosocial interventions versus inactive control; outcome 1: PTSD symptoms, post-treatment

Study	Bias					Overall
	Randomisation process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported results	
Subgroup 1.1.1 Cognitive Behavioural Therapy						
Falsetti 2008						
Foa 1999						
Foa 1999						
Foa 1999						
Foa 2005						
Foa 2005						
Foa 2006						
Littleton 2016						
Resick 2002						
Resick 2002						
Subgroup 1.1.2 Behavioural Therapy						
Bell 2019						
Bomyea 2015						
Brady 2021						
Gray 2020						

Bias						
Study	Randomisation process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported results	Overall
Rajan 2020	✓	✓	✓	~	✓	~
Rothbaum 1997	✗	✓	✓	✓	~	✗
Walsh 2017	~	~	~	✓	✓	~
Subgroup 1.1.3 Psychosocial (low-intensity) interventions						
Creech 2021	✓	✓	✓	✓	✓	✓
Miller 2015	✗	✓	✗	✓	~	✗
Sikkema 2018	✓	✓	~	✓	✓	~
Walsh 2017	~	~	~	✓	✓	~

Risk of bias for analysis 1.3 Psychosocial interventions versus inactive control; outcome 2: Depressive symptoms, post-treatment

Bias						
Study	Randomisation process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported results	Overall
Subgroup 1.3.1 Cognitive Behavioural Therapy						
Falsetti 2008	✗	✗	✗	✓	~	✗
Foa 1999	✗	~	✓	✓	~	✗
Foa 1999	✗	~	✓	✓	~	✗
Foa 1999	✗	~	✓	✓	~	✗
Foa 2005	~	✓	✗	✓	~	✗
Foa 2005	~	✓	✗	✓	~	✗

Bias						
Study	Randomisation process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported results	Overall
Foa 2006	~	~	~	✓	~	~
Littleton 2016	✓	✓	~	✓	~	~
Resick 2002	~	✓	~	✓	✓	~
Resick 2002	~	✓	~	✓	✓	~
Rothbaum 2005	✗	~	~	✓	~	✗
Subgroup 1.3.2 Behavioural Therapy						
Bomyea 2015	✓	✓	~	✓	~	~
Brady 2021	~	✓	~	✓	✓	~
Rothbaum 1997	✗	✓	✓	✓	~	✗
Rothbaum 2005	✗	~	~	✓	~	✗
Subgroup 1.3.3 Psychosocial (low-intensity) interventions						
Abrahams 2010	~	✗	~	✓	~	✗
Bowland 2012	~	✓	✓	✓	~	~

Risk of bias for analysis 1.5 Psychosocial interventions versus inactive control; outcome 3: Dropout from treatment

Bias						
Study	Randomisation process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported results	Overall
Bell 2019	✗	✓	✓	✓	✓	✗
Bomyea 2015	✓	✓	✓	~	~	~

Bias						
Study	Randomisation process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported results	Overall
Brady 2021	⚠	✓	✓	✓	✓	⚠
Foa 2006	⚠	✓	✓	⚠	⚠	⚠
Littleton 2016	✓	✓	✓	✗	⚠	✗

Risk of bias for analysis 1.6 Psychosocial interventions versus inactive control; outcome 4: Adverse events

Bias						
Study	Randomisation process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported results	Overall
Abrahams 2010	⚠	⚠	✓	✓	⚠	⚠
Brady 2021	⚠	✓	✓	✓	✓	⚠
Gray 2020	✓	✓	✓	⚠	⚠	⚠
Krakow 2001	✓	✓	✗	✓	⚠	✗
Littleton 2016	✓	✓	✗	✓	⚠	✗
Rajan 2020	✓	✓	✓	✓	✓	✓

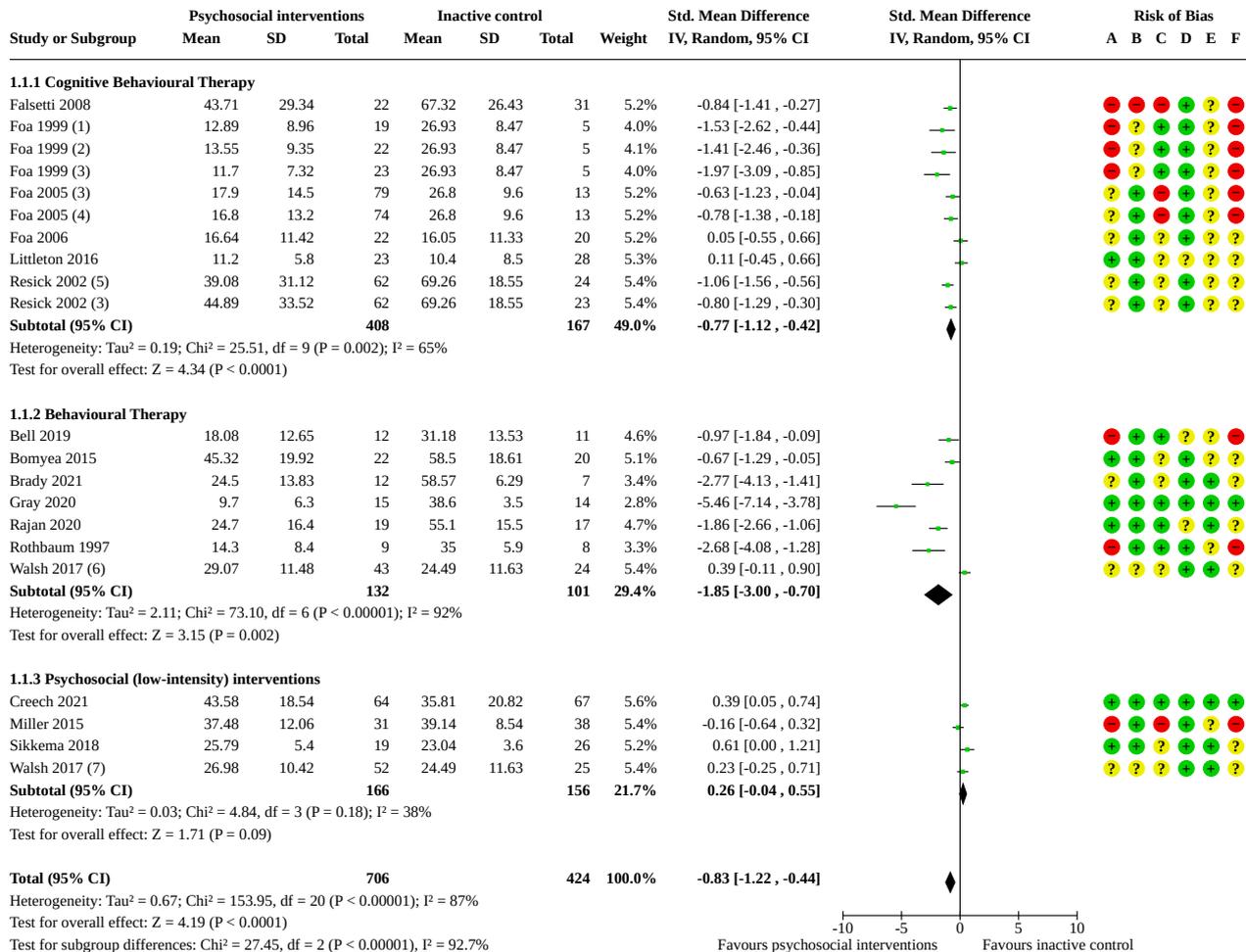
DATA AND ANALYSES

Comparison 1. Psychosocial interventions versus inactive control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Psychosocial interventions versus inactive control; outcome 1: PTSD symptoms, post-treatment	16	1130	Std. Mean Difference (IV, Random, 95% CI)	-0.83 [-1.22, -0.44]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1.1 Cognitive Behavioural Therapy	6	575	Std. Mean Difference (IV, Random, 95% CI)	-0.77 [-1.12, -0.42]
1.1.2 Behavioural Therapy	7	233	Std. Mean Difference (IV, Random, 95% CI)	-1.85 [-3.00, -0.70]
1.1.3 Psychosocial (low-intensity) interventions	4	322	Std. Mean Difference (IV, Random, 95% CI)	0.26 [-0.04, 0.55]
1.2 Psychosocial interventions versus inactive control; outcome 1: PTSD symptoms, 3 months	7	770	Std. Mean Difference (IV, Random, 95% CI)	-0.13 [-0.42, 0.17]
1.3 Psychosocial interventions versus inactive control; outcome 2: Depressive symptoms, post-treatment	12	901	Std. Mean Difference (IV, Random, 95% CI)	-0.82 [-1.17, -0.48]
1.3.1 Cognitive Behavioural Therapy	7	595	Std. Mean Difference (IV, Random, 95% CI)	-0.73 [-1.13, -0.33]
1.3.2 Behavioural Therapy	4	123	Std. Mean Difference (IV, Random, 95% CI)	-1.51 [-2.58, -0.44]
1.3.3 Psychosocial (low-intensity) interventions	2	183	Std. Mean Difference (IV, Random, 95% CI)	-0.34 [-1.12, 0.44]
1.4 Psychosocial interventions versus inactive control; outcome 2: Depressive symptoms, 3 months	3	376	Std. Mean Difference (IV, Random, 95% CI)	-0.05 [-0.39, 0.29]
1.5 Psychosocial interventions versus inactive control; outcome 3: Dropout from treatment	5	242	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.51, 1.44]
1.6 Psychosocial interventions versus inactive control; outcome 4: Adverse events	6	622	Risk Ratio (M-H, Random, 95% CI)	1.92 [0.30, 12.41]
1.7 Psychosocial interventions versus inactive control; outcome 5: Anxiety symptoms, post-treatment	10	436	Std. Mean Difference (IV, Random, 95% CI)	-0.84 [-1.26, -0.42]
1.8 Psychosocial interventions versus inactive control; outcome 5: Anxiety symptoms, 3 months	4	449	Std. Mean Difference (IV, Random, 95% CI)	-0.26 [-0.44, -0.07]
1.9 Psychosocial interventions versus inactive control; outcome 6: Global mental health/distress, post-treatment	3	80	Std. Mean Difference (IV, Random, 95% CI)	-0.92 [-1.70, -0.13]

Analysis 1.1. Comparison 1: Psychosocial interventions versus inactive control, Outcome 1: Psychosocial interventions versus inactive control; outcome 1: PTSD symptoms, post-treatment



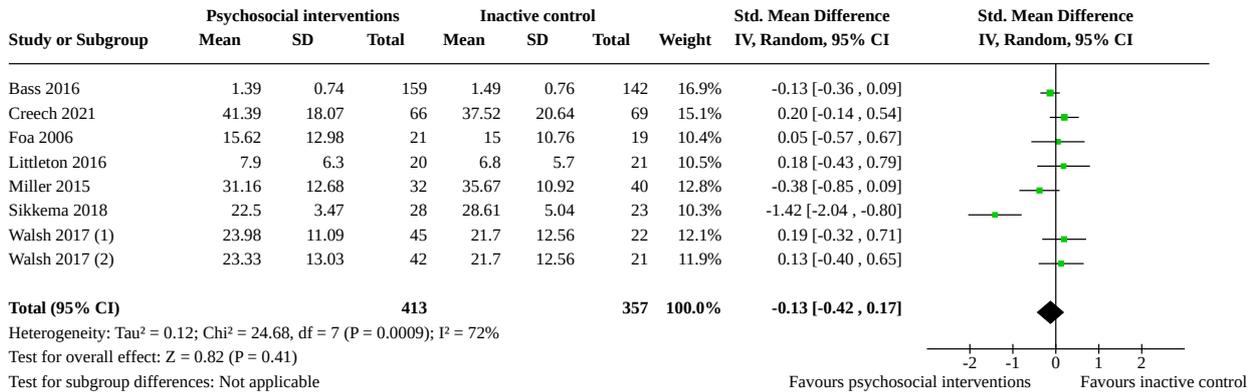
Footnotes

- (1) CBT (SIT) vs wait-list
- (2) CBT mixed (PE and SIT) vs wait-list
- (3) CBT (PE) vs wait-list
- (4) CBT mixed (PE + CR) vs wait-list
- (5) CBT (CPT) vs wait-list
- (6) Behavioural (Pleasant imagery and relaxation instruction video) v Usual care
- (7) Other psychosocial interventions (Prevention of post-rape stress video) v Usual care

Risk of bias legend

- (A) Bias arising from the randomization process
- (B) Bias due to deviations from intended interventions
- (C) Bias due to missing outcome data
- (D) Bias in measurement of the outcome
- (E) Bias in selection of the reported result
- (F) Overall bias

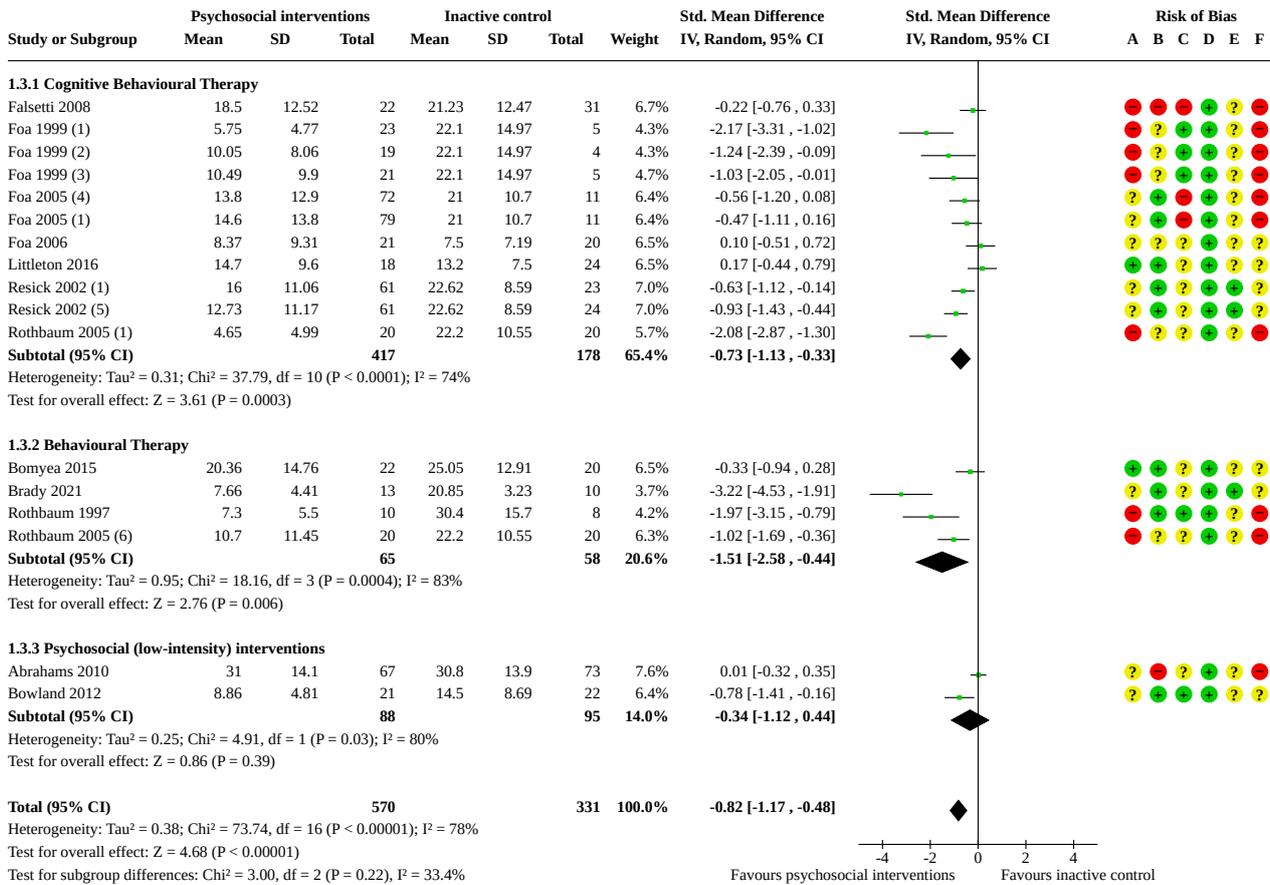
Analysis 1.2. Comparison 1: Psychosocial interventions versus inactive control, Outcome 2: Psychosocial interventions versus inactive control; outcome 1: PTSD symptoms, 3 months



Footnotes

- (1) Other psychosocial interventions (prevention of post-rape stress video) vs usual care
- (2) Behavioural (pleasant imagery and relaxation instruction video) vs usual care

Analysis 1.3. Comparison 1: Psychosocial interventions versus inactive control, Outcome 3: Psychosocial interventions versus inactive control; outcome 2: Depressive symptoms, post-treatment



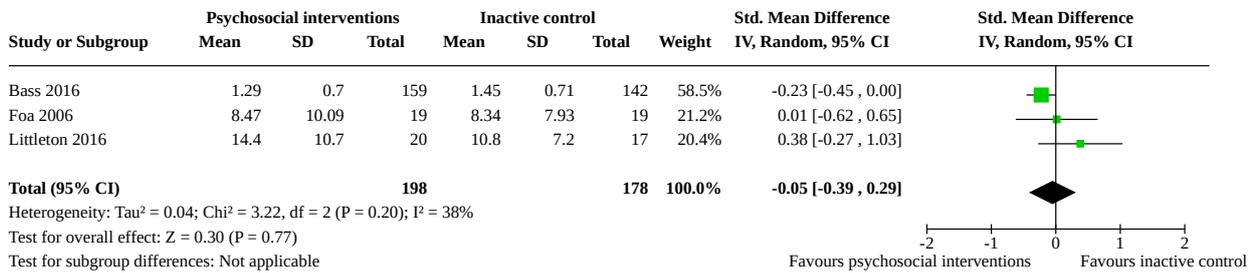
Footnotes

- (1) CBT (PE) vs wait-list
- (2) CBT (SIT) vs wait-list
- (3) CBT mixed (PE + SIT) vs wait-list
- (4) CBT mixed (PE + CR) vs wait-list
- (5) CBT (CPT) vs wait-list
- (6) Behaviour therapies (EMDR) v Waiting-list

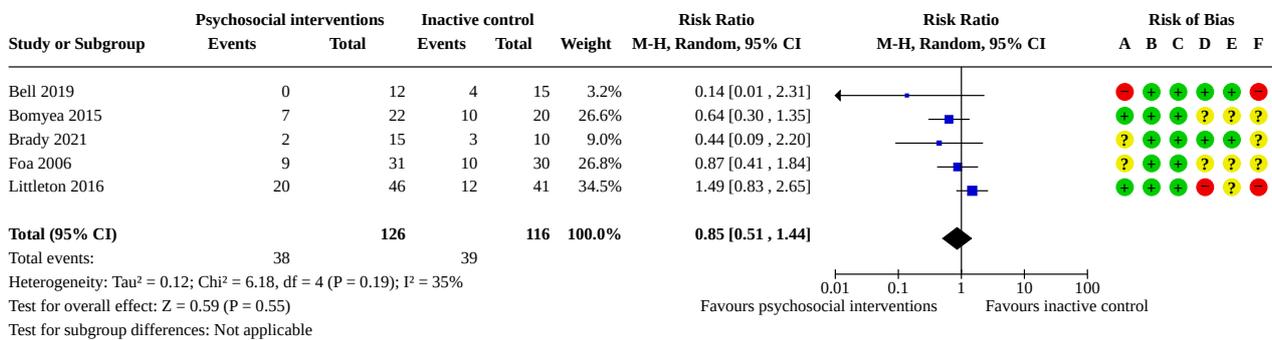
Risk of bias legend

- (A) Bias arising from the randomization process
- (B) Bias due to deviations from intended interventions
- (C) Bias due to missing outcome data
- (D) Bias in measurement of the outcome
- (E) Bias in selection of the reported result
- (F) Overall bias

Analysis 1.4. Comparison 1: Psychosocial interventions versus inactive control, Outcome 4: Psychosocial interventions versus inactive control; outcome 2: Depressive symptoms, 3 months



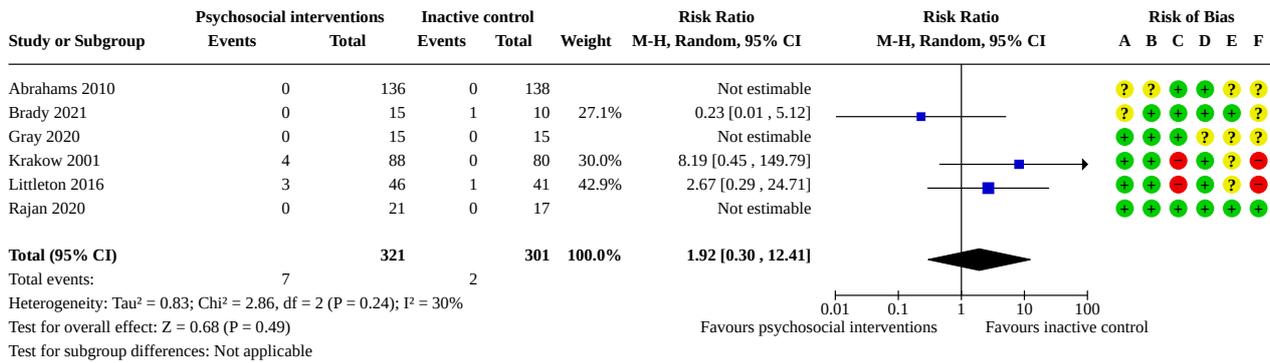
Analysis 1.5. Comparison 1: Psychosocial interventions versus inactive control, Outcome 5: Psychosocial interventions versus inactive control; outcome 3: Dropout from treatment



Risk of bias legend

- (A) Bias arising from the randomization process
- (B) Bias due to deviations from intended interventions
- (C) Bias due to missing outcome data
- (D) Bias in measurement of the outcome
- (E) Bias in selection of the reported result
- (F) Overall bias

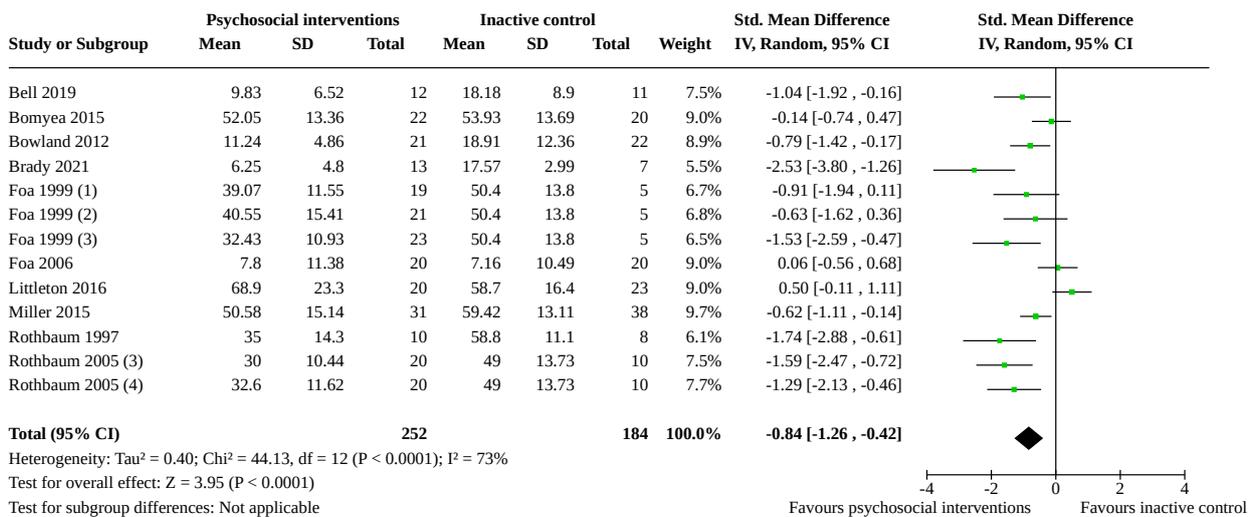
Analysis 1.6. Comparison 1: Psychosocial interventions versus inactive control, Outcome 6: Psychosocial interventions versus inactive control; outcome 4: Adverse events



Risk of bias legend

- (A) Bias arising from the randomization process
- (B) Bias due to deviations from intended interventions
- (C) Bias due to missing outcome data
- (D) Bias in measurement of the outcome
- (E) Bias in selection of the reported result
- (F) Overall bias

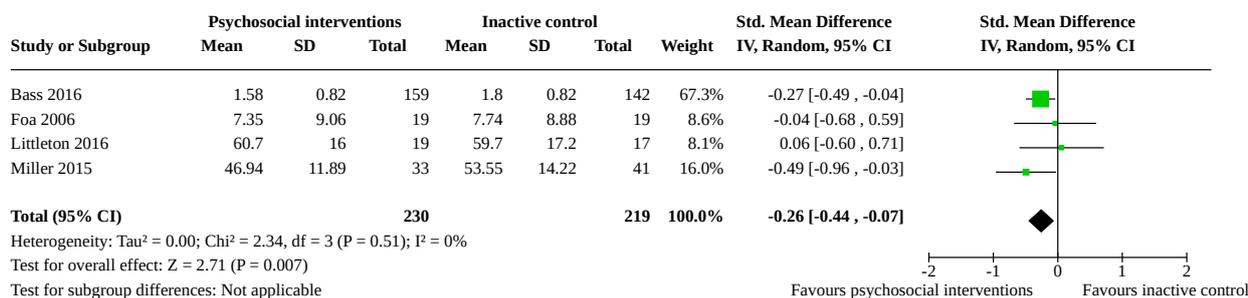
Analysis 1.7. Comparison 1: Psychosocial interventions versus inactive control, Outcome 7: Psychosocial interventions versus inactive control; outcome 5: Anxiety symptoms, post-treatment



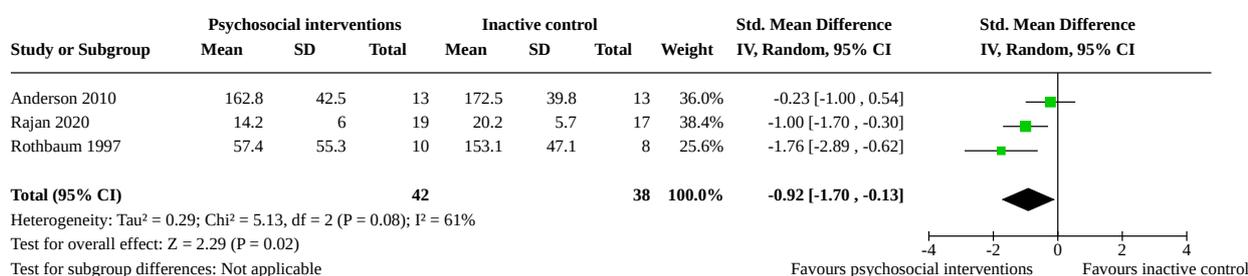
Footnotes

- (1) CBT (SIT) vs wait-list
- (2) CBT mixed (PE + SIT) vs wait-list
- (3) CBT (PE) vs wait-list
- (4) EMDR vs wait-list

Analysis 1.8. Comparison 1: Psychosocial interventions versus inactive control, Outcome 8: Psychosocial interventions versus inactive control; outcome 5: Anxiety symptoms, 3 months



Analysis 1.9. Comparison 1: Psychosocial interventions versus inactive control, Outcome 9: Psychosocial interventions versus inactive control; outcome 6: Global mental health/distress, post-treatment

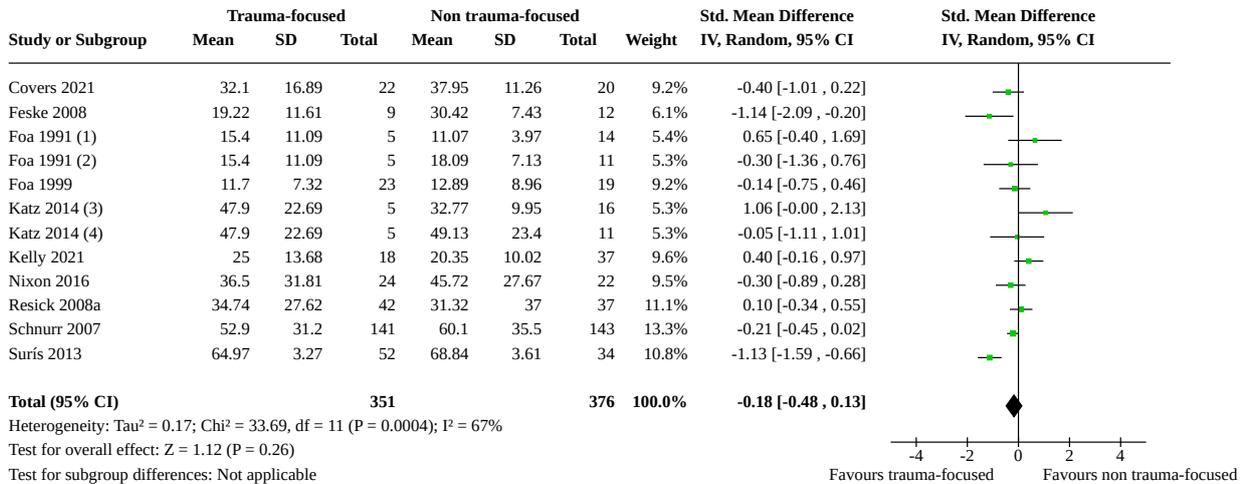


Comparison 2. Trauma-focused versus non trauma-focused interventions

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Trauma-focused versus non trauma-focused interventions; outcome 1: PTSD symptoms, post-treatment	10	727	Std. Mean Difference (IV, Random, 95% CI)	-0.18 [-0.48, 0.13]
2.2 Trauma-focused versus non trauma-focused interventions; outcome 1: PTSD symptoms, 3 months	8	584	Std. Mean Difference (IV, Random, 95% CI)	-0.33 [-0.49, -0.16]
2.3 Trauma-focused versus non trauma-focused interventions; outcome 1: PTSD symptoms, 6 months	5	533	Std. Mean Difference (IV, Random, 95% CI)	-0.21 [-0.43, 0.01]
2.4 Trauma-focused versus non trauma-focused interventions; outcome 2: Depressive symptoms, post-treatment	9	673	Std. Mean Difference (IV, Random, 95% CI)	-0.21 [-0.54, 0.12]
2.5 Trauma-focused versus non trauma-focused interventions; outcome 2: Depressive symptoms, 3 months	7	535	Std. Mean Difference (IV, Random, 95% CI)	-0.56 [-0.97, -0.15]
2.6 Trauma-focused versus non trauma-focused interventions; outcome 2: Depressive symptoms, 6 months	5	532	Std. Mean Difference (IV, Random, 95% CI)	-0.68 [-1.49, 0.13]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.7 Trauma-focused versus non trauma-focused interventions; outcome 3: Dropout from treatment	10	859	Risk Ratio (M-H, Random, 95% CI)	1.43 [1.08, 1.87]
2.8 Trauma-focused versus non trauma-focused interventions; outcome 4: Adverse events	5	591	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.29, 1.37]
2.9 Trauma-focused versus non trauma-focused interventions; outcome 5: Anxiety symptoms, post-treatment	7	540	Std. Mean Difference (IV, Random, 95% CI)	-0.15 [-0.42, 0.13]
2.10 Trauma-focused versus non trauma-focused interventions; outcome 5: Anxiety symptoms, 3 months	5	403	Std. Mean Difference (IV, Random, 95% CI)	-0.23 [-0.49, 0.02]
2.11 Trauma-focused versus non trauma-focused interventions; outcome 5: Anxiety symptoms, 6 months	3	399	Std. Mean Difference (IV, Random, 95% CI)	-0.05 [-0.37, 0.28]
2.12 Trauma-focused versus non-trauma focused interventions; outcome 7: Trauma-related beliefs, post-treatment	3	152	Std. Mean Difference (IV, Random, 95% CI)	0.16 [-0.17, 0.50]
2.13 Trauma-focused versus non trauma-focused interventions; outcome 7: Global mental health/distress, post-treatment	3	342	Std. Mean Difference (IV, Random, 95% CI)	0.07 [-0.36, 0.51]
2.14 Trauma-focused versus non trauma-focused interventions; outcome 7: Global mental health/distress, 3 months	3	341	Std. Mean Difference (IV, Random, 95% CI)	-0.35 [-1.00, 0.31]

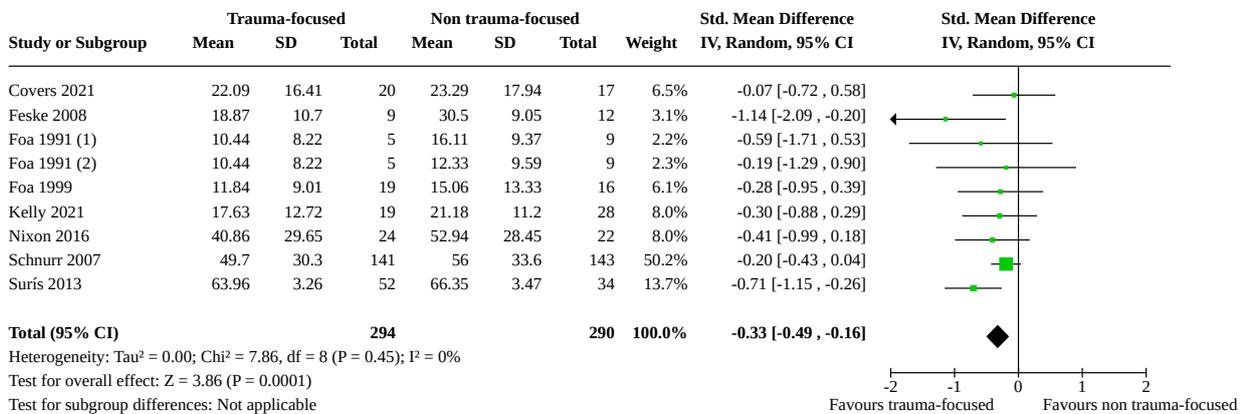
Analysis 2.1. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 1: Trauma-focused versus non trauma-focused interventions; outcome 1: PTSD symptoms, post-treatment



Footnotes

- (1) CBT (PE) vs CBT (SIT)
- (2) CBT (PE) vs supportive counselling
- (3) CBT (PE) vs holographic reprocessing
- (4) CBT (PE) vs person-centred therapy

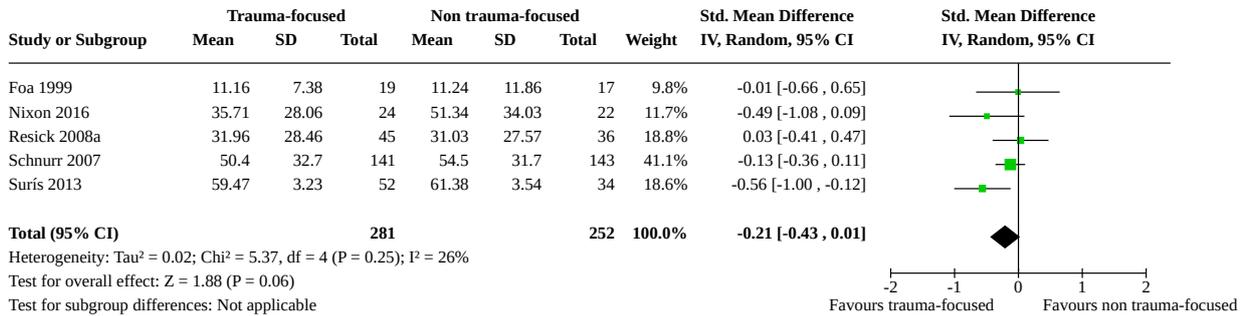
Analysis 2.2. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 2: Trauma-focused versus non trauma-focused interventions; outcome 1: PTSD symptoms, 3 months



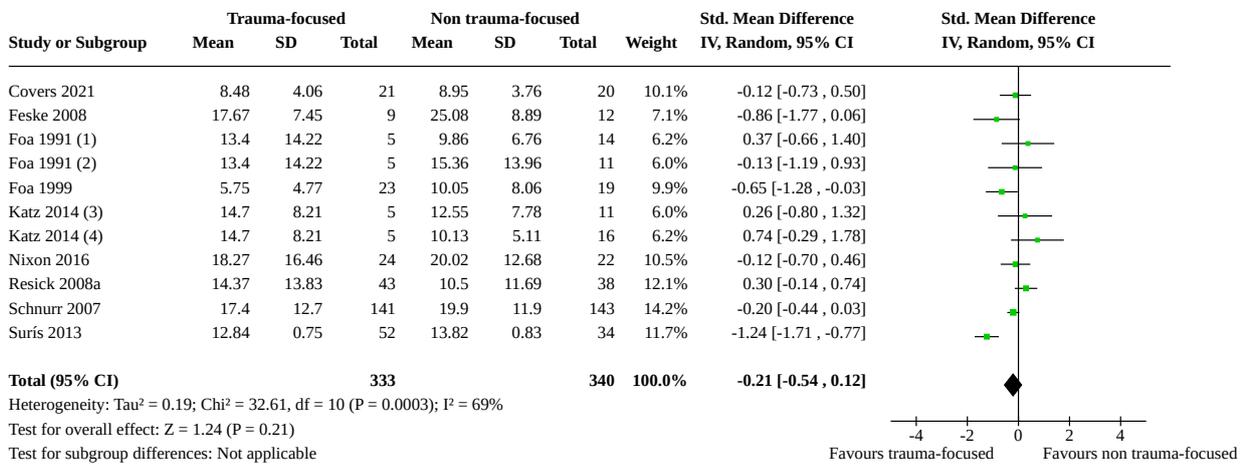
Footnotes

- (1) CBT (PE) vs supportive counselling
- (2) CBT (PE) vs CBT (SIT)

Analysis 2.3. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 3: Trauma-focused versus non trauma-focused interventions; outcome 1: PTSD symptoms, 6 months



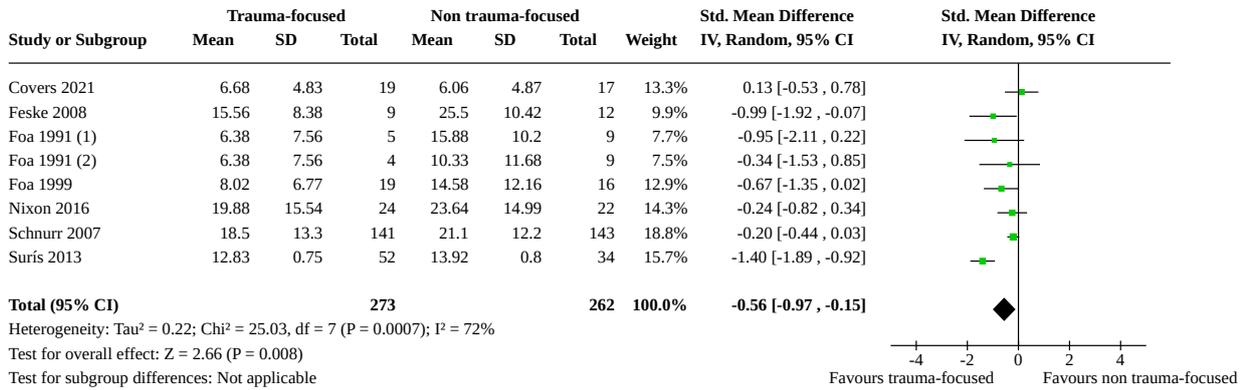
Analysis 2.4. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 4: Trauma-focused versus non trauma-focused interventions; outcome 2: Depressive symptoms, post-treatment



Footnotes

- (1) CBT (PE) vs CBT (SIT)
- (2) CBT (PE) vs supportive counselling
- (3) CBT (PE) vs person-centred therapy
- (4) CBT (PE) vs holographic reprocessing

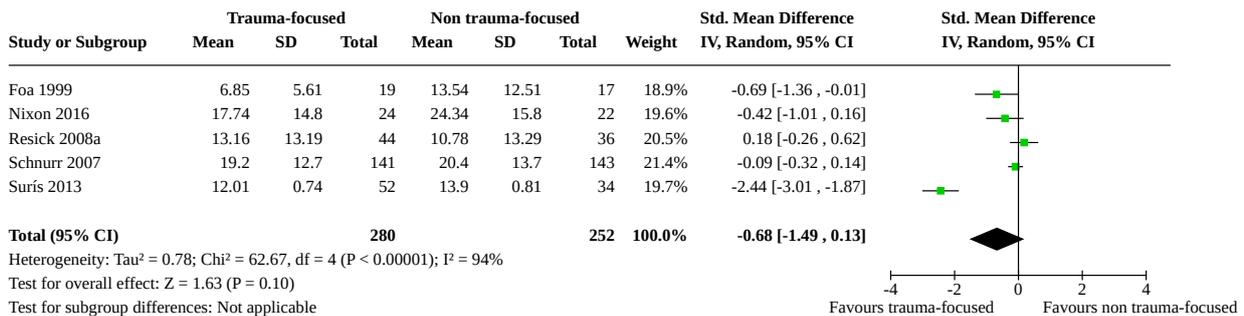
Analysis 2.5. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 5: Trauma-focused versus non trauma-focused interventions; outcome 2: Depressive symptoms, 3 months



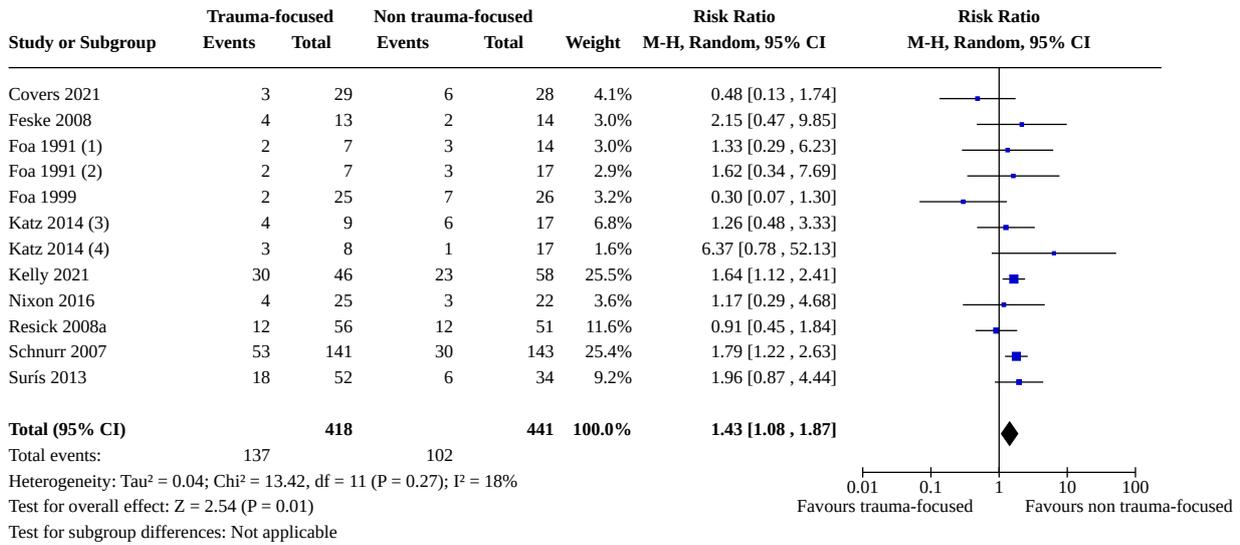
Footnotes

- (1) CBT (PE) vs supportive counselling
- (2) CBT (PE) vs CBT (SIT)

Analysis 2.6. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 6: Trauma-focused versus non trauma-focused interventions; outcome 2: Depressive symptoms, 6 months



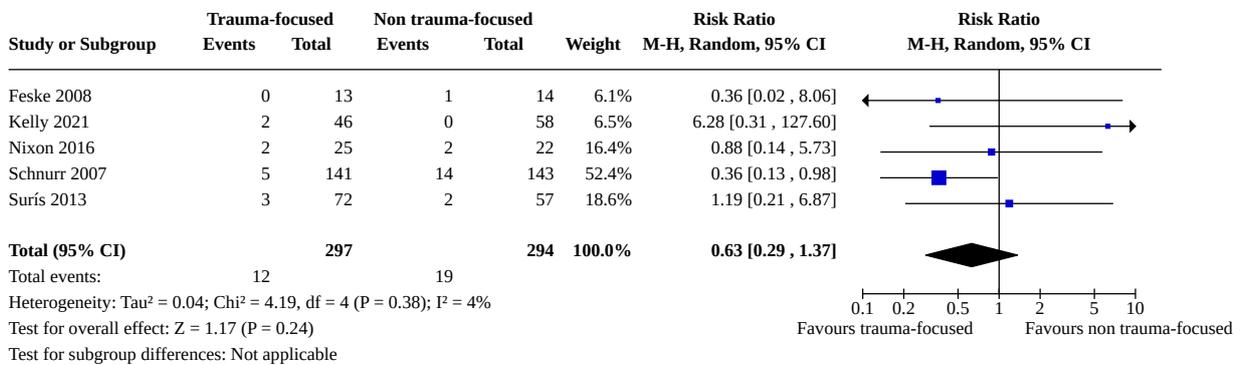
Analysis 2.7. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 7: Trauma-focused versus non trauma-focused interventions; outcome 3: Dropout from treatment



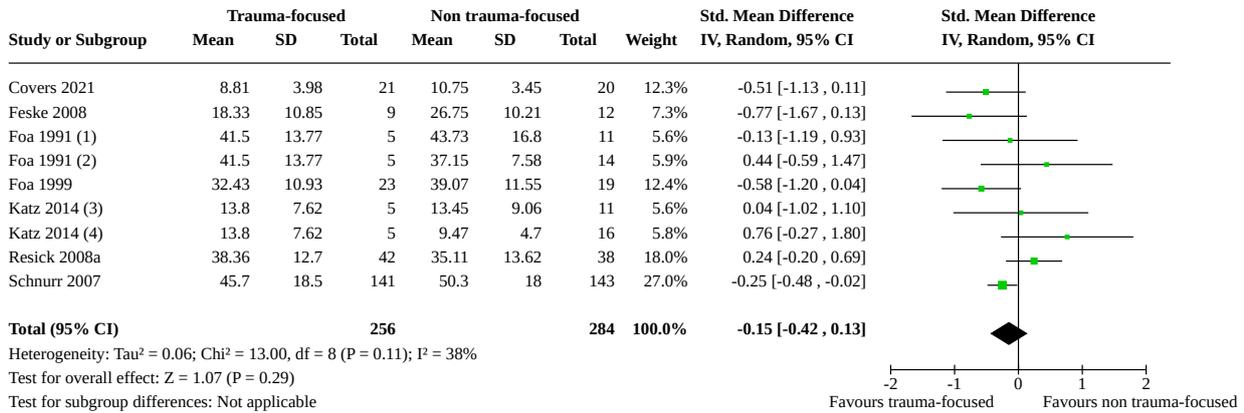
Footnotes

- (1) CBT (PE) vs supportive counselling
- (2) CBT (PE) vs CBT (SIT)
- (3) CBT (PE) vs person-centred therapy
- (4) CBT (PE) vs holographic reprocessing

Analysis 2.8. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 8: Trauma-focused versus non trauma-focused interventions; outcome 4: Adverse events



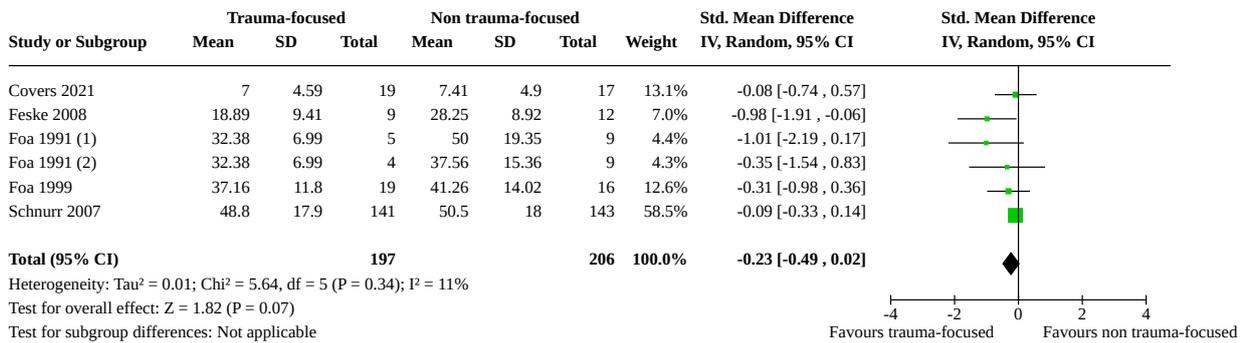
Analysis 2.9. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 9: Trauma-focused versus non trauma-focused interventions; outcome 5: Anxiety symptoms, post-treatment



Footnotes

- (1) CBT (PE) vs supportive counselling
- (2) CBT (PE) vs CBT (SIT)
- (3) CBT (PE) vs person-centred therapy
- (4) CBT (PE) vs holographic reprocessing

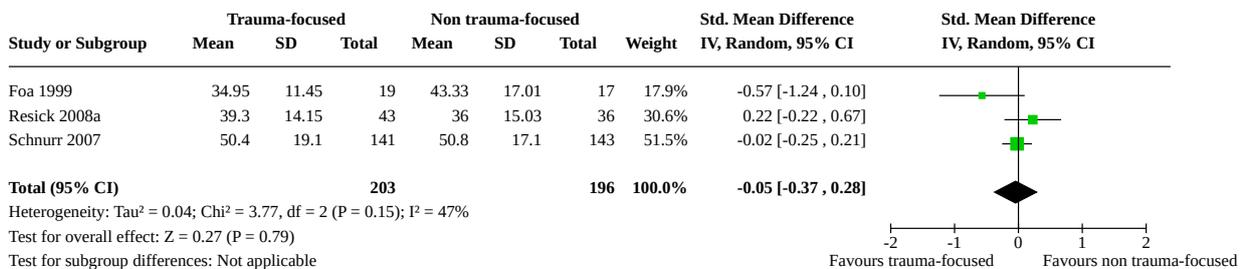
Analysis 2.10. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 10: Trauma-focused versus non trauma-focused interventions; outcome 5: Anxiety symptoms, 3 months



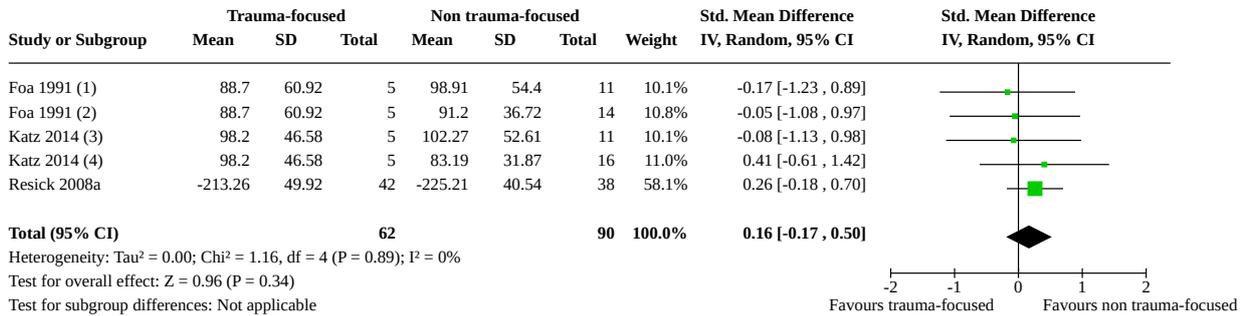
Footnotes

- (1) CBT (PE) vs supportive counselling
- (2) CBT (PE) vs CBT (SIT)

Analysis 2.11. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 11: Trauma-focused versus non trauma-focused interventions; outcome 5: Anxiety symptoms, 6 months



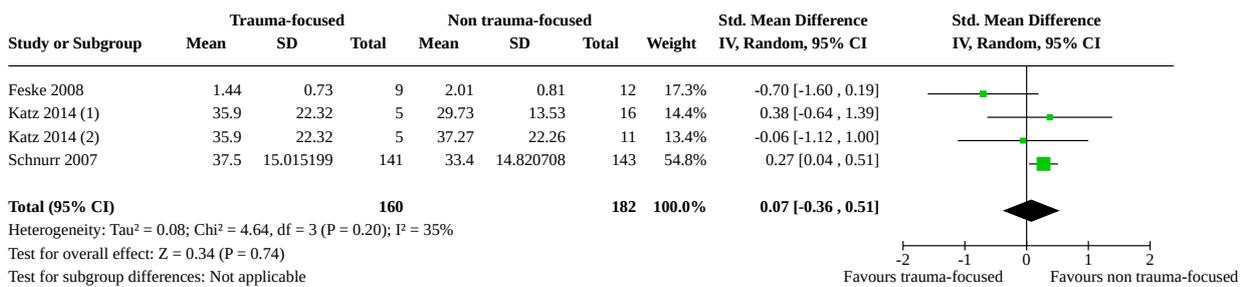
Analysis 2.12. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 12: Trauma-focused versus non-trauma focused interventions; outcome 7: Trauma-related beliefs, post-treatment



Footnotes

- (1) CBT (PE) vs supportive counselling
- (2) CBT (PE) vs CBT (SIT)
- (3) CBT (PE) vs person-centred therapy
- (4) CBT (PE) vs holographic reprocessing

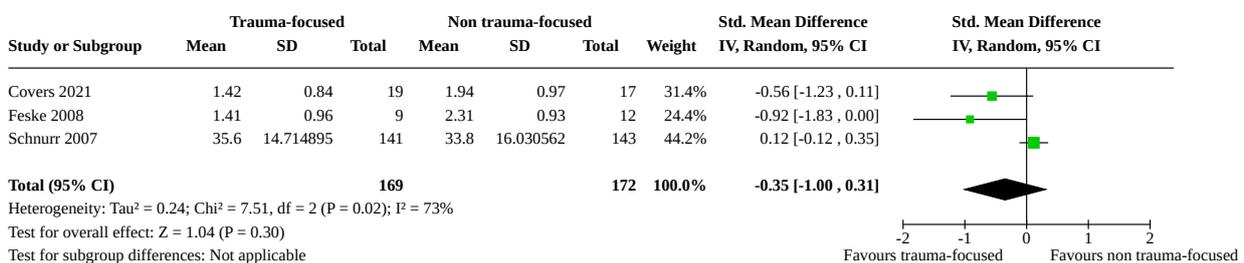
Analysis 2.13. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 13: Trauma-focused versus non trauma-focused interventions; outcome 7: Global mental health/distress, post-treatment



Footnotes

- (1) CBT (PE) vs person-centred therapy
- (2) CBT (PE) vs holographic reprocessing

Analysis 2.14. Comparison 2: Trauma-focused versus non trauma-focused interventions, Outcome 14: Trauma-focused versus non trauma-focused interventions; outcome 7: Global mental health/distress, 3 months



ADDITIONAL TABLES

Table 1. List of studies by number of active and comparative arms

Design	Number of studies	Studies
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Table 1. List of studies by number of active and comparative arms (Continued)

2-arm trial of intervention vs control	16	Abrahams 2010; Anderson 2010; Bass 2016; Bell 2019; Bomyea 2015; Bowland 2012; Brady 2021; Creech 2021; Falsetti 2008; Gray 2020; Krakow 2001; Littleton 2016; Miller 2015; Rajan 2020; Rothbaum 1997; Sikkema 2018
2- or 3-active arm trial vs control group	7	Foa 1991; Foa 1999; Foa 2005; Foa 2006; Resick 2002; Rothbaum 2005; Walsh 2017
2- or 3-active arm trial	13	Acierno 2021; Bass 2013; Belleville 2018; Covers 2021; Echeburua 1996; Feske 2008; Galovski 2016; Katz 2014; Kelly 2021; Nixon 2016; Resick 2008a; Schnurr 2007; Surís 2013

Table 2. List of included studies reporting primary outcome data

Primary outcome	Number of studies	Studies
PTSD symptoms	32	Acierno 2021; Anderson 2010; Bass 2013; Bass 2016; Bell 2019; Belleville 2018; Bomyea 2015; Covers 2021; Creech 2021; Echeburua 1996; Falsetti 2008; Feske 2008; Foa 1991; Foa 1999; Foa 2005; Foa 2006; Galovski 2016; Gray 2020; Katz 2014; Kelly 2021; Krakow 2001; Littleton 2016; Miller 2015; Nixon 2016; Rajan 2020; Resick 2002; Resick 2008a; Rothbaum 1997; Schnurr 2007; Sikkema 2018; Surís 2013; Walsh 2017
Depressive symptoms	23	Abrahams 2010; Acierno 2021; Bass 2016; Bomyea 2015; Bowland 2012; Covers 2021; Echeburua 1996; Falsetti 2008; Feske 2008; Foa 1991; Foa 1999; Foa 2005; Foa 2006; Galovski 2016; Katz 2014; Littleton 2016; Nixon 2016; Resick 2002; Resick 2008a; Rothbaum 1997; Rothbaum 2005; Schnurr 2007; Surís 2013
Dropout	32	Abrahams 2010; Acierno 2021; Bass 2013; Bell 2019; Bomyea 2015; Bowland 2012; Covers 2021; Creech 2021; Echeburua 1996; Falsetti 2008; Feske 2008; Foa 1991; Foa 1999; Foa 2005; Foa 2006; Galovski 2016; Gray 2020; Katz 2014; Kelly 2021; Krakow 2001; Littleton 2016; Miller 2015; Nixon 2016; Rajan 2020; Resick 2002; Resick 2008a; Rothbaum 1997; Rothbaum 2005; Schnurr 2007; Sikkema 2018; Surís 2013; Walsh 2017
Adverse events	16	Abrahams 2010; Acierno 2021; Brady 2021; Covers 2021; Foa 2005; Feske 2008; Gray 2020; Katz 2014; Kelly 2021; Krakow 2001; Littleton 2016; Nixon 2016; Rajan 2020; Resick 2008a; Schnurr 2007; Surís 2013

We included studies in adverse events if they reported a count of adverse events affecting participants.

PTSD: post-traumatic stress disorder

Table 3. List of included studies reporting secondary outcome data

Outcome	Number of studies	Studies
Anxiety symptoms	17	Bass 2016; Bell 2019; Bomyea 2015; Bowland 2012; Covers 2021; Echeburua 1996; Feske 2008; Foa 1991; Foa 1999; Foa 2006; Katz 2014; Littleton 2016; Miller 2015; Resick 2008a; Rothbaum 1997; Rothbaum 2005; Schnurr 2007
Dissociation symptoms	2	Covers 2021; Rothbaum 2005
Global mental health functioning/distress	10	Anderson 2010; Bass 2013; Bass 2016; Belleville 2018; Covers 2021; Feske 2008; Katz 2014; Rajan 2020; Rothbaum 1997; Schnurr 2007

Table 3. List of included studies reporting secondary outcome data (Continued)

Trauma-related beliefs	9	Bass 2013; Bass 2016; Covers 2021; Echeburua 1996; Foa 1991; Foa 2006; Katz 2014; Resick 2002; Resick 2008a
Substance use	3	Creech 2021; Schnurr 2007; Walsh 2017
QoL	1	Schnurr 2007

QoL: quality of life

Table 4. List of included studies in Comparison 1 reporting adverse events data

Study	Approach to reporting adverse events	Count
Abrahams 2010	Study explicitly states that there were no recorded adverse events.	0/136 telephonic psychosocial support vs 0/138 minimal intervention
Anderson 2010	Study highlights that, in terms of emotional processes at the session level, women in the CBT (CAED) group reported significantly greater levels of negative affect following each of the sessions (except Session 3), relative to the control group; however, it does not provide the numbers. It states, "Hence, overall the CAED sessions appeared to achieve the expected increase in negative affect." Beyond this, the study lacks specific information about recording of or actual adverse events and harms.	—
Bass 2016	There was no reference to any methods around assessing adverse events or harms. Authors state, "We learned that it is possible to implement targeted strategies to include sexual violence survivors in VSLA groups in a safe and ethical manner, and that sexual violence survivors even those with severe trauma symptoms, can benefit from this participation."	—
Bell 2019	The study lists a range of stressors that participants were exposed to during the study but does not provide numbers for these. They make the point that "many participants who were exposed to triggers and stressors reported feeling lower levels of stress reactivity and enhanced levels of self-regulation in response to these stressors than they had prior to the study." The study refers to how stressors may confound the findings and acknowledges triggering experiences occurring in participants' lives but does not give attention to harms arising from its interventions. Notwithstanding this, there was just 1 withdrawal, and that was in the control (or minimal intervention) group.	—
Bomyea 2015	"No participants experienced clinically significant deterioration." The authors acknowledge the high rate of treatment dropout but did not gather systematic data or reasons for this. Overall, the study does not report a systematic approach to recording adverse events and harms.	—
Bowland 2012	Treatment dropout was low: "One did not attend any groups and was unable to be reached after the randomization procedure". Overall, the study does not report a systematic approach to recording adverse events and harms.	—
Brady 2021	"Overall, retention in both arms of the trial was acceptable. Within the NET group, one individual discovered that she was in the advanced stages of pregnancy soon after allocation. It was not feasible for her to receive a full course of treatment, so she was withdrawn from the study. One individual dropped out of therapy after eight sessions, stating that they no longer wanted to engage in trauma-focused therapy. All other participants in the NET group (n =	0/15 narrative exposure therapy vs 1/10 minimal intervention (psychoeducation)

Table 4. List of included studies in Comparison 1 reporting adverse events data *(Continued)*

	<p>13) completed NET. In the wait-list group, one participant was removed from the trial before the end of the waiting period owing to a significant increase in their risk of suicide. The remaining participants in the wait-list group completed the waiting period. However, two participants dropped out of the study at the point of post-wait assessment, owing to a deterioration in their physical health, and were therefore lost to follow-up. The remaining participants in the wait-list group were offered the opportunity to receive NET, and all took up this offer." The researchers make reference to deterioration in scores – for example, in the NET group, two people had worse scores on the CAPS-5 – but this was not clinically significant, and we did not count it.</p>	
Falsetti 2008	<p>It is indicated that "Additionally, 16 participants dropped out of the study, including six individuals in the treatment group who attended only one session and 10 participants who dropped out at a later point in the study (two from the treatment group and eight from the control group)." However, reasons for treatment noncompletion are not furnished. There is no other reference to assessment of adverse events or harms in the study.</p>	—
Foa 1991	<p>No specific reference to adverse events or harm is made.</p>	—
Foa 1999	<p>The study provides an analysis of the differences in baseline characteristics between treatment completers and noncompleters but does not offer any explanations as to why people elected to exit the intervention. "More participants dropped out from SIT and PE-SIT (27%) than from the PE and WL conditions (5%)... There were no significant differences between dropouts and completers on any of the pretreatment measures of psychopathology. A significant difference on one demographic variable emerged: nonworking participants (30%) were more likely to drop out than participants who were working full or part time (10%)." No specific reference to adverse events or harm is made.</p>	—
Foa 2005	<p>Greater detail in this subsequent study by Foa and colleagues on the nature of events: "Twelve serious adverse events led to termination in the study, six of which are included in the postrandomization removal category in Figure 1 (4 participants reassaulted, 1 developing a life-threatening illness, and 1 death). The remaining six serious adverse events were classified as drop-outs (4 had severe depression and suicidal ideation that required immediate intervention, 2 of which were hospitalized, and 2 exhibited extreme dissociative symptoms)." This study also examined symptom worsening. Whilst this study has provided detail at the individual level not seen in others, it is limited by not providing events by group and thus cannot be meta-analysed.</p>	12/179
Foa 2006	<p>"Twenty-four participants (26.7%) dropped out of the intervention, leaving 66 completers. Dropouts were distributed as follows: 9 (29%) in the B-CBT condition, 10 (33.3%) in the AC, and 5 (17.2%) in the SC condition. The dropout rate did not differ across conditions... No significant differences between completers and dropouts emerged on pre-intervention psychopathology and demographic variables." The authors state, "Finally, we did not collect systematic information about how many people were excluded from the study or the reasons why." Overall, this study lacks detail on adverse events and harms.</p>	—
Gray 2020	<p>Dropout from this study was low – one person exited the post-wait intervention group. The study states that "No reportable adverse events occurred" across the 30 randomised participants.</p>	0/15 RTM vs 0/15 waiting list
Krakow 2001	<p>Four participants were lost from the intervention. The study states, "Imagery rehearsal therapy produces imagery adverse effects; 4 patients reported increased negative imagery and eventually withdrew, and 12 of 66 who completed treatment did not complete follow-up for unknown reasons." Some limitations around the potential for wider harms to be detected.</p>	4/88 CBT/IRT vs 0/80 waiting list

Table 4. List of included studies in Comparison 1 reporting adverse events data (Continued)

Littleton 2016	<p>This study was explicit about any increases in symptoms (PTSD, anxiety and depression) at the individual level, e.g. "No participants reported a clinically significant increase in PTSD symptoms from pre-treatment to follow-up. Two participants in the interactive program reported continued clinically significant increases in depression symptoms from pre-treatment to follow-up... One participant assigned to the psycho-educational website also experienced a clinically significant increase in depressive symptoms from pre-treatment to follow-up. Finally, one additional participant in the interactive program reported a clinically significant increase in anxiety at follow-up." This study shows positive attention to individual journeys through the treatment; however, it confines its assessment to the outcome measures.</p>	<p>3/46 interactive CBT vs 1/41 minimal interven- tion website</p>
Miller 2015	<p>Only 1 person is reported to not have tolerated the psychoeducation video; however, attrition was very high in this study at nearly 60%. "Participants were questioned about whether the examination or participating in research increased their distress. Overall, they responded that neither increased distress so this is unlikely to relate to the attrition." There is a lack of information about the qualitative component of this research. There are many unknowns in regard to the reasons why attrition was so elevated.</p>	—
Rajan 2020	<p>Treatment completion was high, and attrition was low. "No harms were detected (i.e., there were no elevated scores on IES-R, or NSESSS at time point two or three)." The authors explain, "Because this was the first randomized controlled treatment study conducted for the method, we followed the results in order to be able to detect adverse effects (i.e., elevated scores on self-rating at time point two)." This study showed an awareness of monitoring adverse effects, although it appears to confine this to the outcome measures.</p>	<p>0/21 modified lifes- pan integration vs 0/17 waiting list</p>
Resick 2002	<p>This study makes some attempt to provide reasons for early postrandomisation withdrawals, though it is not systematic about this: "Of 181 women randomized into the trial, 10 were terminated from the study as a result of meeting exclusion criteria subsequent to new violence (women had to be at least 3 months posttrauma), changes in medication, or substance dependence relapse. Therefore, the intent-to-treat (ITT) sample included 171 women, among whom 13 never returned for the first session." The study provides an analysis on the differences in baseline characteristics between treatment completers and noncompleters but does not offer any explanations as to why a further 37 women left the treatment", "Thirty-seven women dropped out of treatment, and 121 women completed treatment along with at least the posttreatment assessment: 41 CPT clients, 40 PE clients, and 40 MA clients. Dropout rates for the two active treatment groups were similar: 26.8% for CPT and 27.3% for PE. In the MA condition, 14.9% did not return for the second assessment. 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." This study lacks a systematic approach to recording adverse events and harms.</p>	—
Rothbaum 1997	<p>No specific statement on adverse events or harm is offered; however, reasons for attrition of 3 people in the study are provided, and none raise concerns.</p>	—
Rothbaum 2005	<p>"Of the 74 women enrolled in the study, 1 dropped out during the assessment phase, 1 was terminated and referred during treatment for not meeting treatment criteria, 12 dropped out during treatment, and 60 women (83.3%) completed the protocol. The dropout rate across the three groups was not significantly different, PE: 13.0% (n = 3, 2 before MID); EMDR: 20.0% (n = 5, 4 before MID); and WAIT: 16.7% (n = 4)." This study lacks a systematic approach to recording adverse events and harms.</p>	—

Table 4. List of included studies in Comparison 1 reporting adverse events data (Continued)

Sikkema 2018	This study highlights the barriers to gaining reasons for treatment noncompletion when people are not contactable: of the 13 who left the treatment, 12 were not reachable and 1 had scheduling issues; of the 6 who exited the standard care condition, 4 were not reachable and 2 had scheduling issues. In terms of attrition, "Participants lost to follow-up at the 6-month assessment were significantly more likely than those retained to have reported hazardous drinking (69.2% vs. 37.3%, $p = 0.04$) and recent physical intimate partner violence at baseline (46.2% vs. 17.65%, $p = 0.03$)." This study lacks a systematic approach to recording adverse events and harms.	—
Walsh 2017	"The PANAS was administered pre-exam as a measure of potential differences in distress across groups as well as post-exam as a validity check regarding intervention condition." We did not see any reporting of scores beyond a check when a change in length of the video was introduced. This study lacks a systematic approach to recording adverse events and harms.	—

AC: assessment control; B-CBT: brief cognitive behaviour therapy; CAED: Clinician-Assisted Emotional Disclosure; CAPS-5: Clinician-Administered PTSD Scale for DSM-5; CBT: cognitive behavioural therapy; CPT: cognitive processing therapy; EMDR: eye movement desensitisation and reprocessing; IES-R: Impact of Event Scale – Revised; IRT: imagery rehearsal therapy; MA: minimal attention condition; MID: minimally important difference; NET: narrative exposure therapy; NSESS: National Stressful Events Survey PTSD Short Scale; PANAS: Positive and Negative Affect Schedule; PE: prolonged exposure; PE-SIT: prolonged exposure combined with stress inoculation therapy; PTSD: post-traumatic stress disorder; RTM: reconsolidation of traumatic memories; SC: supportive counselling; SIT: stress inoculation therapy; VSLA: Village Savings and Loans Associations; WAIT: wait-list control; WL: wait-list

Table 5. List of included studies in Comparison 2 reporting adverse events data

Study	Approach to reporting adverse events	Count
Covers 2021	"Only one participant discontinued participation due to increased suicide ideation. No other (serious) adverse events were found."	1/29 behavioural (EMDR) vs 0/28 other psychosocial interventions (telephonic psychosocial support)
Feske 2008	"Two PE clients and 1 TAU client were withdrawn because they changed their medication. Two PE clients dropped out for unknown reasons; one TAU client dropped out because her depression worsened after the third TAU session."	0/13 CBT/PE and 1/14 integrative (TAU) (non-trauma focused)
Foa 1991	No specific reference to adverse events or harm is made.	—
Foa 1999	No specific reference to adverse events or harm is made.	—
Katz 2014	"The study was monitored by the local IRB and no adverse events were reported."	0/17 PE vs 0/17 integrative/holographic reprocessing (non-trauma focused) vs 0/17 PCT (non-trauma focused)
Kelly 2021	"There were no safety problems or unanticipated adverse events reported during this study. There were no study-related physical injuries. Two participants in the CPT group withdrew due to increased psychological distress and were referred for individual therapy. The study included a Data Safety Monitoring Board (DSMB) in the final year with the addition of the second site. The DSMB met with the study Principal Investigator and had no concerns regarding safety of participants or data."	2/46 CBT/CPT vs 0/59 trauma-sensitive yoga (non-trauma focused)

Table 5. List of included studies in Comparison 2 reporting adverse events data (Continued)

Nixon 2016	"There were no significant adverse events in either condition." Based on available data and using a change of > 12 points on the CAPS as an indicator of reliable change, 2 participants in CPT demonstrated worsening of symptoms at different periods. Two participants in the group that received integrative care (as part of TAU) had an increase of exactly 12 points on the CAPS at 6-month follow-up. This worsening of symptoms was not seen on participants' PCL scores.	2/25 CPT vs 2/22 integrative (non-trauma focused)
Resick 2008a	"Of 162 women randomized into the trial, 12 were terminated from the study, by design, for meeting exclusion criteria subsequent to new violence (women had to be at least 3 months posttrauma), changes in medication, or psychosis. Among them, 1 WA participant was terminated from the trial when the therapist stopped the protocol because of increased suicidal ideation. These terminations were evenly distributed across groups. Therefore, the intent-to-treat (ITT) sample included 150 women. There was one other unrelated adverse event during the trial." We had already excluded the WE group from Comparison 2, and it is not clear which group the other person with an adverse event was assigned to.	—
Schnurr 2007	"There were 5 serious adverse events in prolonged exposure (4 psychiatric hospitalizations and 1 suicide attempt) and 14 in present-centered therapy (2 deaths [nonsuicidal], 9 psychiatric hospitalizations, and 3 suicide attempts). No events were regarded as study-related; the suicide attempt in prolonged exposure was coded as possibly related."	5/141 CBT/PE vs 14/143 PCT (non-trauma focused)
Surís 2013	"During the course of the study there were three adverse events in the CPT condition (one suicide attempt by overdose and two psychiatric hospitalizations) and two adverse events in the PCT condition (one suicide attempt by overdose and one psychiatric hospitalization). No events were deemed definitely study-related; however, one psychiatric hospitalization in the CPT condition was deemed possibly related."	3/72 CBT/CPT vs 2/57 PCT (non-trauma focused)

CAPS: Clinician Administered PTSD Scale; CBT: cognitive behavioural therapy; CPT: cognitive processing therapy; EMDR: eye movement desensitisation and reprocessing; IRB: institutional review board; PCL: Post-Traumatic Stress Disorder Checklist; PCT: present-centred therapy; PE: prolonged exposure; TAU: treatment as usual; WA: written account; WE: written exposure

APPENDICES

Appendix 1. Appendix 1. How the intervention might work

Cognitive behavioural interventions are based on the proposition that behaviours are cognitively mediated (Butler 2006). Mental health and social problems may be influenced by cognitions and resulting behaviours. Because cognitive activity may be monitored and altered, behaviours may be changed through cognitive changes (Dobson 2009). Therefore, interventions that address certain thinking patterns and beliefs may result in positive changes in symptoms, problems and behaviours, which may reduce some of the negative trauma-related outcomes of rape or sexual assault (Butler 2006). In the case of trauma, theorists believe that the appraisal of fear involves the activation of trauma-induced schema that lead the survivor to pay attention to information that is consistent with the schema and to ignore evidence that is inconsistent (Resick 1992). This means that benign or ambiguous events can trigger a fear appraisal in trauma survivors (Beck 1985). Hence, cognitive theory, as applied to the process of post-traumatic stress disorder (PTSD) (Veronen 1983), focuses on two processes: 1) changing a person's cognitive appraisal of the traumatic event, or changing the process by which an individual attaches meaning to an event, and 2) changing a person's attribution of the event. Coping skill treatments are designed to equip survivors with an array of skills to manage their trauma. Some interventions are designed to be delivered within a short period of time following the assault or rape (less than three months), whereas others are used for survivors over the longer term. The former is an attempt to provide prophylactic treatment to prevent chronic problems, while others intend to facilitate faster recovery (Vickerman 2009).

Interventions for sexual assault and rape survivors typically employ a combination of approaches, for example, in the case of stress inoculation therapy, prolonged exposure therapy and cognitive processing therapy, as outlined below.

Stress inoculation therapy (SIT) was adapted (Veronen 1983) from anxiety management procedures (Meichenbaum 1977). It incorporates three elements: 1) behaviourally based psychoeducation so that survivors can understand and normalise fear and avoidance behaviours; 2) guided hierarchical in vivo assignments to target rape-related phobias (e.g. darkness); and 3) training in six behavioural and cognitive behavioural coping strategies, which are thought-stopping, guided self-dialogue, muscle relaxation, controlled breathing, covert modelling and role-playing. The goal of SIT is to increase the survivor's awareness of conditioned stimuli to improve early detection of anxiety-provoking cues, which facilitates the use of coping skills early in the stress response to reduce anxiety (Sherman 1998).

Prolonged exposure therapy (PET) was developed from earlier treatments using flooding exposure techniques and emotion processing theory with patients with anxiety disorders (Foa 1986). These techniques were extended by Foa and colleagues (Foa 1986; Foa 1994), who argued that it is the encoding of memories under extreme distress that leads to disjointed and disorganised memories, which impede natural recovery and lead to PTSD. The aim of PET is to decrease the anxiety associated with rape memories. PET begins with psychoeducation, breathing training and the development of a fear and avoidance hierarchy for in vivo exposures. In therapy, people are asked to relive the rape scene and describe it aloud as they are imagining it, using present tense and vivid detail, which may be done several times in one therapy session. The survivor's narrative is recorded, and daily homework requires them to listen to their recorded account for further exposure (Foa 1991).

Cognitive processing therapy (CPT) was developed from emotional processing theory to identify a rape survivor's 'stuck points', which are the parts of the traumatic narratives that cause them the greatest conflict (Resick 1992; Resick 1993). These are manifestations of unsuccessful attempts to accommodate information in relation to the trauma into pre-existing memory and belief structures. The goal of CPT is to help individuals to integrate their trauma into pre-existing schemas, to decrease avoidance and intrusions of unintegrated aspects of the trauma. Unlike PET, CPT seeks to directly correct misconceptions or misinformation about trauma (for example, 'I'm not safe anywhere' or 'I can't trust anyone'). CPT also includes psychoeducation, exposure and cognitive methods. Exposure is achieved via the individual writing accounts of the rape and its meaning, which they re-read between sessions, and writing about the impact of the trauma multiple times, in order to incorporate new understandings and evaluation. Therapy then addresses one of five themes (safety, trust, power and control, esteem and intimacy) in each of the last five sessions, via the use of cognitive-restructuring worksheets, Socratic questioning and discussion.

Behavioural therapies are based on the premise that all behaviours are learnt and, therefore, that unhealthy behaviours can be changed. Techniques such as systematic desensitisation and flooding are often used with this population, which emphasise the importance of extinguishing anxiety and reducing avoidant behaviours. For example, Foa and colleagues believe that exposure to the trauma allows mistaken evaluations and faulty stimulus-response associations to be corrected (Foa 1986; Foa 1994). Survivors are taught to replace a fear response with relaxation responses. This can be done gradually, with systematic desensitisation, or more quickly via flooding.

Eye movement desensitisation and reprocessing (EMDR) was developed by Shapiro 1995 for the treatment of PTSD. It involves exposure elements and cognitive techniques. In EMDR, a scene is used to represent the entire trauma. The survivor imagines the scene and recites words related to the scene, while the therapist moves their fingers back and forth in front of the survivor, so that the survivor performs rhythmic, multi saccadic eye movements (quick, simultaneous movements of both eyes between two or more phases of fixation in the same direction) by watching the therapist's fingers. This movement is argued to facilitate the processing of trauma memory through the dual attention required to focus on attending to the therapist's finger movement (external stimulus) and the trauma scene (internal stimulus). When the survivor's anxiety to the scene has decreased, a new adaptive belief is rehearsed until this new belief feels true (Rothbaum 1997). EMDR is similar to the behavioural techniques of flooding and systematic desensitisation (Boudewyns 1996a), and studies comparing EMDR with and without eye movements suggest that EMDR without eye movements leads to equivalent outcomes as EMDR with eye movements (Boudewyns 1996b; Pitman 1996).

Third-wave cognitive behavioural therapies (e.g. acceptance and commitment therapy and mindfulness) act on changing the function of psychological events and the individuals' relationship to them through acceptance, being present and committed action (Hayes 2006).

Counselling encompasses a range of interventions that may be employed by, for example, rape crisis centres (Cryer 1980; Foa 1991; Resick 1988). Counselling can be premised on a number of approaches (e.g. humanist, psychodynamic) and may be delivered as an intervention in itself or in combination with other approaches. Counselling is likely to be very individually focused in order to discuss issues raised by the survivor, and the necessary variation makes it difficult to specify exactly what is included in each session.

Humanistic and supportive therapies include an eclectic mix of therapeutic techniques. Supportive therapy is almost always non-directive, that is, the survivor is empowered to guide the content and the therapist avoids offering direct advice (Cohen 2005; Deblinger 2001). The focus is on developing a supportive relationship between the therapist and participant (Cohen 2005). Supportive therapy can be conducted in either an individual or group format.

Other psychologically orientated interventions include a diverse range of therapies that aim to help survivors cope with, express and work through trauma through, for example, expressive writing (Harte 2013) or mindfulness (Brotto 2012). For instance, equine-assisted therapy for anxiety and post-traumatic stress symptoms has been shown to reduce symptoms of post-traumatic stress, severe emotional responses to trauma, generalised anxiety, symptoms of depression and alcohol use, as well as increasing the use of mindfulness strategies (Earles 2015).

Psychosocial interventions include a wide range of interventions that target interpersonal, social and environmental factors that relate to recovery from the trauma of rape and sexual assault in addition to, or instead of, the individual factors that are the focus of psychological therapies. The way in which the interventions might work will be dependent on the factors that are targeted. Psychoeducation elements aim to provide information, modelling and training, for example, to explain maladaptive and adaptive coping strategies and to encourage the use of the latter (e.g. see [Sikkema 2018](#)). Group programmes and the provision of advisors or mentors provide social support; these may be important given the stigma and shame associated with rape and sexual assault and which can lead to social isolation. Psychosocial interventions may increase self-esteem ([Sikkema 2018](#)) and provide practical assistance and emotional support ([Home Office 2017](#)).

Appendix 2. Search strategies

Cochrane Central Register of Controlled Trials (CENTRAL)

Searched 5 July 2019 (1494 records)

Searched 8 March 2021 (439 records)

Searched 10 January 2022 (160 records)

#1 [mh ^"sex offenses"]

#2 [mh Incest]

#3 [mh "intimate partner violence"]

#4 [mh "human trafficking"]

#5 [mh rape]

#6 [mh "spouse abuse"]

#7 (sex* NEAR/5 (abuse* or assault* or attack* or aggress* or coer* or exploit* or force* or molest* or offen* or traffick* or trauma* or unlawful* or unwanted or violen*)):ti,ab,kw

#8 (intercourse NEAR/5 (coer* or force* or unwanted)):ti,ab,kw

#9 ("intimate partner violence" or "intimate partner abuse"):ti,ab,kw

#10 (rape or raped or incest*):ti,ab,kw

#11 (sex* NEAR/3 (victim* or revictim* or re-victim* or survivor*)):ti,ab,kw

#12 {or #1-#11}

#13 MeSH descriptor: [Anxiety Disorders] explode all trees and with qualifier(s): [therapy - TH]

#14 [mh "Adaptation, Psychological"]

#15 [mh "Behavior Therapy"]

#16 [mh "Combined Modality Therapy"]

#17 [mh ^"community networks"]

#18 [mh "Complementary therapies"]

#19 [mh Counseling]

#20 MeSH descriptor: [Depression] this term only and with qualifier(s): [therapy - TH]

#21 MeSH descriptor: [Depressive Disorder, Major] explode all trees and with qualifier(s): [therapy - TH]

#22 [mh Exercise]

#23 [mh "Exercise therapy"]

#24 [mh "Health Education"]

#25 [mh "Health Knowledge, Attitudes, Practice"]

#26 [mh "Interview, Psychological"]

#27 [mh "mind body therapies"]

#28 [mh "Psychological adjustment"]

#29 MeSH descriptor: [Psychological Trauma] explode all trees and with qualifier(s): [prevention & control - PC, rehabilitation - RH, therapy - TH]

#30 [mh "psychosocial support systems"]

#31 [mh "psychotherapy"]

#32 [mh "Referral and Consultation"]

#33 [mh "Self-Help Groups"]

#34 [mh "Social Support"]

#35 MeSH descriptor: [Stress Disorders, Post-Traumatic] explode all trees and with qualifier(s): [prevention & control - PC, rehabilitation - RH, therapy - TH]

#36 MeSH descriptor: [Video Recording] this term only

#37 MeSH descriptor: [Videotape Recording] this term only

#38 [mh Writing]

#39 ((abreaction or desensitization or exposure or implosive) NEAR/3 therap*):ti,ab,kw

#40 "acceptance and commitment therapy":ti,ab,kw

#41 (advisor* or advocate* or advocacy):ti,ab,kw

#42 ((animal* or art or colo?r or creative* or dance or dancing or equine or experiential or music or narrative or play* or sensory or singing) NEAR/3 (program* or intervention* or therap*)):ti,ab,kw

#43 (autogenic or autosuggestion* or auto next suggestion* or breathing next exercise* or hypnosis or hypno next therapy or hypnotherapy):ti,ab,kw

Psychosocial interventions for survivors of rape and sexual assault experienced during adulthood (Review)

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#44 behavio* next activation:ti,ab,kw
 #45 (behavio* NEAR/3 (intervention* or program* or therap* or training or treatment*)):ti,ab,kw
 #46 ((biofeedback or feedback or imagery) NEAR/3 (intervention* or therap* or train* or treatment*)):ti,ab,kw
 #47 ((brief or combination or compass* next focus* or integrated or integrative or time next limited) NEAR/3 (intervention* or therap* or treatment*)):ti,ab,kw
 #48 ((client next focus* or non next direct* or nondirect* or solution next focus* or trauma* or talking) NEAR/3 therap*)
 #49 (cognitiv* or cognition):ti,ab,kw
 #50 CBT:ti,ab,kw
 #51 ((cope or coping) NEAR/1 (intervention* or mechanism* or skill* or technique*)):ti,ab,kw
 #52 counsel*ing:ti,ab,kw
 #53 ((couple* or family or group or systemic* or multimodal* or multi next modal*) NEAR/3 (program* or intervention* or therap* or treat*)):ti,ab,kw
 #54 dialectical next behavio*r* next therap*:ti,ab,kw
 #55 (exercise* or physical next training):ti,ab,kw
 #56 ((existential or gestalt or humanistic or interpersonal or milieu or person-centred or residential or socioenvironmental or socio next environmental) NEXT therap*):ti,ab,kw
 #57 expressive next writing:ti,ab,kw
 #58 ("Eye Movement Desensitization and Reprocessing" or EMDR):ti,ab,kw
 #59 (meditat* or mental next training or mindfulness* or mind next training or brain next training or yoga):ti,ab,kw
 #60 motivational next interview*:ti,ab,kw
 #61 (reality next therap* or problem next solving):ti,ab,kw
 #62 (psycho* next therap* or psychotherap*)
 #63 (psychoanalytic* or psycho next analytic* or psychodynamic* or psycho next dynamic*):ti,ab,kw
 #64 (psychodrama or psycho next drama or acting next out or role next play):ti,ab,kw
 #65 (psychosocial or psycho next social or psychoeducation* or psycho next education*):ti,ab,kw
 #66 rational next emotive:ti,ab,kw
 #67 (Relax* NEAR/3 (training* or treatment* or therap*)):ti,ab,kw
 #68 (Service* NEAR/3 (refer* or use*)):ti,ab,kw
 #69 (stress next inoculation next training or SIT or prolonged next exposure next therapy or PET or cognitive next processing next therapy or CPT):ti,ab,kw
 #70 ((support or advice or advisor*) NEAR/1 (centre* or center* or community or group* or network* or social or staff*)):ti,ab,kw
 #71 (therapeutic next allianc* or therapeutic next relationship* or therapeutic next communit*):ti,ab,kw
 #72 Third next wave:ti,ab,kw
 #73 {or #13-#72}
 #74 #12 and #73
 #75 (rape near/1 (centre* or center* or service* or support)):ti,ab,kw
 #76 ((sex* next assault NEAR/3 centre) or (sex* next assault NEAR/3 center) or (sex* next assault NEAR/3 service) or (sex* next assault NEAR/3 support)):ti,ab,kw
 #77 ((sex* next abuse* NEAR/3 centre) or (sex* next abuse* NEAR/3 center) or (sex* next abuse* NEAR/3 service) or (sex* next abuse* NEAR/3 support)):ti,ab,kw
 #78 {or #74-#77}
 #79 (IRCT* OR RBR* OR JPRN* OR TCTR* OR SLCTR* OR CTRI* OR EUCT* OR NCT* OR ISRCTN* OR ACTRN* OR DRKS* OR PACT*):AU
 #80 #78 and #7
 #81 #78 not #80 (Note: final line 2019. Trial registry records were excluded from the CENTRAL search. A separate search for trials was conducted via trials registry websites)
 #82 #78 in Trials Limited by Added between 05/07/2019 and 08/03/2021 (Note: final line 2021)
 #83 #78 in Trials Limited by Added between 08/03/2021 and 10/01/2022 (Note: final line 2022)

CCMDCTR-Studies register

Searched 2 July 2019 (308 records)

Not searched in 2021 as no further records had been added

The CCMDCTR-Studies register was searched using the following controlled vocabulary terms:

("sexual abuse" or "sexual assault victim" or rape):SCM,SCO,STC AND (adolescent or adult or aged or "not stated" or unclear):XAGE AND STUDY:CRSTYPE AND INREGISTER n=14 studies (24 refs)

[Key to study field codes. SCO: Health Care Condition; SCM: Co-morbid Health Care Condition; STC: Target Condition; XAGE: Age of participants]

The CCMDCTR-References register was also searched using a more sensitive set of keywords (all fields) to find additional uncoded/untagged references:

(rape or raped or (sex* adj3 (abuse* or assault* or victim* or violent*))) not (sex* adj3 (child or children)):ti
n=304

Total from both searches = 328

Duplicates removed= 20

Records to screen = 308

Ovid MEDLINE(R)

Searched 2 July 2019 (2699 records)

Searched 8 March 2021 (322 records)

Searched 10 January 2022 (244 records)

- 1 sex offenses/
- 2 Incest/
- 3 intimate partner violence/
- 4 human trafficking/
- 5 rape/
- 6 spouse abuse/
- 7 (sex\$ adj5 (abuse\$ or assault\$ or attack\$ or aggress\$ or coer\$ or exploit\$ or force\$ or molest\$ or offen\$ or traffick\$ or trauma\$ or unlawful \$ or unwanted or violen\$)).tw,kf.
- 8 (intercourse adj5 (coer\$ or force\$ or unwanted)).tw,kf.
- 9 intimate partner violence.tw,kf.
- 10 (rape or raped or incest\$).tw,kf.
- 11 (sex\$ adj3 (victim\$ or revictim\$ or re-victim\$ or survivor\$)).tw,kf.
- 12 or/1-11
- 13 Anxiety/th
- 14 Anxiety Disorders/th
- 15 Adaptation, Psychological/
- 16 exp Behavior Therapy/
- 17 Combined Modality Therapy/
- 18 community networks/
- 19 exp Complementary therapies/
- 20 exp Counseling/
- 21 Depression/th
- 22 Depressive Disorder/th)
- 23 Depressive Disorder, Major/th
- 24 Exercise/
- 25 Exercise therapy/
- 26 Health Education/
- 27 Health Knowledge, Attitudes, Practice/
- 28 Interview, Psychological/
- 29 exp mind body therapies/
- 30 Psychological adjustment/
- 31 Psychological Trauma/pc, rh, th
- 32 psychosocial support systems/
- 33 exp psychotherapy/
- 34 "Referral and Consultation"/
- 35 Self-Help Groups/
- 36 Social Support/
- 37 Stress Disorders, Post-Traumatic/pc, rh, th
- 38 video recording/ or videotape recording/
- 39 Writing/
- 40 ((abreaction or desensitization or exposure or implosive) adj3 therap\$).tw,kf.
- 41 "acceptance and commitment therapy".tw,kf.
- 42 (advisor\$ or advocate\$ or advocacy).tw,kf.
- 43 ((animal\$ or art or colo?r or creative\$ or dance or dancing or drama or equine or experiential or music or narrative or play\$ or sensory or singing) adj3 (program\$ or intervention\$ or therap\$)).tw,kf.
- 44 (autogenic or autosuggestion\$ or auto-suggestion\$ or breathing exercise\$ or hypnosis or hypno-therapy or hypnotherapy).tw,kf.
- 45 behavio\$ activation.tw,kf.
- 46 (behavio?r\$ adj3 (intervention\$ or program\$ or therap\$ or training or treatment\$)).tw,kf.
- 47 ((biofeedback or feedback or imagery) adj3 (intervention\$ or therap\$ or train\$ or treatment\$)).tw,kf.

48 ((brief or combination or compass\$ focus\$ or integrated or integrative or time-limited) adj3 (intervention\$ or therap\$ or treatment \$)).tw,kf.
 49 ((client focus\$ or non-direct\$ or nondirect\$ or solution focus\$ or trauma\$ or talking) adj3 therap\$).tw,kf.
 50 (cognitiv\$ or cognition).tw,kf.
 51 CBT.tw,kf.
 52 ((cope or coping) adj1 (intervention\$ or mechanism\$ or skill\$ or technique\$)).tw,kf.
 53 counsel?ing.tw,kf.
 54 ((couple\$ or family or group or systemic\$ or multimodal\$ or multi-modal\$) adj3 (program\$ or intervention\$ or therap\$ or treat\$)).tw,kf.
 55 dialectical behavio?r\$ therap\$.tw,kf.
 56 (exercise\$ or physical training).tw,kf.
 57 ((existential or gestalt or humanistic or interpersonal or milieu or person-centred or residential or socioenvironmental or socio-environmental) adj therap\$).tw,kf.
 58 expressive writing.tw,kf.
 59 ("Eye Movement Desensitization and Reprocessing" or EMDR).tw,kf.
 60 (meditat\$ or mental training or mindfulness\$ or mind training or brain training or yoga).tw,kf.
 61 motivational interview\$.tw,kf.
 62 (reality therap\$ or problem solving).tw,kf.
 63 (psycho\$ therap\$ or psychotherap\$).tw,kf.
 64 (psychoanalytic\$ or psycho-analytic\$ or psychodynamic\$ or psycho-dynamic\$).tw,kf.
 65 (psychodrama or psycho-drama or acting out or role play).tw,kf.
 66 (psychosocial or psycho-social or psychoeducation\$ or psycho-education\$).tw,kf.
 67 rational emotive.tw,kf.
 68 (Relax\$ adj3 (training\$ or treatment\$ or therap\$)).tw,kf.
 69 (Service\$ adj3 (refer\$ or use\$)).tw,kf.
 70 (stress inoculation training or SIT or prolonged exposure therapy or PET or cognitive processing therapy or CPT).tw,kf.
 71 ((support or advice or advis\$1) adj1 (centre\$1 or center\$1 or community or group\$ or network\$ or social or staff\$)).tw,kf.
 72 (therapeutic allianc\$ or therapeutic relationship\$ or therapeutic communit\$).tw,kf.
 73 Third wave.tw,kf.
 74 or/13-73
 75 12 and 74
 76 (rape adj3 (centre\$ or center\$ or service\$ or support)).tw,kf.
 77 ((sex\$ assault adj3 centre) or (sex\$ assault adj3 center) or (sex\$ assault adj3 service) or (sex\$ assault adj3 support)).tw,kf.
 78 ((sex\$ abuse\$ adj3 centre) or (sex\$ abuse\$ adj3 center) or (sex\$ abuse\$ adj3 service) or (sex\$ abuse\$ adj3 support)).tw,kf.
 79 or/76-78
 80 75 or 79
 81 randomized controlled trial.pt.
 82 controlled clinical trial.pt.
 83 randomi#ed.ab.
 84 placebo\$.ab.
 85 drug therapy.fs.
 86 randomly.ab.
 87 trial.ab.
 88 groups.ab.
 89 or/81-88
 90 exp animals/ not humans.sh.
 91 89 not 90
 92 80 and 91
 93 (201907* or 201908* or 201909* or 201910* or 201911* or 201912* or 2020* or 2021*).dt,ez,da.
 94 92 and 93
 95 (202103* or 202104* or 202105* or 202106* or 202107* or 202108* or 202109* or 202110* or 202111* or 202112* or 2022*).dt,ez,da.
 96 92 and 95

Ovid MEDLINE In-process and other nonindexed citations

Searched 2 July 2019 (490 records)

Searched 8 March 2021 (252 records)

Searched 10 January 2022 (46 new records)

1 (sex\$ adj5 (abuse\$ or assaul\$ or attack\$ or aggress\$ or coer\$ or exploit\$ or force\$ or molest\$ or offen\$ or traffick\$ or trauma\$ or unlawful \$ or unwanted or violen\$)).tw,kf.

2 (intercourse adj5 (coer\$ or force\$ or unwanted)).tw,kf.

3 intimate partner violence.tw,kf.

- 4 (rape or raped or incest\$.tw,kf.
 5 (sex\$ adj3 (victim\$ or revictim\$ or re-victim\$ or survivor\$)).tw,kf.
 6 or/1-5
 7 therapy.ti.
 8 ((abreaction or desensitization or exposure or implosive) adj3 therap\$).ab,kf.
 9 "acceptance and commitment therapy".ab,kf.
 10 (advisor\$ or advocate\$ or advocacy).tw,kf.
 11 ((animal\$ or art or colo?r or creative\$ or dance or dancing or drama or equine or experiential or music or narrative or play\$ or sensory or singing) adj3 (program\$ or intervention\$ or therap\$)).tw,kf.
 12 (autogenic or autosuggestion\$ or auto-suggestion\$ or breathing exercise\$ or hypnosis or hypno-therapy or hypnotherapy).tw,kf.
 13 behavio\$ activation.tw,kf.
 14 (behavio?r\$ adj3 (intervention\$ or program\$ or therap\$ or training or treatment \$)).tw,kf.
 15 ((biofeedback or feedback or imagery) adj3 (intervention\$ or therap\$ or train\$ or treatment\$)).tw,kf.
 16 ((brief or combination or compass\$ focus\$ or integrated or integrative or time- limited) adj3 (intervention\$ or therap\$ or treatment \$)).tw,kf.
 17 ((client focus\$ or non-direct\$ or nondirect\$ or solution focus\$ or trauma\$ or talking) adj3 therap\$).tw,kf.
 18 (cognitiv\$ or cognition or CBT).tw,kf.
 19 ((cope or coping) adj1 (intervention\$ or mechanism\$ or skill\$ or technique \$)).tw,kf.
 20 counsel?ing.tw,kf.
 21 ((couple\$ or family or group or systemic\$ or multimodal\$ or multi-modal\$) adj3 (program\$ or intervention\$ or therap\$ or treat\$)).tw,kf.
 22 dialectical behavio?r\$ therap\$.tw,kf.
 23 (exercise\$ or physical training).tw,kf.
 24 ((existential or gestalt or humanistic or interpersonal or milieu or person- centred or residential or socioenvironmental or socio-environmental) adj therap\$).tw,kf.
 25 expressive writing.tw,kf.
 26 ("Eye Movement Desensitization and Reprocessing" or EMDR).tw,kf.
 27 (meditat\$ or mental training or mindfulness\$ or mind training or brain training or yoga).tw,kf.
 28 motivational interview\$.tw,kf.
 29 (reality therap\$ or problem solving).tw,kf.
 30 (psycho\$ therap\$ or psychotherap\$).tw,kf.
 31 (psychoanalytic\$ or psycho-analytic\$ or psychodynamic\$ or psycho-dynamic\$).tw,kf.
 32 (psychodrama or psycho-drama or acting out or role play).tw,kf.
 33 (psychosocial or psycho-social or psychoeducation\$ or psycho-education\$).tw,kf.
 34 rational emotive.tw,kf.
 35 (Relax\$ adj3 (training\$ or treatment\$ or therap\$)).tw,kf.
 36 (Service\$ adj3 (refer\$ or use\$)).tw,kf.
 37 (stress inoculation training or SIT or prolonged exposure therapy or PET or cognitive processing therapy or CPT).tw,kf.
 38 ((support or advice or advis\$1) adj1 (centre\$1 or center\$1 or community or group\$ or network\$ or social or staff\$)).tw,kf.
 39 (therapeutic allianc\$ or therapeutic relationship\$ or therapeutic communit\$).tw,kf.
 40 Third wave.tw,kf.
 41 or/7-40
 42 6 and 41
 43 (rape adj3 (centre\$ or center\$ or service\$ or support)).tw,kf.
 44 ((sex\$ assault adj3 centre) or (sex\$ assault adj3 center) or (sex\$ assault adj3 service) or (sex\$ assault adj3 support)).tw,kf.
 45 ((sex\$ abuse\$ adj3 centre) or (sex\$ abuse\$ adj3 center) or (sex\$ abuse\$ adj3 service) or (sex\$ abuse\$ adj3 support)).tw,kf.
 46 or/42-45
 47 (random\$ or control\$ or group\$ or cluster\$ or placebo\$ or trial\$ or assign\$ or prospectiv\$ or meta-analysis or systematic review or longitudinal\$).tw,kf.
 48 46 and 47
 49 limit 48 to ("in data review" or in process or "pubmed not medline")

Ovid MEDLINE Epub Ahead of Print

Searched 2 July 2019 (247 records)

Searched 8 March 2021 (279 records)

Searched 10 January 2022 (229 records)

- 1 (sex\$ adj5 (abuse\$ or assaul\$ or attack\$ or aggress\$ or coer\$ or exploit\$ or force\$ or molest\$ or offen\$ or traffick\$ or trauma\$ or unlawful \$ or unwanted or violen\$)).tw,kf.
 2 (intercourse adj5 (coer\$ or force\$ or unwanted)).tw,kf.
 3 intimate partner violence.tw,kf.
 4 (rape or raped or incest\$.tw,kf.
 5 (sex\$ adj3 (victim\$ or revictim\$ or re-victim\$ or survivor\$)).tw,kf.

Psychosocial interventions for survivors of rape and sexual assault experienced during adulthood (Review)

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- 6 or/1-5
 7 therapy.ti.
 8 ((abreaction or desensitization or exposure or implosive) adj3 therap\$).ab,kf.
 9 "acceptance and commitment therapy".ab,kf.
 10 (advisor\$ or advocate\$ or advocacy).tw,kf.
 11 ((animal\$ or art or colo?r or creative\$ or dance or dancing or drama or equine or experiential or music or narrative or play\$ or sensory or singing) adj3 (program\$ or intervention\$ or therap\$)).tw,kf.
 12 (autogenic or autosuggestion\$ or auto-suggestion\$ or breathing exercise\$ or hypnosis or hypno-therapy or hypnotherapy).tw,kf.
 13 behavio\$ activation.tw,kf.
 14 (behavio?r\$ adj3 (intervention\$ or program\$ or therap\$ or training or treatment \$)).tw,kf.
 15 ((biofeedback or feedback or imagery) adj3 (intervention\$ or therap\$ or train\$ or treatment\$)).tw,kf.
 16 ((brief or combination or compass\$ focus\$ or integrated or integrative or time- limited) adj3 (intervention\$ or therap\$ or treatment \$)).tw,kf.
 17 ((client focus\$ or non-direct\$ or nondirect\$ or solution focus\$ or trauma\$ or talking) adj3 therap\$).tw,kf.
 18 (cognitiv\$ or cognition or CBT).tw,kf.
 19 ((cope or coping) adj1 (intervention\$ or mechanism\$ or skill\$ or technique \$)).tw,kf.
 20 counsel?ing.tw,kf.
 21 ((couple\$ or family or group or systemic\$ or multimodal\$ or multi-modal\$) adj3 (program\$ or intervention\$ or therap\$ or treat\$)).tw,kf.
 22 dialectical behavio?r\$ therap\$.tw,kf.
 23 (exercise\$ or physical training).tw,kf.
 24 ((existential or gestalt or humanistic or interpersonal or milieu or person- centred or residential or socioenvironmental or socio-environmental) adj therap\$).tw,kf.
 25 expressive writing.tw,kf.
 26 ("Eye Movement Desensitization and Reprocessing" or EMDR).tw,kf.
 27 (meditat\$ or mental training or mindfulness\$ or mind training or brain training or yoga).tw,kf.
 28 motivational interview\$.tw,kf.
 29 (reality therap\$ or problem solving).tw,kf.
 30 (psycho\$ therap\$ or psychotherap\$).tw,kf.
 31 (psychoanalytic\$ or psycho-analytic\$ or psychodynamic\$ or psycho-dynamic\$).tw,kf.
 32 (psychodrama or psycho-drama or acting out or role play).tw,kf.
 33 (psychosocial or psycho-social or psychoeducation\$ or psycho-education\$).tw,kf.
 34 rational emotive.tw,kf.
 35 (Relax\$ adj3 (training\$ or treatment\$ or therap\$)).tw,kf.
 36 (Service\$ adj3 (refer\$ or use\$)).tw,kf.
 37 (stress inoculation training or SIT or prolonged exposure therapy or PET or cognitive processing therapy or CPT).tw,kf.
 38 ((support or advice or advis\$1) adj1 (centre\$1 or center\$1 or community or group\$ or network\$ or social or staff\$)).tw,kf.
 39 (therapeutic allianc\$ or therapeutic relationship\$ or therapeutic communit\$).tw,kf.
 40 Third wave.tw,kf.
 41 or/7-40
 42 6 and 41
 43 (rape adj3 (centre\$ or center\$ or service\$ or support)).tw,kf.
 44 ((sex\$ assault adj3 centre) or (sex\$ assault adj3 center) or (sex\$ assault adj3 service) or (sex\$ assault adj3 support)).tw,kf.
 45 ((sex\$ abuse\$ adj3 centre) or (sex\$ abuse\$ adj3 center) or (sex\$ abuse\$ adj3 service) or (sex\$ abuse\$ adj3 support)).tw,kf.
 46 or/42-45
 47 (random\$ or control\$ or group\$ or cluster\$ or placebo\$ or trial\$ or assign\$ or prospectiv\$ or meta-analysis or systematic review or longitudinal\$).tw,kf.
 48 46 and 47

Embase Ovid

Searched 2 July 2019 (2335 records)
 Searched 8 March 2021 (878 records)
 Searched 10 January 2022 (515 records)

- 1 sexual assault/
 2 sexual abuse/
 3 sexual violence/
 4 sexual coercion/
 5 sexual exploitation/
 6 incest/
 7 partner violence/
 8 human trafficking/
 9 exp rape/

Psychosocial interventions for survivors of rape and sexual assault experienced during adulthood (Review)

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- 10 (sex\$ adj5 (abuse\$ or assault\$ or attack\$ or aggress\$ or coer\$ or exploit\$ or force\$ or molest\$ or offen\$ or traffick\$ or trauma\$ or unlawful\$ or unwanted\$ or violen\$)).tw,kw.
- 11 (intercourse adj5 (coer\$ or force\$ or unwanted)).tw,kw.
- 12 intimate partner violence.tw,kw.
- 13 (rape or raped or incest\$).tw,kw.
- 14 (sex\$ adj3 (victim\$ or revictim\$ or re-victim\$ or survivor\$)).tw,kw.
- 15 or/1-14
- 16 adaptive behavior/
- 17 exp alternative medicine/
- 18 anxiety/th [Therapy]
- 19 exp anxiety disorder/th [Therapy]
- 20 exp behavior therapy/
- 21 community care/
- 22 exp coping behavior/
- 23 exp counseling/
- 24 exp depression/th [Therapy]
- 25 exp exercise/
- 26 exp kinesiotherapy/
- 27 health education/ or psychoeducation/
- 28 health education/
- 29 psychoeducation/
- 30 psychological interview/
- 31 Psychological adjustment/
- 32 psychotrauma/rh, th
- 33 psychosocial care/
- 34 exp psychotherapy/
- 35 patient referral/
- 36 self help/ or exp self care/
- 37 social support/
- 38 exp videorecording/
- 39 writing/
- 40 ((abreaction or desensitization or exposure or implosive) adj3 therap\$).tw,kw.
- 41 "acceptance and commitment therapy".tw,kw.
- 42 (advisor\$ or advocate\$ or advocacy).tw,kw.
- 43 ((animal\$ or art or colo?r or creative\$ or dance or dancing or drama or equine or experiential or music or narrative or play\$ or sensory or singing) adj3 (program\$ or intervention\$ or therap\$)).tw,kw.
- 44 (autogenic or autosuggestion\$ or auto-suggestion\$ or breathing exercise\$ or hypnosis or hypno-therapy or hypnotherapy).tw,kw.
- 45 behavio\$ activation.tw,kw.
- 46 (behavio?r\$ adj3 (intervention\$ or program\$ or therap\$ or training or treatment \$)).tw,kw.
- 47 ((biofeedback or feedback or imagery) adj3 (intervention\$ or therap\$ or train\$ or treatment\$)).tw,kw.
- 48 ((brief or combination or compass\$ focus\$ or integrated or integrative or time- limited) adj3 (intervention\$ or therap\$ or treatment \$)).tw,kw.
- 49 ((client focus\$ or non-direct\$ or nondirect\$ or solution focus\$ or trauma\$ or talking) adj3 therap\$).tw,kw.
- 50 (cognitiv\$ or cognition).tw,kw.
- 51 CBT.tw,kw.
- 52 ((cope or coping) adj1 (intervention\$ or mechanism\$ or skill\$ or technique \$)).tw,kw.
- 53 counsel?ing.tw,kw.
- 54 ((couple\$ or family or group or systemic\$ or multimodal\$ or multi-modal\$) adj3 (program\$ or intervention\$ or therap\$ or treat\$)).tw,kw.
- 55 dialectical behavio?r\$ therap\$.tw,kw.
- 56 (exercise\$ or physical training).tw,kw.
- 57 ((existential or gestalt or humanistic or interpersonal or milieu or person- centred or residential or socioenvironmental or socio-environmental) adj therap\$).tw,kw.
- 58 expressive writing.tw,kw.
- 59 ("Eye Movement Desensitization and Reprocessing" or EMDR).tw,kw.
- 60 (meditat\$ or mental training or mindfulness\$ or mind training or brain training or yoga).tw,kw
- 61 motivational interview\$.tw,kw.
- 62 (reality therap\$ or problem solving).tw,kw.
- 63 (psycho\$ therap\$ or psychotherap\$).tw,kw.
- 64 (psychoanalytic\$ or psycho-analytic\$ or psychodynamic\$ or psycho-dynamic\$).tw,kw.
- 65 (psychodrama or psycho-drama or acting out or role play).tw,kw.
- 66 (psychosocial or psycho-social or psychoeducation\$ or psycho-education\$).tw,kw.
- 67 rational emotive.tw,kw.

68 (Relax\$ adj3 (training\$ or treatment\$ or therap\$)).tw,kw.
 69 (Service\$ adj3 (refer\$ or use\$)).tw,kw.
 70 (stress inoculation training or SIT or prolonged exposure therapy or PET or cognitive processing therapy or CPT).tw,kw.
 71 ((support or advice or advis\$1) adj1 (centre\$1 or center\$1 or community or group\$ or network\$ or social or staff\$)).tw,kw.
 72 (therapeutic allianc\$ or therapeutic relationship\$ or therapeutic communit \$).tw,kw.
 73 Third wave.tw,kw.
 74 or/16-73
 75 15 and 74
 76 (rape adj3 (centre\$ or center\$ or service\$ or support)).tw,kw.
 77 ((sex\$ assault adj3 centre) or (sex\$ assault adj3 center) or (sex\$ assault adj3 service) or (sex\$ assault adj3 support)).tw,kw.
 78 ((sex\$ abuse\$ adj3 centre) or (sex\$ abuse\$ adj3 center) or (sex\$ abuse\$ adj3 service) or (sex\$ abuse\$ adj3 support)).tw,kw.
 79 or/76-78
 80 75 or 79
 81 Randomized controlled trial/
 82 Controlled clinical study/
 83 random\$.ti,ab.
 84 randomization/
 85 intermethod comparison/
 86 placebo.ti,ab.
 87 (compare or compared or comparison).ti.
 88 ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab.
 89 (open adj label).ti,ab.
 90 ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab.
 91 double blind procedure/
 92 parallel group\$1.ti,ab.
 93 (crossover or cross over).ti,ab.
 94 ((assign\$ or match or matched or allocation) adj5 (alternate or group\$1 or intervention\$1 or patient\$1 or subject\$1 or participant \$1)).ti,ab.
 95 (assigned or allocated).ti,ab.
 96 (controlled adj7 (study or design or trial)).ti,ab.
 97 (volunteer or volunteers).ti,ab.
 98 human experiment/
 99 trial.ti.
 100 or/81-99
 101 (random\$ adj sampl\$ adj7 ("cross section\$" or questionnaire\$1 or survey\$ or database\$1)).ti,ab. not (comparative study/ or controlled study/ or randomi?ed controlled.ti,ab. or randomly assigned.ti,ab.) (8480)
 102 Cross-sectional study/ not (randomized controlled trial/ or controlled clinical study/ or controlled study/ or randomi?ed controlled.ti,ab. or control group\$1.ti,ab.) (262553)
 103 (((case adj control\$) and random\$) not randomi?ed controlled).ti,ab.
 104 (Systematic review not (trial or study)).ti.
 105 (nonrandom\$ not random\$).ti,ab.
 106 "Random field\$".ti,ab.
 107 (random cluster adj3 sampl\$).ti,ab.
 108 (review.ab. and review.pt.) not trial.ti. (873499)
 109 "we searched".ab. and (review.ti. or review.pt.)
 110 "update review".ab.
 111 (databases adj4 searched).ab.
 112 (rat or rats or mouse or mice or swine or porcine or murine or sheep or lambs or pigs or piglets or rabbit or rabbits or cat or cats or dog or dogs or cattle or bovine or monkey or monkeys or trout or marmoset\$1).ti. and animal experiment/
 113 Animal experiment/ not (human experiment/ or human/)
 114 or/101-113
 115 100 not 114
 116 80 and 115 (Note: Final line 2019)
 117 limit 116 to yr="2019 -Current"
 118 limit 116 to dc=20190701-20210305
 119 117 or 118 (Note: Final line 2021)
 120 limit 116 to dc=20210305-20220107
 121 limit 116 to yr="2021 -Current"
 122 120 or 121 (Note: Final line 2022)

PsycINFO (Ovid)

Searched 3 July 2019 (3087)

Searched 8 March 2021 (275 records)

Searched 10 January 2022 (145 records)

- 1 exp sexual abuse/
- 2 Incest/
- 3 intimate partner violence/
- 4 exp Human Trafficking/
- 5 (sex\$ adj5 (abuse\$ or assaul\$ or attack\$ or aggress\$ or coer\$ or exploit\$ or force\$ or molest\$ or offen\$ or traffick\$ or trauma\$ or unlawful \$ or unwanted or violen\$)).tw,id.
- 6 (intercourse adj5 (coer\$ or force\$ or unwanted)).tw,id.
- 7 intimate partner violence.tw,id.
- 8 (rape or raped or incest\$).tw,id.
- 9 (sex\$ adj3 (victim\$ or revictim\$ or re-victim\$ or survivor\$)).tw,id.
- 10 or/1-9
- 11 adaptive behavior/
- 12 exp alternative medicine/
- 13 exp behavior therapy/
- 14 biofeedback training/
- 15 exp community services/
- 16 exp counseling/
- 17 exp creative arts therapy/
- 18 Creative Writing/ or journal writing/
- 19 exp exercise/
- 20 movement therapy/
- 21 exp Health Education/
- 22 health knowledge/
- 23 psychological assessment/
- 24 exp Mind Body Therapy/
- 25 exp Emotional Adjustment/
- 26 exp psychotherapy/
- 27 professional referral/ or self-referral/
- 28 self-expression/
- 29 exp Self-Help Techniques/
- 30 exp Social Support/
- 31 exp Support Groups/
- 32 ((abreaction or desensitization or exposure or implosive) adj3 therap\$).tw,id.
- 33 "acceptance and commitment therapy".tw,id.
- 34 (behavio?r\$ adj3 (intervention\$ or program\$ or therap\$ or training or treatment\$)).tw,id.
- 35 ((biofeedback or feedback or imagery) adj3 (intervention\$ or therap\$ or train\$ or treatment\$)).tw,id.
- 36 ((brief or combination or compass\$ focus\$ or integrated or integrative or time-limited) adj3 (intervention\$ or therap\$ or treatment \$)).tw,id.
- 37 ((client focus\$ or non-direct\$ or nondirect\$ or solution focus\$ or trauma\$ or talking) adj3 therap\$).tw,id.
- 38 ((cognitiv\$ or cognition) adj5 (therap\$ or treatment\$)).tw,id.
- 39 CBT.tw,id.
- 40 ((cope or coping) adj1 (intervention\$ or mechanism\$ or skill\$ or technique\$)).tw,id.
- 41 counsel?ing.tw,id.
- 42 ((couple\$ or family or group or systemic\$ or multimodal\$ or multi-modal\$) adj3 (program\$ or intervention\$ or therap\$ or treat\$)).tw,id.
- 43 dialectical behavio?r\$ therap\$.tw,id.
- 44 (exercise\$ or physical training).tw,id.
- 45 ((existential or gestalt or humanistic or interpersonal or milieu or person-centred or residential or socioenvironmental or socio-environmental) adj therap\$).tw,id.
- 46 expressive writing.tw,id.
- 47 ("Eye Movement Desensitization and Reprocessing" or EMDR).tw,id.
- 48 (meditat\$ or mental training or mindfulness\$ or mind training or brain training or yoga).tw,id.
- 49 motivational interview\$.tw,id.
- 50 (psycho\$ therap\$ or psychotherap\$).tw,id.
- 51 (psychoanalytic\$ or psycho-analytic\$ or psychodynamic\$ or psycho-dynamic\$).tw,id.
- 52 (psychodrama or psycho-drama or acting out or role play).tw,id.
- 53 (psychosocial or psycho-social or psychoeducation\$ or psycho-education\$).tw,id.

54 rational emotive.tw,id.
 55 (reality therap\$ or problem solving).tw,id.
 56 (Relax\$ adj3 (training\$ or treatment\$ or therap\$)).tw,id.
 57 (Service\$ adj3 (refer\$ or use\$)).tw,id.
 58 (stress inoculation training or SIT or prolonged exposure therapy or PET or cognitive processing therapy or CPT).tw,id.
 59 ((support or advice or advis\$1) adj1 (centre\$1 or center\$1 or community or group\$ or network\$ or social or staff\$)).tw,id.
 60 (therapeutic allianc\$ or therapeutic relationship\$ or therapeutic communit\$).tw,id.
 61 Third wave.tw,id.
 62 or/11-61
 63 10 and 62
 64 (rape adj3 (centre\$ or center\$ or service\$ or support)).tw,id.
 65 ((sex\$ assault adj3 centre) or (sex\$ assault adj3 center) or (sex\$ assault adj3 service) or (sex\$ assault adj3 support)).tw,id.
 66 ((sex\$ abuse\$ adj3 centre) or (sex\$ abuse\$ adj3 center) or (sex\$ abuse\$ adj3 service) or (sex\$ abuse\$ adj3 support)).tw,id.
 67 or/64-66
 68 63 or 67
 69 clinical trials/
 70 random sampling/
 71 placebo/
 72 Experiment controls/
 73 (control\$ adj3 (study or trial\$ or experiment\$)).tw,id.
 74 ((compar\$ or control\$ or experiment\$ or treat\$) adj3 (subjects or group\$)).ab,id.
 75 ("treat\$ as usual" or "usual treatment" or tau or "wait\$ list").ab.
 76 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj3 (blind\$ or mask\$)).tw.
 77 (random\$ or RCT).ti.
 78 (randomiz\$ or randomis\$).ab,id.
 79 (assigned or allocated).ab.
 80 exp program evaluation/
 81 exp treatment outcomes/
 82 exp treatment effectiveness evaluation/
 83 ((effectiveness or evaluat\$) adj3 (stud\$ or research\$)).tw,id.
 84 or/69-83
 85 68 and 84
 86 limit 85 to up=20190701-20210309 (Note: final line 2021)
 87 limit 85 to up=20210309-20220103 (Note: final line 2022)

CINAHL Plus (EBSCOhost)

Searched 3 July 2019 (1259 records)
 Searched 9 March 2021 (226 records)
 Searched 11 January 2022 (133 records)

S1 (MH "Sexual Abuse")
 S2 (MH "Incest")
 S3 (MH "Rape")
 S4 (MH "Intimate Partner Violence")
 S5 (MH "Human Trafficking")
 S6 TI((sex* N5 (abuse* or assault* or attack* or aggress* or coer* or exploit* or force* or molest* or offen* or traffick* or trauma* or unlawful* or unwanted or violen*)) OR AB((sex* N5 (abuse* or assault* or attack* or aggress* or coer* or exploit* or force* or molest* or offen* or traffick* or trauma* or unlawful* or unwanted or violen*)))
 S7 TI (intercourse N5 (coer* or force* or unwanted)) OR AB (intercourse N5 (coer* or force* or unwanted))
 S8 ti(intimate partner violence) OR AB(intimate partner violence)
 S9 TI(rape or raped or incest*) OR AB(rape or raped or incest*)
 S10 (sex* N3 (victim* or revictim* or re-victim* or survivor*))
 S11 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10
 S12 (MH "Anxiety/TH")
 S13 (MH "Adaptation, Physiological")
 S14 (MH "Combined Modality Therapy")
 S15 (MH "Community Mental Health Services")
 S16 (MH "Community Networks")
 S17 (MH "Alternative Therapies+")
 S18 (MH "Counseling+")
 S19 (MH "Depression+/TH")
 S20 (MH "Exercise+")

Psychosocial interventions for survivors of rape and sexual assault experienced during adulthood (Review)

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S21 (MH "Therapeutic Exercise+")
 S22 (MH "Health Education+")
 S23 (MH "Mind Body Techniques+")
 S24 (MH "Psychological Trauma/TH")
 S25 (MH "Psychotherapy+")
 S26 (MH "Referral and Consultation")
 S27 (MH "Support Groups")
 S28 (MH "Support, Psychosocial")
 S29 (MH "Stress Disorders, Post-Traumatic+/TH")
 S30 (MH "Videorecording")
 S31 (MH "Writing")
 S32 TI((abreaction or desensitization or exposure or implosive) N3 therap*) OR AB((abreaction or desensitization or exposure or implosive) N3 therap*)
 S33 TI (advisor* or advocate* or advocacy) OR AB (advisor* or advocate* or advocacy)
 S34 TI ("acceptance and commitment therapy") OR AB("acceptance and commitment therapy")
 S35 TI((animal* or art or colo*r or creative* or dance or dancing or drama or equine or experiential or music or narrative or play* or sensory or singing) N3 (program* or intervention* or therap*) OR AB((animal* or art or colo*r or creative* or dance or dancing or drama or equine or experiential or music or narrative or play* or sensory or singing) N3 (program* or intervention* or therap*))
 S36 TI((autogenic or autosuggestion* or auto-suggestion* or "breathing exercise*" or hypnosis or hypno-therapy or hypnotherapy) OR AB((autogenic or autosuggestion* or auto-suggestion* or "breathing exercise*" or hypnosis or hypno-therapy or hypnotherapy)
 S37 TI("behavio* activation") OR AB("behavio* activation")
 S38 TI(behavio*r* N3 (intervention* or program* or therap* or training or treatment*)) OR AB(behavio*r* N3 (intervention* or program* or therap* or training or treatment*))
 S39 TI((((biofeedback or feedback or imagery) N3 (intervention* or therap* or train* or treatment*) or AB((((biofeedback or feedback or imagery) N3 (intervention* or therap* or train* or treatment*)))
 S40 TI((brief or combination or "compass* focus*" or integrated or integrative or time-limited) N3 (intervention* or therap* or treatment*)) OR AB((brief or combination or "compass* focus*" or integrated or integrative or time-limited) N3 (intervention* or therap* or treatment*))
 S41 TI(("client focus*" or non-direct* or nondirect* or "solution focus*" or trauma* or talking) N3 therap*) OR AB(("client focus*" or non-direct* or nondirect* or "solution focus*" or trauma* or talking) N3 therap*)
 S42 TI(cognitiv* or cognition OR CBT) OR AB(cognitiv* or cognition OR CBT)
 S43 TI((cope or coping) N1 (intervention* or mechanism* or skill* or technique*)) OR AB((cope or coping) N1 (intervention* or mechanism* or skill* or technique*))
 S44 TI(counsel*ing) OR AB (counsel*ing)
 S45 TI((couple* or family or group or systemic* or multimodal* or multi-modal*) N3 (program* or intervention* or therap* or treat*)) OR AB((couple* or family or group or systemic* or multimodal* or multi-modal*) N3 (program* or intervention* or therap* or treat*))
 S46 TI("dialectical behavio*r* therap*") OR AB("dialectical behavio*r* therap*")
 S47 TI(exercise* or "physical training") OR AB(exercise* or "physical training")
 S48 TI((existential or gestalt or humanistic or interpersonal or milieu or person-centred or residential or socioenvironmental or socio-environmental) N1 therap*) OR AB((existential or gestalt or humanistic or interpersonal or milieu or person-centred or residential or socioenvironmental or socio-environmental) N1 therap*)
 S49 TI("expressive writing") OR AB("expressive)
 S50 TI("Eye Movement Desensitization and Reprocessing" or EMDR) OR AB("Eye Movement Desensitization and Reprocessing" or EMDR)
 S51 TI(meditat* or "mental training" or mindfulness* or "mind training" or "brain training" or yoga) OR AB(meditat* or "mental training" or mindfulness* or "mind training" or "brain training" or yoga)
 S52 TI("motivational interview") OR AB(" motivational interview")
 S53 TI("reality therap*" or "problem solving") OR AB("reality therap*" or "problem solving")
 S54 TI(("psycho* therap*" or psychotherap*) OR AB ("psycho* therap*" or psychotherap*)
 S55 TI((psychoanalytic* or psycho-analytic* or psychodynamic* or psycho-dynamic*) OR AB((psychoanalytic* or psycho-analytic* or psychodynamic* or psycho-dynamic*)
 S56 TI((psychodrama or psycho-drama or "acting out" or "role play") OR AB((psychodrama or psycho-drama or "acting out" or "role play")
 S57 TI (psychosocial or psycho-social or psychoeducation* or psycho-education*) OR AB (psychosocial or psycho-social or psychoeducation* or psycho-education*)
 S58 TI("rational emotive") OR AB("rational emotive")
 S59 TI(Relax* N3 (training* or treatment* or therap*)) OR AB(Relax* N3 (training* or treatment* or therap*))
 S60 TI(Service* N3 (refer* or use*)) OR AB(Service* N3 (refer* or use*))
 S61 TI("stress inoculation training" or SIT or "prolonged exposure therapy" or PET or "cognitive processing therapy" or CPT) OR AB("stress inoculation training" or SIT or "prolonged exposure therapy" or PET or "cognitive processing therapy" or CPT)
 S62 TI((support or advice or advis*) N1 (centre* or center* or community or group* or network* or social or staff*)) OR AB((support or advice or advis*) N1 (centre* or center* or community or group* or network* or social or staff*))
 S63 TI(("therapeutic allianc*" or "therapeutic relationship*" or "therapeutic communit*") OR AB(("therapeutic allianc*" or "therapeutic relationship*" or "therapeutic communit*")
 S64 TI("Third wave") OR AB("Third wave")

S65 S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29
 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47
 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64
 S66 S11 AND S65
 S67 TI(rape N3 (centre* or center* or service* or support)) OR AB(rape N3 (centre* or center* or service* or
 S68 TI((sex* assault N3 centre) or (sex* assault N3 center) or (sex* assault N3 service) or (sex* assault N3 support)) OR AB((sex* assault N3
 centre) or (sex* assault N3 center) or (sex* assault N3 service) or (sex* assault N3 support))
 S69 TI((sex* abuse* N3 centre) or (sex* abuse* N3 center) or (sex* abuse* N3 service) or (sex* abuse* N3 support)) OR AB((sex* abuse* N3
 centre) or (sex* abuse* N3 center) or (sex* abuse* N3 service) or (sex* abuse* N3 support))
 S70 S67 OR S68 OR S69
 S71 S66 OR S70
 S72 MH ("Randomized Controlled Trials")
 S73 MH "Double-Blind Studies")
 S74 MH "Single-Blind Studies")
 S75 MH "Random Assignment")
 S76 MH "Pretest-Posttest Design")
 S77 MH ("Cluster Sample")
 S78 TI (randomised OR randomized)
 S79 AB (random*)
 S80 TI (trial)
 S81 (MH "Sample Size") AND AB (assigned OR allocated OR control)
 S82 MH (Placebos)
 S83 PT (Randomized Controlled Trial)
 S84 AB (control W5 group)
 S85 MH ("Crossover Design") OR MH ("Comparative Studies")
 S86 AB (cluster W3 RCT)
 S87 (MH "Animals+")
 S88 MH ("Animal Studies")
 S89 TI (animal model*)
 S90 S87 OR S88 OR S89
 S91 MH ("Human")
 S92 S90 NOT S91
 S93 S72 OR S73 OR S74 OR S75 OR S76 OR S77 OR S78 OR S79 OR S80 OR S81 OR S82 OR S83 OR S84 OR S85 OR S86
 S94 S93 NOT S92
 S95 S71 AND S94 [Note: Final line 2019]
 S96 EM 20190701-
 S97 S95 AND S96 [Note: Final line 2021]
 S98 EM 20210301-
 S99 S95 AND S98 [Note: Final line 2022]

ERIC (EBSCOhost)

Searched 3 July 2019 (729 records)
 Searched 9 March 2021 (83 records)
 Searched 11 January 2022 (2 records)

S1 DE "Sexual Abuse"
 S2 DE "Rape"
 S3 DE "Family Violence" AND sex*
 S4 TI(sex* N5 (abuse* or assaul* or attack* or aggress* or coer* or exploit* or force* or molest* or offen* or traffick* or trauma* or unlawful*
 or unwanted or violen*)) OR AB(sex* N5 (abuse* or assaul* or attack* or aggress* or coer* or exploit* or force* or molest* or offen* or traffick*
 or trauma* or unlawful* or unwanted or violen*))
 S5 TI (intercourse N5 (coer* or force* or unwanted)) OR AB (intercourse N5 (coer* or force* or unwanted))
 S6 ti(intimate partner violence) OR AB(intimate partner violence)
 S7 TI(rape or raped or incest*) OR AB(rape or raped or incest*)
 S8 TI(sex* N3 (victim* or revictim* or re-victim* or survivor*)) OR AB(sex* N3 (victim* or revictim* or re-victim* or survivor*))
 S9 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8
 S10 (DE "Psychotherapy" OR DE "Milieu Therapy" DE "Relaxation Training")
 S11 DE "Relaxation Training") OR (DE "Art Therapy" OR DE "Behavior Modification" OR DE "Contingency Management" OR DE "Desensitization" OR DE "Positive Behavior Supports" OR DE "Bibliotherapy" OR DE "Cognitive Restructuring" OR DE "Counseling" OR DE "Career Counseling" OR DE "Cocounseling" OR DE "Educational Counseling" OR DE "Family Counseling" OR DE "Group Counseling" OR DE "Individual Counseling" OR DE "Marriage Counseling" OR DE "Nondirective Counseling" OR DE "Parent Counseling" OR DE "Peer Counseling" OR DE "Rehabilitation Counseling" OR DE "School Counseling" OR DE "Counseling Psychology" OR DE "Crisis Intervention"

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OR DE "Emotional Adjustment" OR DE "Group Therapy" OR DE "Hypnosis" OR DE "Individual Psychology" OR DE "Music Therapy" OR DE "Occupational Therapy" OR DE "Rehabilitation" OR DE "Correctional Rehabilitation" OR DE "Drug Rehabilitation" OR DE "Vocational Rehabilitation" OR DE "Role Playing" OR DE "Dramatic Play" OR DE "Therapeutic Environment" OR DE "Therapeutic Recreation" OR DE "Play Therapy")
 S12 DE "Crisis Intervention"
 S13 (DE "Self Help Programs")
 S14 DE "Positive Behavior Supports" OR DE "Biofeedback"
 S15 TI("support group*") OR AB("support group*")
 S16 DE "Social Support Groups"
 S17 (DE "Health Education")
 S18 DE "Video Technology"
 S19 TI((abreaction or desensitization or exposure or implosive) N3 therap*) OR AB((abreaction or desensitization or exposure or implosive) N3 therap*)
 S20 TI (advisor* or advocate* or advocacy) OR AB (advisor* or advocate* or advocacy)
 S21 TI ("acceptance and commitment therapy") OR AB("acceptance and commitment therapy")
 S22 TI((animal* or art or colo*r or creative* or dance or dancing or drama or equine or experiential or music or narrative or play* or sensory or singing) N3 (program* or intervention* or therap*) OR AB((animal* or art or colo*r or creative* or dance or dancing or drama or equine or experiential or music or narrative or play* or sensory or singing) N3 (program* or intervention* or therap*))
 S23 TI((autogenic or autosuggestion* or auto-suggestion* or "breathing exercise*" or hypnosis or hypno-therapy or hypnotherapy) OR AB((autogenic or autosuggestion* or auto-suggestion* or "breathing exercise*" or hypnosis or hypno-therapy or hypnotherapy) S37 TI("behavior* activation") OR AB("behavior* activation")
 S24 TI(behavior*r* N3 (intervention* or program* or therap* or training or treatment*)) OR AB(behavior*r* N3 (intervention* or program* or therap* or training or treatment*))
 S25 TI(((biofeedback or feedback or imagery) N3 (intervention* or therap* or train* or treatment*) or AB(((biofeedback or feedback or imagery) N3 (intervention* or therap* or train* or treatment*)))
 S26 TI((brief or combination or "compass* focus*" or integrated or integrative or time-limited) N3 (intervention* or therap* or treatment*)) OR AB((brief or combination or "compass* focus*" or integrated or integrative or time-limited) N3 (intervention* or therap* or treatment*))
 S27 TI(("client focus*" or non-direct* or nondirect* or "solution focus*" or trauma* or talking) N3 therap*) OR AB(("client focus*" or non-direct* or nondirect* or "solution focus*" or trauma* or talking) N3 therap*)
 S28 TI(cognitiv* or cognition OR CBT) OR AB(cognitiv* or cognition OR CBT)
 S29 TI((cope or coping) N1 (intervention* or mechanism* or skill* or technique*)) OR AB((cope or coping) N1 (intervention* or mechanism* or skill* or technique*))
 S30 TI(counsel*ing) OR AB (counsel*ing)
 S31 TI((couple* or family or group or systemic* or multimodal* or multi-modal*) N3 (program* or intervention* or therap* or treat*)) OR AB((couple* or family or group or systemic* or multimodal* or multi-modal*) N3 (program* or intervention* or therap* or treat*))
 S32 TI("dialectical behavior*r* therap*") OR AB("dialectical behavior*r* therap*")
 S33 TI(exercise* or "physical training") OR AB(exercise* or "physical training")
 S34 TI((existential or gestalt or humanistic or interpersonal or milieu or person-centred or residential or socioenvironmental or socio-environmental) N1 therap*) OR AB((existential or gestalt or humanistic or interpersonal or milieu or person-centred or residential or socioenvironmental or socio-environmental) N1 therap*)
 S35 TI("expressive writing") OR AB("expressive writing")
 S36 TI("Eye Movement Desensitization and Reprocessing" or EMDR) OR AB("Eye Movement Desensitization and Reprocessing" or EMDR)
 S37 TI(meditat* or "mental training" or mindfulness* or "mind training" or "brain training" or yoga) OR AB(meditat* or "mental training" or mindfulness* or "mind training" or "brain training" or yoga)
 S38 TI("motivational interview") OR AB("motivational interview")
 S39 TI("reality therap*" or "problem solving") OR AB("reality therap*" or "problem solving")
 S40 TI(("psycho* therap*" or psychotherap*) OR AB(("psycho* therap*" or psychotherap*))
 S41 TI(psychoanalytic* or psycho-analytic* or psychodynamic* or psycho-dynamic*) OR AB(psychoanalytic* or psycho-analytic* or psychodynamic* or psycho-dynamic*)
 S42 TI(psychodrama or psycho-drama or "acting out" or "role play") OR AB(psychodrama or psycho-drama or "acting out" or "role play")
 S43 TI (psychosocial or psycho-social or psychoeducation* or psycho-education*) OR AB (psychosocial or psycho-social or psychoeducation* or psycho-education*)
 S44 TI("rational emotive") OR AB("rational emotive")
 S45 TI(Relax* N3 (training* or treatment* or therap*)) OR AB(Relax* N3 (training* or treatment* or therap*))
 S46 TI(Service* N3 (refer* or use*)) OR AB(Service* N3 (refer* or use*))
 S47 TI("stress inoculation training" or "prolonged exposure therapy" or "inoculation training" or "prolonged exposure therapy" or "cognitive processing therapy" or CPT) OR AB("stress inoculation training" or "prolonged exposure therapy" or "inoculation training" or "prolonged exposure therapy" or "cognitive processing therapy" or CPT)
 S48 TI((support or advice or advis*) N1 (centre* or center* or community or group* or network* or social or staff*)) OR AB((support or advice or advis*) N1 (centre* or center* or community or group* or network* or social or staff*))
 S49 TI("therapeutic allianc*" or "therapeutic relationship*" or "therapeutic communit*") OR AB("therapeutic allianc*" or "therapeutic relationship*" or "therapeutic communit*")

S50 TI("Third wave") OR AB("Third wave")
 S51 S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50
 S52 TI(rape N3 (centre* or center* or service* or support)) OR AB(rape N3 (centre* or center* or service* or support))
 S53 TI((sex* assault N3 centre) or (sex* assault N3 center) or (sex* assault N3 service) or (sex* assault N3 support)) OR AB((sex* assault N3 centre) or (sex* assault N3 center) or (sex* assault N3 service) or (sex* assault N3 support))
 S54 TI((sex* abuse* N3 centre) or (sex* abuse* N3 center) or (sex* abuse* N3 service) or (sex* abuse* N3 support)) OR AB((sex* abuse* N3 centre) or (sex* abuse* N3 center) or (sex* abuse* N3 service) or (sex* abuse* N3 support))
 S55 S52 OR S53 OR S54
 S56 S9 AND S51
 S57 S55 OR S56
 S58 DE "Meta Analysis" OR DE "Evaluation Research" OR DE "Control Groups" OR DE "Experimental Groups" OR DE "Longitudinal Studies" OR DE "Followup Studies" OR DE "Program Effectiveness" OR DE "Program Evaluation"
 S59 TI (random* or trial* or experiment* or PROSPECTIVE* OR longitudinal or BLIND* or CONTROL*) OR AB (random* or trial* or experiment* or PROSPECTIVE* OR longitudinal or BLIND* or CONTROL*)
 S60 S58 OR S59
 S61 S57 AND S60
 S62 S57 AND S60 Limiters - Date Published: 20190101-20211231 (Note: Final line 2021)
 S63 S57 AND S60 Limiters - Date Published: 20210101-20221231 (Note: Final line 2022)

Social Policy and Practice Ovid

Searched 3 July 2019 (1021 records)
 Searched 9 March 2021 (297 records)
 Searched 11 January 2022 (14 records)

1 (sex\$ adj5 (abuse\$ or assaul\$ or attack\$ or aggress\$ or coer\$ or exploit\$ or force\$ or molest\$ or offen\$ or traffick\$ or trauma\$ or unlawful \$ or unwanted or violen\$)).ti,ab,de.
 2 (intercourse adj5 (coer\$ or force\$ or unwanted)).ti,ab,de.
 3 (intimate partner adj (abuse or violence)).ti,ab,de.
 4 (rape or raped or incest\$).ti,ab,de.
 5 (sex\$ adj3 (victim\$ or revictim\$ or re-victim\$ or survivor\$)).ti,ab,de.
 6 (spouse adj (abuse or violence)).ti,ab,de.
 7 (human trafficking adj10 sex\$).ti,ab,de.
 8 or/1-7
 9 ((abreaction or desensitization or exposure or implosive) adj3 therap\$).ti,ab,de.
 10 "acceptance and commitment therapy".ti,ab,de.
 11 (advisor\$ or advocate\$ or advocacy).ti,ab,de.
 12 ((animal\$ or art or colo?r or creative\$ or dance or dancing or drama or equine or experiential or music or narrative or play\$ or sensory or singing) adj3 (program\$ or intervention\$ or therap\$)).ti,ab,de.
 13 (autogenic or autosuggestion\$ or auto-suggestion\$ or breathing exercise\$ or hypnosis or hypno-therapy or hypnotherapy).ti,ab,de.
 14 behavio\$ activation.ti,ab,de.
 15 (behavio?r\$ adj3 (intervention\$ or program\$ or therap\$ or training or treatment\$)).ti,ab,de.
 16 ((biofeedback or feedback or imagery) adj3 (intervention\$ or therap\$ or train\$ or treatment\$)).ti,ab,de.
 17 ((brief or combination or compass\$ focus\$ or integrated or integrative or time-limited) adj3 (intervention\$ or therap\$ or treatment \$)).ti,ab,de.
 18 ((client focus\$ or non-direct\$ or nondirect\$ or solution focus\$ or trauma\$ or talking) adj3 therap\$).ti,ab,de.
 19 (cognitiv\$ or cognition or CBT).ti,ab,de.
 20 ((cope or coping) adj1 (intervention\$ or mechanism\$ or skill\$ or technique\$)).ti,ab,de.
 21 counsel?ing.ti,ab,de.
 22 ((couple\$ or family or group or systemic\$ or multimodal\$ or multi-modal\$) adj3 (program\$ or intervention\$ or therap\$ or treat \$)).ti,ab,de.
 23 dialectical behavio?r\$ therap\$.ti,ab,de.
 24 (exercise\$ or physical training).ti,ab,de.
 25 ((existential or gestalt or humanistic or interpersonal or milieu or person-centred or residential or socioenvironmental or socio-environmental) adj therap\$).ti,ab,de.
 26 expressive writing.ti,ab,de.
 27 ("Eye Movement Desensitization and Reprocessing" or EMDR).ti,ab,de.
 28 (meditat\$ or mental training or mindfulness\$ or mind training or brain training or yoga).ti,ab,de.
 29 motivational interview\$.ti,ab,de.
 30 (reality therap\$ or problem solving).ti,ab,de.
 31 (psycho\$ therap\$ or psychotherap\$).ti,ab,de.

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32 (psychoanalytic\$ or psycho-analytic\$ or psychodynamic\$ or psycho-dynamic\$).ti,ab,de.
 33 (psychodrama or psycho-drama or acting out or role play).ti,ab,de.
 34 (psychosocial or psycho-social or psychoeducation\$ or psycho-education\$).ti,ab,de.
 35 rational emotive.ti,ab,de.
 36 (Relax\$ adj3 (training\$ or treatment\$ or therap\$)).ti,ab,de.
 37 (Service\$ adj3 (refer\$ or use\$)).ti,ab,de.
 38 (stress inoculation training or SIT or prolonged exposure therapy or PET or cognitive processing therapy or CPT).ti,ab,de.
 39 ((support or advice or advis\$1) adj1 (centre\$1 or center\$1 or community or group\$ or network\$ or social or staff\$)).ti,ab,de.
 40 (therapeutic allianc\$ or therapeutic relationship\$ or therapeutic communit\$).ti,ab,de.
 41 Third wave.ti,ab,de.
 42 or/9-41
 43 8 and 42
 44 (rape adj3 (centre\$ or center\$ or service\$ or support)).ti,ab,de.
 45 ((sex\$ assault adj3 centre) or (sex\$ assault adj3 center) or (sex\$ assault adj3 service) or (sex\$ assault adj3 support)).ti,ab,de.
 46 ((sex\$ abuse\$ adj3 centre) or (sex\$ abuse\$ adj3 center) or (sex\$ abuse\$ adj3 service) or (sex\$ abuse\$ adj3 support)).ti,ab,de.
 47 or/44-46
 48 43 or 47
 49 (random* or RCT or control* or experimental* or trial* or placebo* or group* or blind* or longitudinal study or prospective study or "follow* up" or TAU or "usual care" or "treatment as usual").ti,ab,de.
 50 48 and 49

Web of Science Core Collection Clarivate (SCI,SSCI, CPCI-S, CPCI-SSH)

Searched 4 July 2019 (1452 records)
 Searched 9 March 2021 (297 records)
 Searched 11 January 2022 (48 records)

#46 #42 AND #41

Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2021-2022 (Note: Final line 2022)

45 #42 AND #41

Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2019-2021 (Note: Final line 2021)

44 #42 AND #41

Refined by: [excluding] WEB OF SCIENCE CATEGORIES: (PLANT SCIENCES OR HORTICULTURE OR LANGUAGE LINGUISTICS OR ENVIRONMENTAL SCIENCES OR TROPICAL MEDICINE OR AGRONOMY OR VIROLOGY OR PUBLIC ENVIRONMENTAL OCCUPATIONAL HEALTH OR AGRICULTURAL ENGINEERING OR AGRICULTURE DAIRY ANIMAL SCIENCE OR INFORMATION SCIENCE LIBRARY SCIENCE OR BUSINESS OR AGRICULTURE MULTIDISCIPLINARY OR ENERGY FUELS OR ENTOMOLOGY OR PEDIATRICS OR PATHOLOGY OR FOOD SCIENCE TECHNOLOGY OR FORESTRY OR ECOLOGY OR HISTORY OR ENDOCRINOLOGY METABOLISM OR HOSPITALITY LEISURE SPORT TOURISM OR HUMANITIES MULTIDISCIPLINARY OR MEDICINE RESEARCH EXPERIMENTAL OR LITERATURE GERMAN DUTCH SCANDINAVIAN OR MATERIALS SCIENCE MULTIDISCIPLINARY OR METEOROLOGY ATMOSPHERIC SCIENCES OR MICROBIOLOGY OR VETERINARY SCIENCES OR MYCOLOGY OR PHILOSOPHY OR UROLOGY NEPHROLOGY OR PUBLIC ADMINISTRATION OR EDUCATION SPECIAL OR ENVIRONMENTAL STUDIES OR REGIONAL URBAN PLANNING OR PHARMACOLOGY PHARMACY OR SOIL SCIENCE OR GEOGRAPHY OR IMMUNOLOGY)

#43 #42 AND #41

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

42 TS=(random* or RCT or control* or experimental* or trial* or placebo* or group* or blind* or longitudinal or "follow* up" or TAU or "usual care" or "treatment as usual")

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

41 #40 OR #39

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#40 #37 OR #36 OR #35

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#39 #38 AND #3

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#38 #34 OR #33 OR #32 OR #31 OR #30 OR #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#37 ts= (rape NEAR/1 (centre* or center* or service* or support))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#36 TS= (("sex* abuse*" NEAR/1 centre) or ("sex* abuse*" NEAR/1 center) or ("sex* abuse*" NEAR/1 service*) or ("sex* abuse*" NEAR/1 support))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#35 TS= (("sex* assault" NEAR/1 centre) or ("sex* assault" NEAR/1 center) or ("sex* assault" NEAR/1 service*) or ("sex* assault" NEAR/1 support))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

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#34 TS= ("therapeutic allianc*" or "therapeutic relationship*" or "therapeutic communit*" or "Third wave")
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#33 TS=((support or advice or advis*) NEAR/1 (centre* or center* or communit* or group* or network* or social or staff*))
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#32 TS= ("stress inoculation training" or SIT or "prolonged exposure therapy" or PET or "cognitive processing therapy" or CPT)
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#31 TS=(Service* NEAR/1 (refer* or use*))
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#30 TS= (Relax* NEAR/1 (training* or treatment* or therap*))
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#29 TS=("rational emotive")
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#28 (TS=(psychosocial or "psycho-social" or psychoeducation* or "psycho-education*"))
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#27 TS= (psychodrama or "psycho-drama" or "acting out" or "role play")
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#26 TS=(psychoanalytic* or "psycho-analytic*" or psychodynamic* or "psycho-dynamic*")
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#25 TS= ("psycho* therap*" or psychotherap*)
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#24 TS=("reality therap*" or "problem solving")
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#23 TS=("motivational interview*")
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#22 TS= (meditat* or "mental training" or mindfulness* or "mind training" or "brain training" or yoga)
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#21 TS=("Eye Movement Desensitization and Reprocessing" or EMDR)
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#20 ts=("expressive writing")
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#19 TS=((existential or gestalt or humanistic or interpersonal or milieu or "person-centred" or residential or socioenvironmental or "socio-environmental") NEAR/0 (therap*))
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#18 TS=(exercise* or physical training)
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#17 TS=("dialectical behav* therap*")
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#16 (TS=((couple* or family or group or systemic* or multimodal* or multi-modal*) near/3 (program* or intervention* or therap* or treat*)))
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#15 TS=((cope or coping) near/1 (intervention* or mechanism* or skill* or technique*))
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#14 TS=(cognitiv* or cognition or CBT)
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#13 TS(("client focus*" or non-direct* or nondirect* or "solution focus*" or trauma* or talking) near/3 therap*)
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#12 TS=((brief or combination or "compass* focus*" or integrated or integrative or "time limited") near/3 (intervention* or therap* or treatment*))
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#11 TS=((biofeedback or feedback or imagery) near/3 (intervention* or therap* or train* or treatment*))
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#10 TS= (behavio* near/1 (intervention* or program* or therap* or training or treatment*))
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#9 TS=("behavio* activation")
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#8 TS=(autogenic or autosuggestion* or auto-suggestion* or "breathing exercise*" or hypnosis or hypno-therapy or hypnotherapy)
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#7 TS=((animal* or art or colo*r or creative* or dance or dancing or drama or equine or experiential or music* or narrative or play* or sensory or singing) near/3 (program* or intervention* or therap*))
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#6 TS=(advisor* or advocate* or advocacy)
 Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#5 TS="acceptance and commitment therapy"

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#4 TS= ((abreaction or desensitization or exposure or implosive) near/1 therap*)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#3 (#1 OR #2)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#2 TI=(((rape or raped or incest*) OR (intercourse near/3 coerc*)) NOT offender*)

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

#1 TI=(((sex* near/0 (abuse* or assault* or attack* or aggress* or coer* or exploit* or force* or molest* or offen* or traffick* or trauma* or unlawful* or unwanted or violen*)) NOT (offender*))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years

Searched 5 July 2019 (4 records)

Searched 11 March 2021 (125 records added between 5 July 2019 to 11 March 2021)

Searched 12 January 2022 (No records added between 11 March 2021 to 12 January 2022)

(title:(title:(sex OR sexual) AND (abuse* OR assaul* OR attack* OR aggress* OR coer* OR exploit* OR force* OR molest* OR offen* OR traffick* OR trauma* OR unlawful* OR unwanted OR violen*)) OR title:(intimate partner violence OR intimate partner abuse) OR title:(rape OR raped OR incest*)) OR abstract:(title:(sex OR sexual) AND (abuse* OR assaul* OR attack* OR aggress* OR coer* OR exploit* OR force* OR molest* OR offen* OR traffick* OR trauma* OR unlawful* OR unwanted OR violen*)) OR title:(intimate partner violence OR intimate partner abuse) OR title:(rape OR raped OR incest*)) OR abstract:((((sex OR sexual) AND (abuse* OR assaul* OR attack* OR aggress* OR coer* OR exploit* OR force* OR molest* OR offen* OR traffick* OR trauma* OR unlawful* OR unwanted OR violen*)) OR (intimate partner violence OR intimate partner abuse) OR title:(rape OR raped OR incest*)) NOT title:(offender* OR offending OR offended) NOT title:(child*))

Limited to publication type: systematic review

Cochrane Database of Systematic Reviews (CDSR)

Searched 5 July 2019 (17 records)

Searched 8 March 2021 (4 records)

Searched 10 January 2022 (2 records)

#1 [mh ^"sex offenses"]

#2 [mh Incest]

#3 [mh "intimate partner violence"]

#4 [mh "human trafficking"]

#5 [mh rape]

#6 [mh "spouse abuse"]

#7 (sex* NEAR/5 (abuse* or assaul* or attack* or aggress* or coer* or exploit* or force* or molest* or offen* or traffick* or trauma* or unlawful* or unwanted or violen*)):ti NOT (offender* or offended or offen*es):ti

#8 (intercourse NEAR/5 (coer* or force* or unwanted)):ti,ab,kw

#9 ("intimate partner violence" or "intimate partner abuse"):ti

#10 (rape or raped or incest*):ti 115

#11 (sex* NEAR/3 (victim* or revictim* or re-victim* or survivor*)):ti,ab,kw

#12 {or #1-#11}

#13 MeSH descriptor: [Anxiety Disorders] explode all trees and with qualifier(s): [therapy - TH]

#14 [mh "Adaptation, Psychological"]

#15 [mh "Behavior Therapy"]

#16 [mh "Combined Modality Therapy"]

#17 [mh ^"community networks"]

#18 [mh "Complementary therapies"]

#19 [mh Counseling]

#20 MeSH descriptor: [Depression] this term only and with qualifier(s): [therapy - TH]

#21 MeSH descriptor: [Depressive Disorder, Major] explode all trees and with qualifier(s): [therapy - TH]

#22 [mh Exercise]

#23 [mh "Exercise therapy"]

#24 [mh "Health Education"]

#25 [mh "Health Knowledge, Attitudes, Practice"]

#26 [mh "Interview, Psychological"]

#27 [mh "mind body therapies"]

#28 [mh "Psychological adjustment"]

#29 MeSH descriptor: [Psychological Trauma] explode all trees and with qualifier(s): [prevention & control - PC, rehabilitation - RH, therapy - TH] 20

#30 [mh "psychosocial support systems"] 19

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- #31 [mh "psychotherapy"] 21875
 #32 [mh "Referral and Consultation"] 2157
 #33 [mh "Self-Help Groups"] 743
 #34 [mh "Social Support"] 3164
 #35 MeSH descriptor: [Stress Disorders, Post-Traumatic] explode all trees and with qualifier(s): [prevention & control - PC, rehabilitation - RH, therapy - TH]
 #36 MeSH descriptor: [Video Recording] this term only
 #37 MeSH descriptor: [Videotape Recording] this term only
 #38 [mh Writing]
 #39 ((abreaction or desensitization or exposure or implosive) NEAR/3 therap*):ti,ab,kw
 #40 "acceptance and commitment therapy":ti,ab,kw
 #41 (advisor* or advocate* or advocacy):ti,ab,kw
 #42 ((animal* or art or colo?r or creative* or dance or dancing or drama or equine or experiential or music or narrative or play* or sensory or singing) NEAR/3 (program* or intervention* or therap*)):ti,ab,kw
 #43 (autogenic or autosuggestion* or auto next suggestion* or breathing next exercise* or hypnosis or hypno next therapy or hypnotherapy):ti,ab,kw
 #44 behavio* next activation:ti,ab,kw
 #45 (behavio* NEAR/3 (intervention* or program* or therap* or training or treatment*)):ti,ab,kw
 #46 ((biofeedback or feedback or imagery) NEAR/3 (intervention* or therap* or train* or treatment*)):ti,ab,kw
 #47 ((brief or combination or compass* next focus* or integrated or integrative or time next limited) NEAR/3 (intervention* or therap* or treatment*)):ti,ab,kw
 #48 ((client next focus* or non next direct* or nondirect* or solution next focus* or trauma* or talking) NEAR/3 therap*)
 #49 (cognitiv* or cognition):ti,ab,kw
 #50 CBT:ti,ab,kw
 #51 ((cope or coping) NEAR/1 (intervention* or mechanism* or skill* or technique*)):ti,ab,kw
 #52 counsel*ing:ti,ab,kw
 #53 ((couple* or family or group or systemic* or multimodal* or multi next modal*) NEAR/3 (program* or intervention* or therap* or treat*)):ti,ab,kw
 #54 dialectical next behavio*r* next therap*:ti,ab,kw
 #55 (exercise* or physical next training):ti,ab,kw
 #56 ((existential or gestalt or humanistic or interpersonal or milieu or person-centred or residential or socioenvironmental or socio next environmental) NEXT therap*):ti,ab,kw
 #57 expressive next writing:ti,ab,kw
 #58 ("Eye Movement Desensitization and Reprocessing" or EMDR):ti,ab,kw
 #59 (meditat* or mental next training or mindfulness* or mind next training or brain next training or yoga):ti,ab,kw
 #60 motivational next interview*:ti,ab,kw
 #61 (reality next therap* or problem next solving):ti,ab,kw
 #62 (psycho* next therap* or psychotherap*)
 #63 (psychoanalytic* or psycho next analytic* or psychodynamic* or psycho next dynamic*):ti,ab,kw
 #64 (psychodrama or psycho next drama or acting next out or role next play):ti,ab,kw
 #65 (psychosocial or psycho next social or psychoeducation* or psycho next education*):ti,ab,kw
 #66 rational next emotive:ti,ab,kw
 #67 (Relax* NEAR/3 (training* or treatment* or therap*)):ti,ab,kw
 #68 (Service* NEAR/3 (refer* or use*)):ti,ab,kw
 #69 (stress next inoculation next training or SIT or prolonged next exposure next therapy or PET or cognitive next processing next therapy or CPT):ti,ab,kw
 #70 ((support or advice or advisor*) NEAR/1 (centre* or center* or community or group* or network* or social or staff*)):ti,ab,kw
 #71 (therapeutic next allianc* or therapeutic next relationship* or therapeutic next communit*):ti,ab,kw
 #72 Third next wave:ti,ab,kw
 #73 {or #13-#72}
 #74 #12 and #73
 #75 (rape NEAR/1 (centre* or center* or service* or support)):ti,ab,kw
 #76 ((sex* next assault NEAR/3 centre) or (sex* next assault NEAR/3 center) or (sex* next assault NEAR/3 service) or (sex* next assault NEAR/3 support)):ti,ab,kw
 #77 ((sex* next abuse* NEAR/3 centre) or (sex* next abuse* NEAR/3 center) or (sex* next abuse* NEAR/3 service) or (sex* next abuse* NEAR/3 support)):ti,ab,kw
 #78 {or #74-#77} in Cochrane Reviews, Cochrane Protocols
 #79 {or #74-#77} with Cochrane Library publication date from Mar 2021 to Jan 2022

ClinicalTrials.gov

Searched 5 July 2019 (182 records after 17 studies about canola oil, or rapeseed were removed)

Searched 11 March 2021 (30 records. First posted from 7 June 2019 to 3 November 2021)
 Searched 12 January 2022 (2 records. First posted from 3 November 2021 to 1 December 2022)

Interventional Studies | (Sexual Abuse OR SEXUAL ASSAULT OR RAPE OR INCEST OR "INTIMATE PARTNER") | Adult, Older Adult

APPLIED FILTERS: INTERVENTIONAL

ADULT 18-64

OLDER ADULT (65+)

WHO ICTRP

Searched 8 July 2019 (229 records)

Search attempted 11 March 2021 but website did not respond

Searched 12 January 2022 (43 records. Date of registration between 8 July 2019 to 12 January 2022)

CONDITION| Sexual Abuse OR SEXUAL ASSAULT OR RAPE OR INCEST OR "INTIMATE PARTNER"

UK Clinical Trials Gateway <https://bepartofresearch.nihr.ac.uk/>

Searched 5 July 2019 (3 records)

Searched 11 March 2021 (3 records)

Searched 12 January 2022 (no new records)

Searched for single terms and phrases:

violence; IPV; incest; sex; sexual; Post-traumatic stress disorder (PTSD)

Appendix 3. Cochrane Common Mental Disorders Controlled Trials Register

Core MEDLINE search

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

1. [MeSH Headings]:

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

2. [Title/ Author Keywords]:

(eating disorder* or anorexia nervosa or bulimi* or binge eat* or (self adj (injur* or mutilat*)) or suicide* or suicidal or parasuicid* or mood disorder* or affective disorder* or bipolar i or bipolar ii or (bipolar and (affective or disorder*)) or mania or manic or cyclothymic* or depression or depressive or dysthymi* or neurotic or neurosis or adjustment disorder* or antidepress* or anxiety disorder* or agoraphobia or obsess* or compulsi* or panic or phobi* or ptsd or posttrauma* or post trauma* or combat or somatoform or somati#ation or medical* unexplained or body dysmorphi* or conversion disorder or hypochondria* or neurastheni* or hysteria or munchausen or chronic fatigue* or gambling or trichotillomania or vaginismus or anhedoni* or affective symptoms or mental disorder* or mental health).ti,kf.

3. [RCT filter]:

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

4. (1 and 2 and 3)

Records were screened for reports of RCTs within the scope of the Cochrane Common Mental Disorders Group. Secondary reports of RCTs were tagged to the appropriate study record. The CCMD-CTR is current to June 2016 only.

Appendix 4. Unused methods

Randomised cross-over trials

Had we found cross-over trials, we would have applied the same approach as recommended in Section 23.2.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021b). As discussed in section 23.2.3 in the Handbook, this would involve using the variant of the Cochrane risk of bias tool designed specifically for cross-over trials. This would have helped address some of the key issues when assessing risk of bias in cross-over trials, including 1) bias arising from the randomisation process, 2) bias due to deviations from intended interventions, 3) bias due to missing outcome data, 4) bias in measurement of the outcome and 5) bias in selection of the reported outcome.

Continuous data

Had studies used the same continuous outcome measure, we would have calculated the mean difference (MD) with 95% confidence interval (CI). We would have presented conceptually distinct outcomes in separate forest plots. Had it been necessary to combine dichotomous data and continuous data in a meta-analysis, we would have needed estimates of the standard error. Standard errors could have been computed for all studies by entering the data into RevMan 5 as dichotomous and continuous outcome type data, as appropriate, and converting the CI for the resulting log odds ratios and standardised mean differences (SMD) into standard errors (Lefebvre 2021). Once we had computed the SMD (or log odds ratios) and their standard errors for all studies in the meta-analysis, we would have combined them using the generic inverse-variance method in RevMan 5 (Review Manager 2014).

Cluster-randomised trials

There was one included cluster trial (Bass 2013); however, this was not included in the meta-analysis due to the nature of the comparison. Had we identified cluster-randomised trials eligible for the meta-analysis, we would have adjusted the standard errors or sample sizes using the method described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021b). As described in section 23.1.4 in the Handbook, the adjustment method would have required the following information from the study: the number of clusters or groups randomised to each intervention group and the total number of participants in the study; the outcome data ignoring the cluster design for the total number of individuals; and an estimation of intracluster (or intraclass) correlation coefficient (ICC). This would have enabled an approximately correct analysis to be performed. Had the ICC not been available, we would have used ICCs from analogous cluster-randomised trials. If analogous studies had not been available, we would have used a series of plausible values in a sensitivity analysis. An approximately correct analysis would proceed to reduce the size of each trial to its 'effective sample size' by dividing by the design effect. For continuous data, only the sample size needs to be reduced. For dichotomous data, the number of participants and those experiencing the event should be divided by the same design effect.

Dealing with missing data

We would have estimated the log rank statistics where these were not published in an article, and we would have used previously reported methods, where applicable (Parmar 1998; Tierney 2007). We would have addressed the potential impact of missing outcome data in the risk of bias assessment. If appropriate, we would have performed a sensitivity analysis to assess the impact of the missing information on our results (see Sensitivity analysis below), using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2021).

Data synthesis

Had it been inappropriate to combine the data in a meta-analysis (on account of insufficient studies or data), we would have reported the effect sizes with 95% CI or standard errors of individual studies, and provided a narrative, rather than quantitative, summary of the findings that addressed the following aspects: 1) What was the direction of effect? 2) What was the size of effect? 3) Was the effect consistent across studies?

Subgroup analysis and investigation of heterogeneity

As described in Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2021), metaregression is an extension to subgroup analyses that allows the effect of continuous as well as categorical characteristics to be investigated and, in principle, allows the effects of multiple factors to be investigated simultaneously. Generally, metaregression should not be considered when there are fewer than 10 studies in a meta-analysis. Had there been more than 10 studies available, we would have used metaregression techniques recommended for Stata (Harbord 2004; Stata 2017).

Participant characteristics have been identified as integral to subgroup analyses, as there may be differences in the efficacy of treatments for different groups of individuals. However, we are aware that subgroup analyses of subsets of participants are challenged because sufficient details to extract data about separate participant types are seldom published in reports. Recruitment setting has also been identified as important, as there may be differences between survivors recruited via mental health clinics as opposed to in the community or acute sexual assault services. Intensity of interventions is also of interest; for example, we might have compared outcomes from intense

psychological therapies versus interventions oriented towards provision of psychosocial support. Finally, it would have been important to stratify analyses by type of intervention given their distinct mechanisms and theoretical underpinnings. Had we found sufficient studies, we would have conducted the following subgroup analyses:

- participant characteristics (e.g. gender, ethnicity, time to treatment, symptom load and types of trauma exposure);
- intensity of intervention (e.g. up to four sessions, five or more sessions);
- mode of intervention delivery (e.g. individual versus group); and
- setting of recruitment or intervention delivery (healthcare, community, acute settings).

Sensitivity analyses

We would have performed the following sensitivity analysis, provided there were sufficient numbers of studies, to examine any effects on the overall outcome:

- re-analysis of the data excluding studies with missing outcome data.

Additional sensitivity analyses would have been required if particular issues related to the studies under review had arisen; for example, if ICCs were not available in included cluster trials or analogous cluster-randomised trials, we would have used a series of plausible values in a sensitivity analysis.

HISTORY

Protocol first published: Issue 10, 2019

CONTRIBUTIONS OF AUTHORS

Conception of the review: SB, LOD

Design of the review: LOD

Co-ordination of the review: LOD

Development of search strategy: SB, NK

Selection of trials: SB, LOD, NK, KB, GC

Extraction of data using Covidence: LOD, SB, GC, KB, MW

Import of data into RevMan Web: MW with checking by LOD

Risk of bias assessment: LT, LOD, MW

Assessment of the certainty in the body of evidence: LOD, KB, SB

Data analysis: MW, LOD

Interpretation of analysis: MW, LOD, SB, KB, KH, GF

Drafting of review: LOD, SB, MW, GC, KB, MW

Topic expertise and editing: SB, KH, GF

Nazanin Khasteganan was involved in the protocol published in 2019 and is no longer included on the author byline. Some of the content retained in this review reflects their contributions as follows: protocol development; screening and selecting studies for inclusion.

LOD is the guarantor for the review.

DECLARATIONS OF INTEREST

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LOD: reports a grant (September 2018 to January 2023) from the NIHR (16/117/04) for the MESARCH project on which she is the Principal Investigator; the grant covers travel support and payment for writing this review; paid to Coventry University.

SB: has declared that she has no conflicts of interest.

MW: has declared that she has no conflicts of interest.

KB: has declared that she has no conflicts of interest.

GC: has declared that she has no conflicts of interest.

LT: has declared that she has no conflicts of interest.

KH: has contributed to a special series on mental health and intimate partner violence for the *Lancet Psychiatry*, and to a narrative review on gender-based violence published in the *Medical Journal of Australia*.

GF: is a GP at Montpelier Health Centre, Bristol, UK, and an unpaid board member of IRISi, a social enterprise that works to improve the healthcare response to gender-based violence, including rape and sexual assault. GF reports having written editorials and blogs on the health care response to domestic violence.

SOURCES OF SUPPORT

Internal sources

- Coventry University, UK

Contributes 20% of the MESARCH (Multidisciplinary Evaluation of Sexual Assault Referral Centres for better Health) project funding awarded to Coventry University and enables authors MW, GC and LOD to work on the review during office hours/salary contributions

- University of Hertfordshire, UK

Contributes 20% of the MESARCH (Multidisciplinary Evaluation of Sexual Assault Referral Centres for better Health) project funding awarded to University of Hertfordshire and enables author KB to work on the review during office hours/salary contribution

- University of Melbourne, Australia

Enables authors KH and LT to work on the review during office hours/salary contributions

- University of Bristol, UK

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In our protocol (Brown 2019), we listed Stress Inoculation Training (SIT), Prolonged Exposure Therapy (PET) and Cognitive Processing Therapy (CPT) as examples of integrative therapies, based on our reading of descriptions of these interventions in the literature we used to guide the development of our review. However, when we started to categorise the interventions identified in studies that met our review criteria, we found that not all easily fit with categories of the former Cochrane Depression, Anxiety and Neurosis Group (CCDAN) list of psychological therapies. We therefore consulted experts and clinical psychologists for guidance and concluded that we had previously miscategorised SIT, PET and CPT, which may be better categorised as Cognitive Behavioural Therapy. In addition, trauma-focused interventions compared to non-trauma-focused was an aspect we raised as important in the Protocol ("It is recognised that the main comparison combines all intervention types in one and that it may be more useful to stakeholders to understand effects by type. Thus, depending on availability of data, we will stratify results using primary outcomes for CBT versus inactive controls and behavioural therapies versus inactive controls, presenting these in additional tables"). However, we had not clearly described trauma-focused interventions in the Protocol. Hence, we edited the [Description of the intervention](#) section in light of our increased learning in the topic and our previous oversight, and used these updated categorisations throughout the review.

In the Protocol, we stated we would include all time points but that the primary time point for treatment efficacy would be three months post-treatment. The selection of this time point had been based on a scoping review done at the outset of the research. However, in the process of selecting studies for inclusion, it became clear that the majority assessed treatment efficacy at post-treatment (in the days and weeks following treatment), and three months was much less common. We still conducted meta-analyses based on the outcomes at three months; however, ultimately post-treatment outcomes were reported in [Summary of findings 1](#).

In the Protocol, we intended to extract sexual identity but this was rarely mentioned in any study and was not ultimately listed among the characteristics of included studies. In the Review, we listed additional features for extraction than initially included in the Protocol. These changes included adding information about interventions such as format of delivery, theoretical basis for the intervention, fidelity, mean number of sessions taken up by participants and completion rates. We were more precise in the review about the difference between dropout and non-completion. Dropout indicated the number of participants who did not complete outcome assessments/evaluation. Non-completion referred to the number of participants allocated to an intervention group that did not receive the intervention (or access a minimum number of intervention sessions predefined by individual studies as the dose required for 'completion'). We differentiated between study setting and recruitment setting. These differences were implemented so that the data extracted accurately reflected what was reported in the included studies and could be synthesised across all studies.

The review, unlike the protocol, specifies a minimum number of included studies required to perform meta-analyses. We performed a meta-analysis if there were three or more studies. This was selected as a threshold given the potential for a very large number of analyses across our four time points and primary and secondary outcomes.