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Guided Self-help Interventions for Posttraumatic Stress Disorder: A Meta-analysis of Randomised Controlled Trials

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Abstract

The current evidence base for the treatment of Posttraumatic Stress Disorder (PTSD) is based upon trauma-focused psychological therapy delivered on an individual, face-to-face basis with a therapist. Many barriers to accessing treatment exist, and if untreated, chronic PTSD can result in significant personal, occupational, social, financial, and health problems, reducing years and quality of life. In 2005, The National Institute for Health and Care Excellence recommended research into newly developed guided self-help (GSH) materials based on trauma-focused psychological interventions. Unlike other common mental health disorders, currently, there is no meta-analytical evidence available to support the implementation of GSH as a low intensity psychological intervention for PTSD. A meta-analysis of eight randomised controlled-trials, was conducted to review the effectiveness of trauma-focused GSH (TF-GSH) for adults with PTSD. These studies compared TF-GSH against active or passive control comparators, and seven of these studies delivered Internet-based interventions. Results show that at postassessment a large treatment effect is associated with TF-GSH in reducing symptoms of PTSD. A moderate effect size was found in favour of TF-GSH in reducing co-morbid symptoms of depression. The rate of dropouts from TF-GSH was comparable to current evidence-based treatments for PTSD. Sensitivity analyses revealed that the magnitude of effect remained when studies judged as at high risk of bias were removed. However, there was statistically significant and clinical heterogeneity present amongst studies, which could not be addressed with additional analysis due to the small number of studies included within the review. The quality of evidence was evaluated, as low and further research is required to increase confidence in estimating the treatment effect of TF-GSH for PTSD.

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1 Background and Introduction

1.1 Chapter Outline

This meta-analysis investigates the effectiveness of trauma-focused guided self-help (TF-GSH) for Posttraumatic Stress Disorder (PTSD). The chapter provides an overview of PTSD and existing treatments for the disorder, with reference to the National Institute for Health and Clinical Excellence (NICE) guidelines and research recommendations. Literature relevant to this field is explored and limitations are highlighted. Finally, the review objectives and questions are presented.

1.2 Overview of PTSD

1.2.1 Trauma definition.

NICE differentiates between a traumatic and stressful event. It states that PTSD develops following an event "of an exceptionally threatening or catastrophic nature, which is likely to cause pervasive distress in almost anyone". The term *trauma* does not encompass distressing situations "that are described as 'traumatic' in everyday language, for example, divorce, loss of a job, or failing an exam" (NICE, 2005). Examples of trauma events include natural disasters, mass interpersonal violence, war, torture, large-scale transportation accident, motor vehicle accident, emergency worker exposure to trauma, fire, rape or sexual assault, physical assault, domestic violence, and child abuse. The trauma can be ongoing such as in the case of assault and abuse (Briere & Scott, 2006).

1.2.2 Diagnostic criteria.

Formerly, PTSD has been categorised as an anxiety disorder within The Diagnostic and Statistical Manual of Mental Disorders (DSM) (4th ed., text rev.; DSM-IV-TR; American Psychiatric Association [APA], 2000). Now, in the 5th edition of the DSM (DSM-5; APA, 2013) it falls under a new category, "trauma and stressor-related disorders". The DSM conceptualises PTSD as occurring when an individual has been exposed to a traumatic event

in which they experienced, witnessed, or was confronted with an event or events that involved "actual or threatened death, serious injury, or sexual violence". The nature of an individual's response to the traumatic event, i.e., "fear, helplessness, or horror" has been removed as a diagnostic criterion from the DSM-5 (APA, 2013).

Within the DSM, symptoms include the traumatic event being persistently re-experienced through "recurrent, involuntary, and intrusive distressing memories" of the event, and intense psychological distress at exposure to cues that resemble an aspect of the traumatic event. The disorder is characterised by "persistent avoidance" of external and internal stimuli, and increased "arousal and reactivity associated with the traumatic event". DSM-5's PTSD construct includes the presence of negative mood and cognitions to create a four-factor model. PTSD is diagnosed when symptoms are present for more than one month. The onset of PTSD can be immediately after the trauma, or at least six months after the event defined as "delayed onset" in the DSM-5 (APA, 2013).

Preliminary revisions of PTSD classification in The World Health Association's 11th edition of the International Classification of Diseases (ICD-11) due to be published in 2018, will adopt a three-factor model (Friedman & Resick, 2014). Core symptoms correspond to re-experiencing, avoidance, and hyperarousal clusters. Symptoms associated with other mood and anxiety disorders, such as cognitive impairment, and negative mood states have been removed. Unlike the DSM-5, ICD-11 will include a new "complex PTSD" diagnosis (Friedman & Resick, 2014).

1.2.3 Epidemiology.

Research on the epidemiology of PTSD includes the concepts of the prevalence of exposure to trauma and the total prevalence of PTSD in the population. Posttraumatic stress is a disorder that can affect individuals of all ages (NICE, 2005). However, there are limited data among youth and older adults, as many of the surveys commonly exclude these life

stages (Norris & Slone, 2014). There is a paucity of data from populations from countries experiencing political violence and conflict, and research on the homeless is an area of neglect (Norris & Slone, 2014).

1.2.3.1 Trauma exposure.

The majority of the population is exposed to a potentially traumatic event within their lifetime (Keane, Marx, Sloan, & De Prince, 2010). Several studies have indicated consistently that men are more likely than women to have been exposed to at least one trauma over their lifetimes (Breslau & Davis, 1997; Frans, Rimmö, Åberg, & Fredrikson, 2005). More women reported rape, sexual molestation, sexual assault, and men more frequently reported fires, disaster, life-threatening accident, physical assault, combat, being threatened with a weapon, and being held captive (Kessler, Sonnega, Bromet, Hughes, & Nelson, 1995; Creamer, Burgess, & McFarlane, 2001).

Trauma exposure prevalence data for some populations such as Asians are sparse and ethnicity studies to date have produced inconsistent results (Norris & Slone, 2014). High rates of severe trauma exposure have been established in postconflict, low-income countries (de Jong et al., 2001), countries exposed to political violence (Mollica, Poole, & Tor, 1998) and amongst refugee populations (Sack et al., 1994).

The 2001 National Survey of Veterans conducted in the United States (NSV; U.S. Department of Veterans Affairs, 2003) showed that across wars and eras, 39% of veterans reported exposure to combat, and 36% exposure to the dead, dying, or wounded. During 2003, the Veterans Health Administration (VHA) conducted a universal screen for *military sexual trauma* (MST). This term refers to "sexual assault and to repeated, threatening sexual harassment occurring during military service" (Hyun, Pavao, & Kimerling, 2009). Data analysis shows that 22% of women and 1% of men had experienced MST (Kimerling, Gima, Smith, Street, & Frayne, 2007). The most prevalent type of exposure amongst men and

women deployed to Afghanistan and Iraq was having a friend wounded or killed (50%) (Schell & Marshall, 2008).

1.2.3.2 Prevalence of PTSD.

Despite the high occurrence of traumatic exposure across the world, the World Health Organisation's (WHO) World Mental Health (WMH) survey found that out of 27 countries, lifetime prevalence of PTSD was no more than 7% (WHO, 1993). Although this reflects a universal human resilience to trauma, an arguably low prevalence rate of current PTSD, for example, 2% in the United States, when applied to its total population, translates to 6.3 million active cases (Norris & Slone, 2014). A household survey carried out in 2007 of adults in the UK estimated a prevalence rate of 2.6% in men and 3.3% in women (McManus, Meltzer, Brugha, Bebbington, & Jenkins, 2009).

However, PTSD rates as high as 80% have been found amongst some refugee populations reporting 25 or more trauma events (Mollica et al., 1998) and rates from 16% to 37% in postconflict countries (de Jong et al., 2001). Despite a higher rate of trauma exposure among men, studies reliably demonstrate that the prevalence of lifetime PTSD is twice as common among women, than men in civilian populations (Friedman, Resick, & Keane, 2014). The role of ethnicity has not demonstrated any differences in prevalence rates of PTSD (Kessler et al., 1995; Norris, 1992).

Higher prevalence rates of PTSD have been found in military and veteran populations compared to civilian populations. The National Vietnam Veterans Readjustment Study (NVVRS; Kulka et al., 1990) found prevalence rates of 31% for men and 27% for women exposed to combat. Rates as high as 18% have been found for service members returning from Iraq and Afghanistan (Hoge et al., 2004; Schell & Marshall, 2008).

1.2.4 Prognosis.

The majority of individuals presenting with PTSD symptomology immediately after exposure to a traumatic event, experience a natural recovery within one to three months of the event (Cahill & Pontoski, 2005). Rates of spontaneous remission tend to decline after three months posttrauma. Chronic PTSD is usually defined as an episode lasting one year or longer (Norris & Slone, 2014). The National Comorbidity Survey (NCS; Kessler et al., 1995) conducted in the United States found that among adults with PTSD who were not treated, the average duration of the condition was over five years. Women are overrepresented amongst lifetime cases of chronic PTSD and are three to four times more likely than men to develop an enduring episode of the disorder (Breslau et al., 1998). Byers, Yaffe, Covinsky, Friedman, and Bruce (2010) found that PTSD prevalence rates declined with age.

1.2.5 Risk factors.

A meta-analysis (Brewin, Andrews, & Valentine, 2000) has shown that gender, age at trauma, and race, as risk factors for developing PTSD have not been reliably supported by studies across various populations. Previous trauma, childhood adversity, and education were factors that more consistently predicted PTSD, although in varying degrees, according to study populations and methods employed. Factors such as individual and family psychiatric history, and reported childhood abuse, were more consistently demonstrated as predictive of PTSD. The review found that stronger effects were associated with trauma severity, lack of social support, and additional life stress. This suggests that factors operating during or after the trauma may be more influential compared with pretrauma factors.

The NCS (Kessler et al., 1995) has established an association between the type of trauma and risk of developing PTSD. The event associated with the highest probability of lifetime PTSD for men (65%) and women (46%) was rape. Other traumas with high

conditional risk included “combat, childhood abuse/neglect, sexual molestation, and physical assault”. Natural disasters, accidents, fire, and witnessing a traumatic event were associated with a lower probability (less than 10%) of precipitating PTSD for both men and women.

Among military and veteran populations the degree of exposure to combat and longer terms of deployment have been identified as factors that increase the risk of precipitating PTSD with lifetime prevalence rates (Schell & Marshall, 2008). Ethnic differences established within veteran samples for current and lifetime rates of PTSD are largely explained by the degree of direct combat exposure (Beals et al., 2002).

Biological risk factors associated with the stress response have been hypothesised as contributing to the development of PTSD. Lower levels of cortisol immediately after the trauma may result in a stronger, more sustained stress reaction (Delahanty, Raimonde, & Spoonster, 2000). One study has shown that trauma survivors with precipitating PTSD had a significantly elevated resting heart rate soon after the trauma compared to those that did not develop the disorder (Shalev et al., 1998). In brief summary, a wealth of studies have investigated and identified several risk factors associated with the development of PTSD, however research to date is not sufficient to precisely or consistently identify individuals posttrauma who may be at most risk of developing PTSD.

1.2.6 PTSD co-morbidity.

A high degree of co-morbidity exists between current and lifetime PTSD and other psychiatric disorders. This has been established within community and veteran studies using outpatient and inpatient samples (Brown, Campbell, Lehman, Grisham, & Mancill, 2001; Kessler, Chiu, Demler, & Walters, 2005; Kulka et al., 1990). Rates of co-morbidity for the Axis I disorders (“All psychological diagnostic categories except mental retardation and personality disorder”, [4th ed.,; DSM-IV; APA, 1994]) ranged from 50-85% of veterans with PTSD (Kehle et al., 2010; Kulka et al., 1990; Magruder et al., 2005), and 92% within a

community outpatient sample (Brown et al., 2001).

The Axis I disorders most frequently presented co-morbidly with PTSD are major depressive disorder, generalised anxiety disorder (GAD), substance dependency or abuse, and other anxiety disorders including social anxiety disorder, panic disorder (PD), phobia, and agoraphobia (Kessler et al., 1995; Brown et al., 2001). One longitudinal study reported that PTSD predicted depression and anxiety, although having a depression or anxiety diagnosis did not increase the likelihood of developing PTSD (Ginzburg, Ein-Dor, & Solomon, 2010). It has been hypothesised based on temporal analysis on NCS data (Kessler et al., 1995), that substance abuse disorders elevated the risk of exposure to trauma and therefore the development of PTSD. Individuals with PTSD are at elevated risk of substance dependency and abuse, thus creating a vicious cycle (Kilpatrick, Acierno, Resnick, Saunders, & Best, 1997). Moreover, experience of multiple traumas has been associated with an increased risk of psychosis (Shevlin, Houston, Dorahy & Adamson, 2008).

1.2.7 Burden of PTSD.

Many individuals with chronic PTSD can experience significant personal, occupational, social, financial, and health problems, reducing years and quality of life (Kessler, 2000). Consequently, the disorder impacts significantly on the wellbeing and functioning of the individual, but also on families, health services, and society as a whole (Solomon & Davidson, 1997). Reduced functional independence among those with severe stress and PTSD resulted in £103 million social and welfare costs in 2003 to 2004 (NICE, 2005).

1.3 Summary: Overview of PTSD

In summary, the prevalence of trauma exposure amongst the global population is prolific; however, only a small percentage develops PTSD. Without treatment, the disorder can develop into a chronic condition lasting many years. Individuals with PTSD are likely to

present with other psychiatric disorders and the burden of the condition not only greatly impacts upon the individual but society as a whole. Several risk factors have been identified as contributing to the development of PTSD.

1.4 Overview of Treatment for PTSD

1.4.1 NICE guidelines.

Within the UK health settings the predominant model of care for PTSD is individual therapy delivered within an outpatient setting typically within primary and secondary care services. Current guidance for treatment of PTSD is a course (8-12 sessions on average) of trauma-focused psychological treatment, specifically trauma-focused cognitive behavioural therapy (TF-CBT) or eye movement desensitisation and reprocessing (EMDR) (NICE, 2005). With regards to early intervention in the treatment of PTSD, single-session interventions, often termed *debriefing*, that focus on the event are not recommended as an initial service response to individuals who have experienced a trauma. A period of "watchful waiting" is advised when individuals present with mild PTSD symptoms for less than four weeks after the trauma (NICE, 2005). If symptoms are severe, NICE (2005) recommends brief TF-CBT (5 sessions) within the first month after the traumatic event. For children and young people, TF-CBT should be offered and adapted based on their age and stage of development (NICE, 2005). Following a major disaster, NICE (2005) recommends the routine use of a brief screening tool for the assessment of PTSD symptoms at one month after the event. Currently, there is insufficient evidence to guide clinical practice for the prevention of PTSD (Skeffington, Rees, & Kane, 2013).

The evidence base for drug treatments is limited and NICE guidelines (2005) recommend that they should not be used as first-line treatment for adults and should be considered when the person does not engage with trauma-focused psychological treatment.

1.4.2 TF-CBT.

TF-CBT is based on various theoretical models, including prolonged exposure (Foa & Rothbaum, 1998), cognitive therapy (Ehlers & Clark, 2000), and cognitive processing therapy (Resick, Monson, & Chard, 2007). There is a substantial evidence base supporting the effectiveness of TF-CBT in reducing symptoms of PTSD (Foa, Keane, Friedman, & Cohen, 2008). Typically, the treatment "comprises psychoeducation, anxiety management, cognitive restructuring, imaginal and *in vivo* exposure, and relapse prevention" (Bryant, 2014). Exposure based techniques are aimed at supporting the individual in confronting feared stimuli associated with the trauma, including external stimuli e.g. objects and situations, and internal stimuli e.g. memories and images (Foa, Rothbaum, & Molnar, 1995). The processing of trauma related material through prolonged exposure and cognitive therapies leads to the extinction of fear associated with the trauma and a reconceptualization of the trauma and current beliefs about the self and others (Gillihan, Cahill, & Foa, 2014).

1.4.3 EMDR.

EMDR is a therapy developed by Shapiro (Shapiro & Solomon, 1995), and there is some evidence to suggest that it is equally as effective as TF-CBT for the treatment of PTSD (Seidler & Wagner, 2006). The therapy involves the client focusing on a distressing image or memory and engaging with the associated emotional and cognitive elements. Once this connection occurs, the therapist introduces bilateral stimulation. Most frequently this involves moving the fingers back and forth in front of the client's eyes and the client is instructed to follow this movement with their eyes. Bilateral stimulation can also be auditory or tactile (Seidler & Wagner, 2006). There is ongoing controversy about the involvement of the eye movement component to the treatment with research suggesting that it provides no incremental effect (Davidson & Parker, 2001).

1.4.4 Guided Self-Help (GSH).

NICE (2011) defines GSH (also referred to as facilitated self-help) as the following: A self-administered intervention, which makes use of a range of books or other self-help manuals, and electronic materials based on the principles of CBT and of an appropriate reading age. A trained practitioner typically facilitates the use of this material by introducing it, and reviewing progress and outcomes. The intervention consists of up to six to eight sessions (face-to-face and via telephone) normally taking place over 9 to 12 weeks, including follow-up.

Whilst TF-CBT is an effective treatment for PTSD (NICE, 2005), only a small percentage of individuals with PTSD receive adequate treatment (Kazdin & Blase, 2011). GSH is a low intensity model of treatment, which has aimed to diminish the gap between demand for CBT and current provision, as it requires, reduced input from therapists, allowing a greater number of individuals to be treated (Khan, Bower, & Rogers, 2007). It is based on the assumptions of efficacy, cost-effectiveness, and acceptability (Bower & Gilbody, 2005). There is considerable evidence for GSH for the treatment of depression and some anxiety disorders (Cuijpers, Donker, van Straten, & Andersson, 2010). Research suggests that GSH is more effective that the provision of information alone in treating depression (Gellatly et al., 2007).

NICE (2011) recommends a stepped-care model to address common mental health disorders within primary care service provisions. Based on NICE guidance, The Improving Access to Psychological Therapies (IAPT) programme delivers evidence based psychological treatment for adults (and 16 and 17-year olds in some services) with depression and anxiety disorders within the NHS (England). As evidence indicates that some individuals respond successfully to low-level interventions, the programme provides a low- and high-intensity service (Clark, 2011). The programme aimed to provide individual choice and flexibility by

delivering low-intensity interventions; designed to increase access to evidence based psychological treatments (Baguley et al., 2010). Within the low-intensity service at Step 2, treatment typically involves self-help and GSH for the management of mild to moderate PD, GAD, obsessive-compulsive disorder (OCD), and depression. In light of the paucity of research, NICE does not recommend a stepped care approach for PTSD. A high-intensity service at Step 3 is offered for individuals with PTSD where intervention comprises weekly, face-to-face, individual sessions with a suitably trained therapist (Clark, 2011).

1.4.5 Development of GSH for PTSD.

Several feasibility studies have developed modular based online GSH treatments for PTSD (Litz, Williams, Wang, Bryant, & Engel, 2004; Klein et al., 2009; Lewis, Roberts, Vick, & Bisson, 2013). Within these studies, the number of modules ranged from 8-11 delivered within the duration of 8-10 weeks. The core modules are comparable to the key ingredients delivered within TF-CBT: Psychoeducation on PTSD, anxiety management strategies, imaginal and in-vivo exposure, cognitive techniques, and relapse prevention. The format of therapist contact included face-to-face, email, and telephone. The length of total therapist contact time varied from approximately 35 minutes (Litz et al., 2004) to at least 180 minutes (Lewis et al., 2014) with varying frequency.

From the Lewis et al. (2014) first pilot study, participants considered that the exposure-based components of the programme had been most helpful in reducing their symptoms of PTSD, supporting the use of a programme focused on these components. Large treatment effect sizes were found for pre to post intervention and the drop out rate from two pilots was 20% and 22%. However, the authors highlighted that “little is known about the *active ingredients* of a successful GSH programme”.

Lange and colleagues developed a 5-week online therapist-assisted treatment programme comprising of three phases (Lange et al., 2000). The participants are required to

compose detailed written accounts of their traumatic experience during the first phase: *Self-confrontation* (imaginal exposure). In the second phase: *Cognitive reappraisal*, the therapists use cognitive restructuring strategies with the participants, and the third phase: *Sharing and farewell ritual,* require the participants to write a letter to themselves or significant others who had been involved in the event. The intervention comprises a total of 10 written assignments and psychoeducation about the treatment rationale and principles. The therapists provide feedback on writing assignments as well as task instructions. This intervention incorporates some of the principles of TF-CBT, focusing on imaginal exposure and cognitive restructuring.

1.4.6 Access to treatment.

Research suggests that individuals with PTSD are reluctant to seek treatment (Solomon & Davidson, 1997). Reasons for not seeking mental health treatment include: Not knowing where to find services, costs associated with treatment, and access e.g. transportation (Wong et al., 2007). Evidence indicates that within military and veteran populations, concerns about the public stigma and personal beliefs about mental health treatment may be barriers to accessing treatment (Pietrzak, Johnson, Goldstein, Malley, & Southwick, 2009).

Specifically to PTSD, Lee, Scragg, and Turner (2001) suggest that overwhelming feelings of shame, guilt, and humiliation in relation to the trauma and self-identity may contribute to the treatment dropout or reluctance to present to services. Data show that self-referrals to IAPT services present higher rates of PTSD and social phobia compared to GP referrals (Clark, 2011), however, individuals with PTSD continue to be under-represented in primary care indicating inequitable access to services (McManus, Meltzer, Brugha, Bebbington, & Jenkins, 2009). A review of 55 studies of evidence-based treatments for PTSD found that dropout rates varied widely, however rates as high as 50% were not

uncommon (Schottenbauer, Glass, Arnkoff, Tendick, & Gray, 2008).

1.4.7 Advances in technology.

As previously described, GSH can incorporate a range of electronic materials based on CBT principles. In the 21st century, the Internet has provided a vehicle for the dissemination of evidence-based care. Currently, there are several empirically tested Internet-based treatments for PTSD which all use CBT techniques, commonly termed *Computerised-Cognitive Behaviour Therapy* (CCBT) or *Internet Based Intervention* (IBI) (Lange et al., 2000; Littleton, Buck, Rosman, & Grills-Taquechel, 2012; Spence et al., 2011; Litz, Engel, Byrant, & Papa, 2007; Klein et al., 2009). The advantages of Internet-based treatments for PTSD include firstly increasing accessibility to treatment, such that many of the logistical challenges are removed (e.g. scheduling appointments and travel) and decreasing associated costs (Wells, Mitchell, Finkelhor, & Becker-Blease, 2007). Secondly, delivery of treatment via the Internet may facilitate greater anonymity and privacy of the individual seeking treatment, thus potentially reducing stigma (Lee et al., 2001). This may also promote disclosure compared to traditional face-to-face therapy contexts (Leibert, Archer, Munson, & York, 2006). Thirdly, Internet-based interventions require less input from trained practitioners, allowing a greater number of people to receive treatment in less time and reducing health care costs (Boasso, Kadesch, & Litz, 2014).

Furthermore, the ubiquitous use of mobile devices (85% of U.S adults own a mobile phone and 53% own a smart phone, [Morland, Hoffman, Greene, & Rosen, 2014]) affords a potentially acceptable and convenient mode of treatment (Granholm, Ben-Zeev, Link, Bradshaw, & Holden, 2011; Rizvi, Dimeff, Skutch, Carroll, & Linehan, 2011). Mobile delivery of treatment interventions allows individuals to engage with treatment via voice, SMS, e-mail, websites, and device applications. Research in this field is emerging rapidly, but is still at an early stage (Morland et al., 2014).

1.5 Summary: Overview of Treatment for PTSD

In sum, the current evidence-based model of treatment for PTSD is individual face-to-face therapy, typically TF-CBT or EMDR. GSH was developed to increase access to psychological therapy for anxiety and depression. However, it is not currently recommended for the treatment of PTSD. Several barriers to mental health treatments in general and specifically to PTSD have been identified. Technological advances including the Internet and mobile devices are nascent in the dissemination of evidence-based treatments for PTSD.

1.6 Review of Literature

1.6.1 Research recommendations.

NICE guidelines (2005) identified the following research recommendation 11 years ago:

A randomised-controlled trial, using newly developed guided self-help materials based on trauma-focused psychological interventions should be conducted to assess efficacy and cost effectiveness of guided self-help compared with trauma-focused psychological interventions for mild and moderate PTSD.

It is essential that clinicians address clinical questions based on the highest level of evidence (Burns, Rohrich, & Chung, 2011). With reference to the National Health and Medical Research Council's (NHMCR) *Evidence Hierarchy*, clinical questions based on interventions require *Level 1* of evidence: A systematic review of randomised controlled trials (RCTs) (Merlin, Weston, & Tooher, 2009). The definitive aim of a systematic review is the "dissemination and incorporation of valid clinical research findings into medical practice" (Burns et al., 2011).

1.6.2 Previous reviews for common mental health disorders.

Numerous reviews and meta-analyses have been conducted for low intensity psychological interventions for common mental health disorders, such as anxiety disorders

and depression. Typically, they have found medium to large effect sizes in favour of the effectiveness of CCBT when compared to control conditions (Grist & Cavanagh, 2013; Andersson & Cuijpers, 2009; Amstadter, Broman-Fulks, Zinzow, Ruggiero, & Cercone, 2009). A recent review that included only one PTSD trial found that therapist-supported CCBT may not be superior to face-to-face CBT in reducing anxiety (Olthuis, Watt, Bailey, Hayden, & Stewart, 2015), however, Cuijpers et al. (2010), suggested equivalence between GSH and face-to-face comparators. Subsequently, evidence suggests that low intensity psychological interventions are effective for the treatment for common mental health disorders. However, PTSD (previously categorised as an anxiety disorder) was not adequately represented within this body of research, and therefore the findings are limited for this population (Grist & Cavanagh, 2013). In a more recent review investigating self-help CBT interventions for anxiety disorders, PTSD was excluded, due to its re-categorization as a trauma and stressor-related disorder (Mayo-Wilson & Montgomery, 2013).

1.6.3 Previous reviews for PTSD.

Efforts have been made to address this paucity of research. A previous meta-analysis investigated the efficacy of *telehealth* treatments for posttraumatic stress-related symptoms (Sloan, Gallagher, Feinstein, Lee, & Pruneau, 2011). Telehealth is "the use of telecommunication technologies (e.g. telephone, video conferencing, Internet) to deliver health care services" (Sloan et al., 2011). A total of 13 included studies employed traditional CBT treatment delivered by video conferencing (14-25 sessions) and low-intensity interventions (2-10 sessions) via the Internet or telephone. Overall results suggest that telehealth interventions were successful in reducing PTSD symptoms compared to waiting list controls, but there was no significant difference when compared to a supportive counselling comparison condition, and an inferior effect was found relative to face-to-face

comparators. The review's conclusions were limited to variability in treatment protocols and only six out of the 13 studies employed a clinical sample.

1.6.4 Current and ongoing research.

At the time of conducting this review two review protocols were identified as relating to this area of research. Lewis, Roberts, Bethell, and Bisson (2015) aim to assess the efficacy of Internet-based cognitive and behavioural therapies (with or without therapist guidance) for PTSD in adults. Similarly, Fricke, Onyimadu, and Humphreys (2014), aim to address Internet-based CBT for adults with PTSD. The latter, intend to exclude studies where participants present with co-morbid mental disorders, including anxiety, depression, and substance abuse. Additionally, a review was published which included 20 RCTs testing IBIs for PTSD. Only four of the studies were identified as using a clinical sample (Kuester, Niemeyer, & Knaevelsrud, 2016). Current research is not limited to IBIs based on TF-CBT principles. In light of the latest proliferation of research, it is evident that advances in technology have generated considerable interest in expanding dissemination and access to psychological therapies for common mental health problems.

1.7 Summary: Review of Literature

Research recommendations from NICE included GSH for trauma-focused interventions for PTSD. The effectiveness of TF-CBT for PTSD is a clinical question requiring the highest level of evidence. Previous literature has indicated that GSH is an effective intervention for depression and some anxiety disorders, however PTSD is underrepresented within this area of research. Current research focuses on IBI for PTSD and includes a variety of high- and low-intensity intervention studies, with or without therapist guidance.

1.8 Objective of the Review

The aim of this review was to determine the effectiveness of TF-GSH for individuals with PTSD. Returning to the research recommendation outlined in NICE guidelines (2005), it is apparent that previous research and reviews have not yet sufficiently addressed whether GSH materials based on trauma-focused psychological interventions are effective for treating PTSD. Previous reviews and protocols within this area are limited for the following reasons: The inclusion of studies using non-clinical samples and a variation of high- and low-intensity interventions, the exclusion of studies using a co-morbid sample, a restriction to IBIs only, and the inclusion of non-trauma-focused interventions.

For reasons of clinical relevance, the review aimed to focus on a clinical PTSD population with or without co-morbid anxiety disorders and depression. Based upon current evidence for the psychological treatment of PTSD and NICE guidance (2005), the review restricted GSH to trauma-focused interventions only.

1.9 Review Questions

Primary

1. How effective is TF-GSH in reducing symptoms of PTSD?

Secondary

2. How effective is TF-GSH in reducing symptoms of co-morbid depression?

3. How acceptable is TF-GSH as an intervention for PTSD, i.e. drop out rates?

2 Methodology

2.1 Chapter Outline

Prior to conducting the review, a protocol outlined the essential stages of the methodology. Stages were guided by the Cochrane Collaboration Handbook (Higgins & Green, 2011) and include the following: Eligibility criteria, search strategies, and data collection and analysis. Any departures from the methodology specified within the protocol are documented and justified within this chapter.

2.2 PROSPERO

The review protocol was prospectively registered with PROSPERO, which is an international prospective register of systematic reviews on 8th September 2015 (See Appendix A for web links and the registered protocol).

2.3 Eligibility Criteria for Considering Studies for this Review

2.3.1 Types of studies.

2.3.1.1 Study design.

As research in this area appears to be in early development, limits on eligibility criteria on study design were less restrictive. The review aimed to include Randomised Controlled Trial (RCT) (cluster, crossover, and parallel) or Controlled Clinical Trial (CCT) study designs. Following guidance from the Cochrane Handbook (Lefebvre, Manheimer, & Glanville, 2011) if the study author(s) include an explicit statement that a random allocation procedure was used then the trial was classified as a RCT. If an explicit statement regarding randomisation was absent, but its use as a procedure could not be ruled out, or the trial used a quasi-method of allocation, it was classified as a CCT.

2.3.1.2 Publication status and sample size.

No restrictions were applied for publication status or sample size.

2.3.2 Types of Participants.

There was no restriction on age. Studies where interventions were aimed at professionals, carers, or the family of the individual with PTSD were excluded. It was anticipated that a broader scope for the type of participants might have provided a comprehensive summary of the available evidence and increased generalizability of the findings.

2.3.2.1 Diagnosis.

Studies were included where a qualified clinician diagnosed participants with PTSD, or the study administered a standardised diagnostic assessment or a PTSD outcome measure to determine the presence of PTSD symptoms (mild to severe). *A posteriori,* a decision was made to derestrict the eligibility criteria to include studies where at least 70% of the sample reached clinical levels of PTSD symptoms as defined by a standardised PTSD outcome measure. This was considered necessary to incorporate all available and relevant evidence within the review. No restrictions were placed on the type of trauma, the amount of time since the traumatic event, or the chronicity of PTSD.

2.3.2.2 Co-morbidities.

Studies were included where individuals had co-morbid Axis 1 disorders (4th ed.,; DSM-IV; APA, 1994). Studies were excluded where participants had additional diagnoses of a mental disorder such as, personality disorder, neurodevelopmental disorder, and learning disability. Participants with severe depression or substance dependency, where their presentation may preclude their suitability for psychological intervention were not considered within this review.

2.3.2.3 Setting.

No limits were placed on setting (e.g. community, hospital, military).

2.3.3 Types of interventions.

2.3.3.1 Experimental interventions.

Studies were included if they defined and employed GSH materials based on TF-CBT, delivered by a trained practitioner. All other interventions were excluded. Interventions delivered on an individual basis only were considered. All group interventions were excluded.

Any studies that combined the relevant intervention with another intervention e.g. multidisciplinary PTSD care team were excluded. Studies that aimed to *prevent* the onset of PTSD, and not treat PTSD, were excluded. The current evidence for GSH for PTSD appears minimal and therefore no limits were set on the variations of GSH (e.g. duration and frequency of GSH intervention, the timing of delivery, the intensity of therapist input, mode of delivery). Modes of intervention delivery included any electronic materials or paper formatted books or manuals. Modes of therapist contact included: Telephone calls, texts, emails, letters, videoconference, and face-to-face. However, these variations of GSH may have been a source of heterogeneity and may affect the interpretation of results. This was considered within the narrative of the discussion section.

2.3.3.2 Comparator interventions.

The use of randomised comparator groups included inactive control (e.g. placebo, no treatment, waiting list, treatment as usual) and active control interventions (e.g. supportive counseling, standalone psychoeducation, pharmacotherapy, a different model of psychological therapy).

2.3.4 Types of Outcomes.

2.3.4.1 Primary Outcomes.

Studies, which used a clinical diagnostic interview or at least one validated outcome measure of PTSD symptomology pre and postintervention, e.g. the Impact of Events Scale-

Revised (IES-R; Weiss & Marmar, 1997), or Posttraumatic Diagnostic Scale (PDS; Foa, 1995), were considered.

2.3.4.2 Secondary Outcomes.

No limits were set on secondary outcomes. *A priori*, it was decided that if any studies employed outcome measures assessing co-morbid depression, these data would be included in a separate meta-analysis. Outcomes assessing the quality of life, therapeutic alliance, and patient satisfaction, were of interest and incorporated into the results and discussion sections. Information regarding drop out rates was extracted to explore the acceptability of the intervention.

A posteriori, data from outcome measures assessing anxiety were synthesized. In DSM-5 (APA, 2013) PTSD is no longer categorised as an anxiety disorder.

2.4 Search Methods for Identification of Studies

To facilitate the aim of achieving reliable estimates of TF-GSH treatment effects, it was necessary to employ a comprehensive and replicable search within a variety of resources, to identify all potentially relevant studies. There is evidence to suggest that an association exists between the quality of trials and the significance of their results and the journal of publication (Pittler, Abbot, Harkness, & Ernst, 2000), known as location bias (Lefebvre et al., 2011). Thus, it was essential to identify *grey literature*, defined as literature that is not formally published in sources such as journal articles, for consideration within this review (Lefebvre et al., 2011). Web links for all sources used within the search process are provided in Appendix B.

2.4.1 Bibliographic database searches.

Database searches were limited from 1980 (the year PTSD was first introduced to the DSM (3rd ed.,; DSM-III; APA, 1980) to week three or four of September 2015.

2.4.1.1 EMBASE (Excerpta Medica dataBASE) and MEDLINE.

Studies were identified by systematic searches of key international general healthcare bibliographic databases EMBASE and MEDLINE. EMBASE is a biomedical and pharmaceutical database produced by Elsevier. MEDLINE is a general medical database produced by the U.S National Library of Medicine.

2.4.1.2 Subject-specific databases.

Searches were carried out using subject-specific databases, PILOTS (Published International Literature on Traumatic Stress) and PsycINFO. The latter is a database that provides journals within international literature in psychology and related disciplines. PILOTS is produced by the National Center for PTSD and is sponsored by the U.S Department of Veterans Affairs. This database aims to include all relevant literature published worldwide relevant to PTSD and mental health presentations associated with traumatic events.

2.4.1.3 Citation indexes.

As an adjunct, citation searching was carried out using Web of Science, allowing for extensive coverage of available literature. This is an "important" search method for identifying relevant studies in "obscure locations" (Greenhalgh & Peacock, 2005).

2.4.1.4 Dissertations and theses databases.

Dissertations and theses were searched via ProQuest Dissertation & Theses A&I. This database provides a comprehensive compilation of dissertations and theses conducted from around the world.

2.4.1.5 Grey literature database.

OpenGrey is a grey literature database for conference abstract sources and was searched in order to minimise publication bias (Rosenthal, 1979). OpenGrey is a multidisciplinary European database covering records of various document types including

technical or research reports, conference papers, official publications, and doctoral dissertations.

2.4.1.6 Specifics of bibliographic database searches.

The dates and sources of conducted searches are presented in Table 1.

2.4.1 Search strategy for bibliographic databases.

The search strategy for the databases detailed formerly (with the exception of PILOTS and OpenGrey), was composed of two concepts, PTSD and GSH, with a comprehensive range of free-text search terms within each concept (See Table 2). This strategy aimed to seek high sensitivity, thus generating a high false-positive rate. Each database was searched separately as the search strategy was adjusted for each specific database and provider. Free-text terms were searched in the field of *Title and Abstract* with a combination of subject terms selected as *Major Descriptors* from the thesaurus of each database. Searches were developed with reference to the Cochrane Highly Sensitive Search Strategies (filters) to identify randomised trials within the applicable databases (Lefebvre et al., 2011).

Within PILOTS, a range of subject terms only was used for the concept of GSH. These included “Self Help Techniques”, “Computer Assisted Psychotherapy”, “Bibliotherapy”, and “Telemedicine” in order to increase precision of the search. Within OpenGrey, free-text terms for types of participants were used within the abstract field; a function applied to records from 1997 onwards. All database search strategies are presented in Appendix C for the purpose of replication.

2.4.1.1 Search restrictions.

No limits except publication year were applied. No language restrictions were imposed. Evidence regarding whether language bias significantly affects the results of meta-

Table 1

Database Sources and Dates of Searches

Database	Source	Date of search
EMBASE	NICE	15/09/2015
MEDLINE	NICE	14/09/2015
PsycINFO	NICE	15/09/2015
PILOTS	ProQuest	15/09/2015
Web of Science	Web of Knowledge	29/09/2015
ProQuest Dissertation & Theses A&I	ProQuest	27/11/2015
OpenGrey	OpenGrey	27/11/2015

Table 2

Search Concepts and Free-text Terms

Concept	Search Terms
Types of particpants[1]	Posttraumatic stress disorder OR post-traumatic stress disorder OR PTSD OR post traumatic stress disorder OR posttraumatic OR post-traumatic OR post traumatic OR traumatic event
Type of Interventions[2]	web* OR comput* OR internet OR online OR bibliotherapy OR videotape OR audiotape OR etherapy OR cybertherapy OR e-health OR videoconferenc* OR videoteleconferenc* OR interapy OR tele* OR electronic OR skype OR instant messaging OR mobile OR tape OR DVD* OR CD* OR self-help OR self-care OR self-directed OR self-change OR self-management OR self-administ* OR guided self-help OR guided self-change OR guided OR self-exposure OR minimal contact OR minimal therapist contact OR reduced contact OR reduced therapist contact OR limited contact OR limited therapist contact OR therapist assisted
Combined	1 AND 2

analyses is conflicting, with research indicating that non-English-language trials were more likely to produce significant results and more favorable intervention effects (Jüni, Holenstein, Sterne, Bartlett, & Egger, 2002). Moher, Pham, Lawson, and Klassen's (2003) research was not consistent with the former finding; however, they found that by removing non-English-language reports, the effect size of meta-analyses was significantly reduced. The Cochrane Collaboration suggests that whilst the potential impact of excluding non-English language reports within a review may be minimal, the effect of bias may be difficult to predict (Lefebvre et al., 2011). University colleagues and an associate translated studies published in German and Chinese.

2.4.2 Searching other resources.

2.4.2.1 Journals electronically available.

Relevant journals were searched, which were prioritised by identifying which journals appeared to be associated with the most retrieved citations within the bibliographic database searches. These included the following: Journals of British Medical Journal Best Practice, Behaviour Research and Therapy, Cognitive Behaviour Therapy, Depression and Anxiety, Journal of Consulting and Clinical Psychology, Journal of Medical Internet Research, Journal of Telemedicine and Telecare, Journal of Traumatic Stress, Cognitive-behavioural Psychotherapy and Research.

2.4.2.2 Other reviews, guidelines, and trials registers as sources of studies.

At least 70 existing reviews relevant to the topic were obtained via bibliographic database searching. The primary researcher checked the references of their included (and excluded) studies. Additionally, reviews were searched via The Cochrane Library, which includes The Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment Database (HTA Database).

The Centre for Reviews and Dissemination (CRD) produces both the latter two databases, providing information on published reviews of the effects of health care.

Guidelines relating to healthcare in the UK and patient-factsheets were searched using the NICE Evidence Search engine.

Information about potentially relevant ongoing studies was obtained and included, allowing for these to be considered if this review were to be later updated. Ongoing studies were identified by searching across a range of trials registers via the International Clinical Trials Registry Platform Search Portal, launched by The World Health Organization (WHO).

2.4.2.3 Web searching.

Additionally, the general search engine, Google Scholar was searched to identify relevant studies and review articles.

2.4.2.4 Correspondence.

To identify any additional studies (unpublished or published) that may be relevant, information requests were sent via email to the principal authors of included studies and key authors, defined as being those authors who had at least two of their associated studies included in the full text screening process. (See Appendix D for a list of contacted authors).

2.5 Data Collection

2.5.1 Selection of studies.

The process of selecting studies is described below. The collaborator is a Research Associate with a Bachelor and Master of Science degree in Forensic Psychology, and is currently a Doctor of Philosophy candidate at the University of East Anglia.

1. Search results were merged using EndNote software (version X7), and duplicate records of reports were removed.
2. The primary researcher examined the titles and abstracts of studies and those studies that were evidently irrelevant were removed. The primary researcher was

overinclusive at this stage of the process, to reduce the possibility that potentially relevant studies were rejected. Studies were included if there was not enough information in the abstract to determine the types of participants, study design, or intervention.

3. Full texts of potentially relevant reports were retrieved.
4. Multiple reports of the same study were linked together.
5. The primary researcher and collaborator (assessors) independently examined and applied the eligibility criteria to 20% of the full-text reports. This allowed a period of training to apply the criteria and to ensure that they could be applied reliably.
6. The assessors corresponded to clarify study eligibility and to resolve any disagreements that arose through discussion. The eligibility criteria were not amended.
7. The assessors independently examined and applied the eligibility criteria to the remainder of the full-text reports.
8. The assessors corresponded to deliberate and resolve any disagreements that arose during the process above. In instances where a resolution was not achieved, the primary and secondary supervisors were contacted for mediation.
9. Study authors were contacted for further information, such as a request for further information regarding the intervention.
10. Final decisions were made on study inclusion before proceeding to data collection.

The assessors involved in the selection of studies process were able to view the names of authors and their affiliated institutions, the journal of publication, and results of the studies when the eligibility criteria were applied. At the point of screening the assessors did not have any associations or prior connections with the above. The collaborator was not knowledgeable about the content of the area under review. This was considered

advantageous, as there is evidence to suggest that familiarity with the topic literature may introduce bias in judging the relevancy of studies (Cooper & Ribble, 1989).

2.5.2 Data extraction and management.

The assessors conducted extraction independently to minimise errors and reduce potential bias. There is evidence to show that independent data extraction results in fewer errors compared to data extraction by one reviewer followed by verification by a second (Buscemi, Hartling, Vandermeer, Tjosvold, & Klassen, 2006).

Data were extracted using a data extraction form with coding instructions (See Appendix E) to obtain data that would be then be inputted into Review Manager (RevMan Version 5.3, 2014) software. The assessors piloted the form using one of the studies reviewed to ensure that coding instructions were clear and comprehensive, and the coding schemes were being applied consistently. Subsequently, the data form was amended for purposes of enhanced clarity.

Extraction of data from the results of studies included: Sample sizes, baseline differences between groups, reported outcome statistics of PTSD, depression, and anxiety scales (means and standard deviations) for intervention and comparator groups at pre and posttreatment, and follow-up assessment (multiple time points), the number of dropouts from intervention and comparator groups, completer characteristics in comparison to dropout characteristics, and reasons for dropouts. Outcome data were collected in the format in which they were presented in the study.

Moreover, following the checklist compiled by the Cochrane Collaboration (Higgins & Deeks, 2011), the subsequent information on methods was gathered: Study design, total study duration, random sequence generation, allocation concealment, blinding of participants and study assessors, blinding of outcome assessment, incomplete outcome data, and selective reporting.

Additionally, information regarding participants included: The total number within the study, setting (e.g. clinical patients, military), diagnostic criteria used, age and sex of the participants (whole study), and intervention and control groups separately, the country where the study took place, trauma type, co-morbidities, socio-demographics (e.g. education level), and ethnicity.

With regards to interventions, the following data were collected: Intervention description, whether the intervention was based on a manual, format (e.g. web, booklet), the length of intervention, mean hours of intervention offered and received, therapist qualifications and training, therapist supervision and adherence to prescribed treatment, therapist contact format (e.g. email, telephone), the number of therapist contacts and hours offered and received, number and format of control groups (e.g. treatment as usual, waiting list).

Outcome data included: PTSD, depression, and anxiety outcome measures (e.g. self-report, clinician report), cut-off or thresholds used, the unit of measurement, upper and lower limits of the measure, direction of benefit, and additional outcomes of interest (e.g. quality of life, participant satisfaction).

The funding source of the study and references to other relevant studies were recorded. The occurrence and resolution of disagreements were recorded, as well as further information obtained via contact with study authors.

2.6 Data Analysis

2.6.1 Assessment of risk of bias in included studies.

The Cochrane Collaboration's tool (Higgins & Green, 2011) for assessing the risk of bias was applied to all included studies with judgments categorised as *low risk of bias*, *high risk of bias* or *unclear risk of bias* for included studies within the review (See Appendix F). This tool is a domain-based evaluation where individual assessments are made for the

following: (a) *random sequence generation*, (b) *allocation concealment*, (c) *blinding of participants and personnel*, (d) *blinding of outcome assessment*, (e) *incomplete outcome data*, (f) *selective reporting*, and (g) *other sources of bias*. Tools based on a scale for assessing quality or risk of bias, producing a summary score, are not supported by empirical evidence (Emerson, Burdick, Hoaglin, Mosteller, & Chalmers, 1990; Schulz, Chalmers, Hayes, & Altman, 1995) and therefore are explicitly discouraged by the Cochrane Collaboration. The primary researcher and collaborator conducted the assessment. All potential sources of bias were considered within the context of their plausible impact and direction of bias. Study authors were contacted to collect missing information. They were asked open-ended questions about their study design and conduct to reduce the evidenced risk of overly positive answers (Haahr & Hróbjartsson, 2006).

2.6.1.1 Selection bias.

Selection bias describes systematic differences between group characteristics at baseline. Random sequence generation and allocation concealment are the two domains, which assess for this source of bias.

2.6.1.1.1 Random sequence generation.

Selection bias may occur due to the unsuccessful randomisation of allocation of participants to interventions and comparator groups. If study authors describe a sequence generation process, which incorporates a random element, such as using a computer random number generator, it was judged as low risk of bias. A judgment of high risk of bias was given to studies where a nonrandom approach was used in the sequence generation process. A judgment of unclear risk was used when the assessors had insufficient information about the sequence generation process to allow a judgment of low or high risk.

2.6.1.1.2 Allocation concealment.

Insufficient concealment of allocations prior to the assignment of participants to groups can produce bias. Criteria for a judgment of low risk of bias for allocation concealment involves a process whereby the investigators of a study enrolling participants into groups were not able to predict or foresee allocations. Methods may include the use of sequentially numbered, opaque, sealed envelopes. Where there was a possibility that investigators could foresee allocations, such as using a list of random numbers, a high risk judgment was given. Where study authors failed to describe the method of allocation concealment or to provide sufficient information to define a low or high risk judgment, the study was described as having an unclear risk of bias with concern to this domain.

2.6.1.2 Performance bias.

Performance bias describes a source of bias introduced when systematic differences occur between groups due to the knowledge of assigned interventions by participants and investigators during the study.

2.6.1.2.1 Blinding of participants and personnel.

Blinding of study participants or investigators is a method used to reduce the risk of performance bias. However, blinding is not possible for either participants or investigators when administering psychological therapy. No blinding or incomplete blinding can be judged as either low or high risk, depending on the judgment that the outcome is not likely or likely to be influenced by the absence of blinding.

2.6.1.3 Detection bias.

Detection bias refers to systematic differences between groups due to the knowledge of allocated interventions to outcome assessors.

2.6.1.3.1 Blinding of outcome assessment.

Criteria for a judgment of low risk of bias include successful blinding of the outcome assessment or where blinding was not used but the outcome measurement is not likely to be

influenced by the absence of blinding. A high risk judgment was given in cases where no blinding was used or was unsuccessful, and the outcome measurement is likely to be influenced by the lack of blinding. Where the study did not address this outcome or there was insufficient information to determine a judgment of low or high risk, the risk was deemed as unclear.

2.6.1.4 Attrition bias.

Attrition bias is attributed to systematic differences between groups introduced by the quantity, nature, or handling of incomplete data. Attrition refers to incomplete and unavailable data due to withdrawals from the study.

2.6.1.4.1 Incomplete outcome data.

Criteria for a judgment of low risk bias with concern to this domain includes the following: No missing outcome data, missing outcome data is balanced across groups with similar rationales for missing data, or missing data have been imputed using appropriate methods. High risk of bias is associated with an imbalance in numbers or reasons for withdrawals between groups, suggesting that the missing outcome data is likely to be related to the true outcome, *as-treated* analysis with a considerable difference of the intervention received from that assigned at allocation, and possible inappropriate application of simple imputation. Consideration was given to whether the likely treatment effect size among the missing outcomes was expected to induce clinically relevant bias on the observed effect size in order to judge the level of risk of bias. Where studies did not address this outcome or attrition was insufficiently reported, an unclear risk of bias judgment was given.

2.6.1.5 Reporting bias.

Reporting bias is associated with selective outcome reporting. Published studies are more likely to report statistically significant results than nonsignificant differences (Chan & Altman, 2005).

2.6.1.5.1 Selective reporting.

Low risk of selective outcome reporting is associated with the availability of a study's protocol and prespecified outcomes are addressed and reported, or where the protocol is not available, it is clear the study includes all prespecified outcomes. Where this was not the case and prespecified outcomes are not reported, or where outcomes were addressed in a manner which was not prespecified, or there is incomplete reporting of outcomes (of interest within the review), or failure to include key outcome results that would have been expected to be reported, the study was judged at high risk of bias within this domain. Insufficient information led to an unclear risk judgment.

2.6.1.6 Other bias.

The assessment of risk will consider bias due to other sources not outlined above. Any potential biases will be described and judged as high risk if the risk appears significant or unclear risk where a risk may exist, but there is insufficient information to assess its importance. Studies where no other sources of bias appear to exist will be judged as low risk.

2.6.2 Analysis of risk of bias assessment.

Forest plots stratified according to the level of risk were used to explore the likely impact of risk of bias on results. This was carried out using RevMan (RevMan Version 5.3, 2014)**.** *A priori*, it was planned that meta-regression would be employed to compare the intervention effects of studies at high risk, unclear risk, and low risk studies. In practice, given that the number of eligible studies was fewer than 10, meta-regression was not considered appropriate (Deeks, Higgins, & Altman, 2011). *A priori,* it was intended that studies would be stratified according to risk of bias producing at least three estimates of the intervention effect: From studies at high risk, at low risk, and from all studies. In practice, due to the results of the risk of bias assessment, two estimates of intervention effects were produced, one from all studies and one excluding those at high risk.

2.6.3 Measures of the treatment effect.

Instruments used to measure PTSD, depression, and anxiety symptomology were based on various self-report measures or structured clinical interviews, providing categorical outcome data. The primary researcher and collaborator verified whether the measurement scale used has been validated to assess the outcome in the study and whether the original or an adapted measure has been used. This review considered ordinal scales to be analysed as continuous data, as an inappropriate choice of cut-point can produce bias (Higgins & Green, 2011). Subsequently, the treatment effect was expressed as the standardised mean difference (SMD), as PTSD, depression, and anxiety symptoms were measured using different psychometric scales. "The SMD expresses the size of the intervention effect in each study relative to the variability observed in that study" (Higgins & Green, 2011).

Cohen's *d* (Cohen, 1988) was calculated as the measure of a between-group treatment effect for each study by subtracting the mean postintervention score of the control group from the mean postintervention score of the experimental group and dividing this result by the pooled standard deviation. Next, Cohen's *d* was transformed into Hedge's *g* (Hedges, 1981) using correction factor *J* to reduce bias from *d*. Cohen's *d* tends to overestimate the absolute value of the effect-size parameter in small samples (Borenstein, Cooper, Hedges, & Valentine, 2009). Cohen's conventional values for effect size were used where an effect size around 0.2 is *small*, 0.5 is *moderate*, and 0.8 or more is considered *large* (Cohen, 1992). All outcomes are presented using 95% confidence intervals.

A priori, it was considered necessary to correct any differences in the direction of the scales if this had occurred. If studies had presented only dichotomous data by employing a specified cut-off point, missing data would have been requested from study authors. If this were not possible, dichotomous and continuous data would have been pooled together where odds ratios are reexpressed as SMDs according to the statistical approach outlined in Chinn

(2000).

If a study included more than one PTSD outcome measure, then a primary measure was identified in order that only one treatment effect was calculated for each study. The measure chosen as primary was based upon superiority of its psychometric properties-reliability and validity. If the equivalence of properties was found, then the measure most frequently employed by other included studies was chosen for purposes of homogeneity. Full-scale scores were used to calculate the treatment effect where studies include both sub-scale and full-scale scores.

2.6.4 Unit of analysis issues.

The protocol outlined that cluster randomised trials would be included within the review. However, to date the searches identified none. If the review were to be updated, the methodology for addressing these types of studies would follow the guidance outlined by the Cochrane handbook (Higgins & Green, 2011). Additionally, planned analyses for a crossover design would only use data from the first randomisation period.

It was planned that for any studies with multiple intervention groups, only the intervention groups of relevance to this review would be combined and included in a pair-wise comparison of intervention groups that would meet the eligibility criteria for including studies in the review.

2.6.5 Dealing with missing data.

In the first instance, where possible, the study authors were contacted to request full data. Assumptions made by study authors of any methods used to manage missing data, such as missing at random or due to poor outcome were addressed within the assessment of risk of bias.

If a study did not provide a full-scale score, sub-scale scores were added to yield a full-scale total score. The standard deviation of the total score was calculated by summing the

variances of the respective sub-scales, as well as the covariances for each pair of sub-scales. Covariances were calculated using the correlation coefficients of subscales identified in the relevant publications (Horowitz, Wilner, & Alvarez, 1979; Rash, Coffey, Baschnagel, Drobes, & Saladin, 2008). The final standard deviation was derived by taking the square-root of these summed variances and covariances.

The proportion of dropouts from intervention and comparator groups was calculated as percentages from the total baseline sample of each group. For the purpose of this review, dropout rate is defined as the percentage of participants who did not adhere to the complete course of the intervention they were assigned to at allocation e.g. only completed four out of seven programme modules.

2.6.6 Assessment of heterogeneity.

Heterogeneity is a term used to describe variability among studies and can refer to clinical diversity (e.g. variability in the participants, interventions, and outcomes) and methodological diversity, which includes variability in study design and risk of bias. Clinical or /and methodological diversity can result in variability in the intervention effects in the studies within a meta-analysis, and this is known as *statistical heterogeneity* (Deeks et al., 2011).

Statistical heterogeneity was assessed using the I^2 statistic, which depicts the percentage of the variability in effect that is due to heterogeneity rather than chance (Higgins & Thompson, 2002). The measurement of heterogeneity was interpreted as follows:

0% to 40%: *Might not be important*

30% to 60%: May represent *moderate* heterogeneity*;

50% to 90%: May represent *substantial* heterogeneity*;

75% to 100%: *Considerable* heterogeneity*.

*The importance of the observed value of I^2 depends on (i) magnitude and direction of effects and (ii) strength of evidence for heterogeneity (e.g. P value from the chi-squared test, or a confidence interval for I^2) (Higgins & Green, 2011).

2.6.7 Assessment of reporting biases.

Publication bias may be a possible cause of *small-study effects* (Richard & Pillemer, 1984, Begg & Berlin, 1988), which is a term used to describe the propensity for intervention effect estimates to be more favourable in smaller studies (Sterne, Gavaghan, & Egger, 2000). This was assessed visually using a funnel plot of the intervention effect estimates against sample size (Richard & Pillmer, 1984). A more marked asymmetry reflects a greater likelihood of substantial bias.

It was decided *a priori* that if there is a variation between standard errors of intervention effect estimates, then the linear regression approach proposed by Egger, Smith, Schneider, and Minder (1997) would be employed to measure funnel plot asymmetry. Results from this test would be interpreted in light of visual inspection of the funnel plot. However, the implementation of this statistical test was not appropriate due to fewer than 10 studies included within the review (Sterne, Egger, & Moher, 2011), and therefore interpretation of funnel plots relied on subjective visual inspection only.

Publication bias may be considered as only one of the possible explanations for the presence of small-study effects (Egger et al., 1997; Sterne et al., 2000). Other important potential sources of funnel plot asymmetry include differences in methodological quality of included studies, true heterogeneity in intervention effects, and play of chance (Egger et al., 1997).

2.6.8 Data synthesis.

Separate meta-analyses were conducted for PTSD, depression, and anxiety data using Review Manager software (RevMan Version 5.3, 2014). The random-effects (DerSimonian

and Laird) model (DerSimonian, 1986) was used based on the assumption that heterogeneity existed amongst the intervention effects across studies. This approach assumes that variation in standard deviations is due to differences in measurement scales and not variability among study populations or the reliability of outcome measures used.

A posteriori analysis included a meta-analysis to combine dropout proportions from the intervention group of each study. A random-effects model for binary data (Conaway, 1990) was used in OpenMetaAnalyst (Wallace et al., 2012) to calculate a summary dropout rate across studies.

2.6.9 Subgroup analyses and investigation of heterogeneity.

A priori decisions about the potential causes of heterogeneity included: Intensity (frequency and duration) of therapist input and intervention, modality of intervention, and sample (military versus civilian). It was planned that meta-regression would be used to explore heterogeneity. However, the Cochrane Collaboration does not recommend sub-group analyses or meta-regression where there are fewer than 10 studies included within a review (Deeks et al., 2011). A substantial number of studies are required to investigate heterogeneity to produce potentially useful findings (Deeks et al., 2011). Subsequently, in practice there were insufficient data to allow subgroup analysis on these potential effect modifiers.

2.6.10 Sensitivity analysis.

Sensitivity analyses were conducted to determine whether conclusions drawn from the review are robust to the various decisions made throughout the review process. Issues, which may warrant sensitivity analysis, were identified during the review process. If analyses demonstrate that the overall conclusions are robust to differential decisions, this allows them to be accepted with a higher degree of certainty.

2.6.11 The GRADE approach

The overall quality of evidence was graded using the system developed by The Grades of Recommendation, Assessment, Development and Evaluation (GRADE) Working Group (2004) (as cited in Schünemann et al., 2011). The GRADE system has been implemented by various organizations include NICE, WHO, BMJ Clinical Evidence, and the Cochrane Collaboration for evaluating the quality of evidence produced by systematic reviews. The Cochrane Collaboration states that this approach "defines the quality of a body of evidence as the extent to which one can be confident that an estimate of effect or association is close to the quantity of specific interest". The GRADE system comprises factors including methodological quality, risk of bias within studies, directness of evidence, heterogeneity, precisions of effect estimates, and risk of publication bias (Schünemann et al., 2011).

2.7 Chapter Summary

This chapter detailed the essential methodological stages undertaken before data synthesis and analysis. The first stage involved developing a set of eligibility criteria for considering studies for this review. This facilitated subsequent search strategies for identifying potentially relevant studies in the second stage. A range of resources was searched in addition to bibliographic databases. The third stage was the selection of eligible studies included within the analysis of the review following a step-wise screening process, and during the fourth stage relevant data from these studies were extracted. These latter two stages incorporated the contribution of a collaborator for purposes of reliability. Finally, methodological considerations of data analyses are presented which include the following: Assessment of risk of bias of the included studies using the Cochrane Collaboration domain-based evaluation tool, Hedge's g as a measure for treatment effects, assessment and investigation of heterogeneity and reporting bias, random effects models for meta-analyses,

the use of sensitivity analyses, and the GRADE approach to assess the overall quality of the evidence.

3 Results

3.1 Chapter Outline

This chapter presents descriptive results of the selection of studies procedure together with a flow diagram. Characteristics of included studies are described and presented within a table. Studies excluded from the review, awaiting classification, or which are ongoing, are listed. The results from the risk of bias assessment are summarised descriptively, figuratively, and graphically. Meta-analytic results are reported for PTSD, depression, and anxiety outcomes and results for additional outcomes, including quality of life, treatment satisfaction. This is followed by an analysis of dropouts and an exploration publication bias. A table presenting a summary of findings is provided towards the end of the chapter.

3.2 Search Results

A total of 3944 citations were identified within the electronic bibliographic databases. The search further identified 3980 potentially relevant records through other sources such as journal searches, reviews, Google Scholar, and correspondence with key authors. A total of 7924 citations formed the screening process of the selection of studies procedure.

Of 7924 records screened for eligibility, 7776 records were excluded. They were identified as duplicates, book chapters, reviews, editorials, or as responses to other publications. Duplicates were identified by Endnote software and by hand due to variation in formatting of some references. Records were further excluded for the following reasons: Not

an intervention study, not a RCT, intervention did not target PTSD symptoms, intervention was evidently not TF-GSH, study population was not individuals with PTSD, publication was a secondary analysis. This number of excluded studies is considerable due to the sensitive search strategy employed.

One hundred and forty-eight studies were assessed for eligibility by screening full texts, which included those published in the German-, and Chinese-language. A further 140 studies were excluded at this stage for the following reasons: 39 were not RCTs, 41 did not use a study population of individuals with PTSD, 50 did not employ a TF-GSH intervention, one did not use an appropriate comparator, two publications were secondary analyses, two used a group intervention. Two studies were preventative studies where treatment was aimed at individuals with acute stress disorder (Byrant & Harvey, 1997). This refers to posttraumatic stress reactions occurring between two days and four weeks subsequently to an experienced trauma. Acute stress disorder has been used to identify individuals who may go on to develop PTSD (Bryant, Sackville, Dang, Moulds, & Guthrie, 1999). Three studies were excluded due to insufficient information, which is required for a judgment of inclusion or exclusion for the review. These studies have been included within the section "Studies awaiting classification".

A total of eight studies met the eligibility criteria and were included within the review. Figure 1 presents a PRISMA (Moher et al., 2009) flow diagram of the study selection process along with reasons for exclusion of studies.

3.3 Description of Studies

Information is summarised within the sections below and the Characteristics of Included Studies Tables (3-5).

3.3.1 Included studies.

A total of eight studies met eligibility criteria and two supplementary papers (Knaevelsrud & Maercker, 2009; Wagner & Maercker, 2007) reported long term follow-up on two of the eight studies. The included studies comprised eight comparisons of TF-GSH to

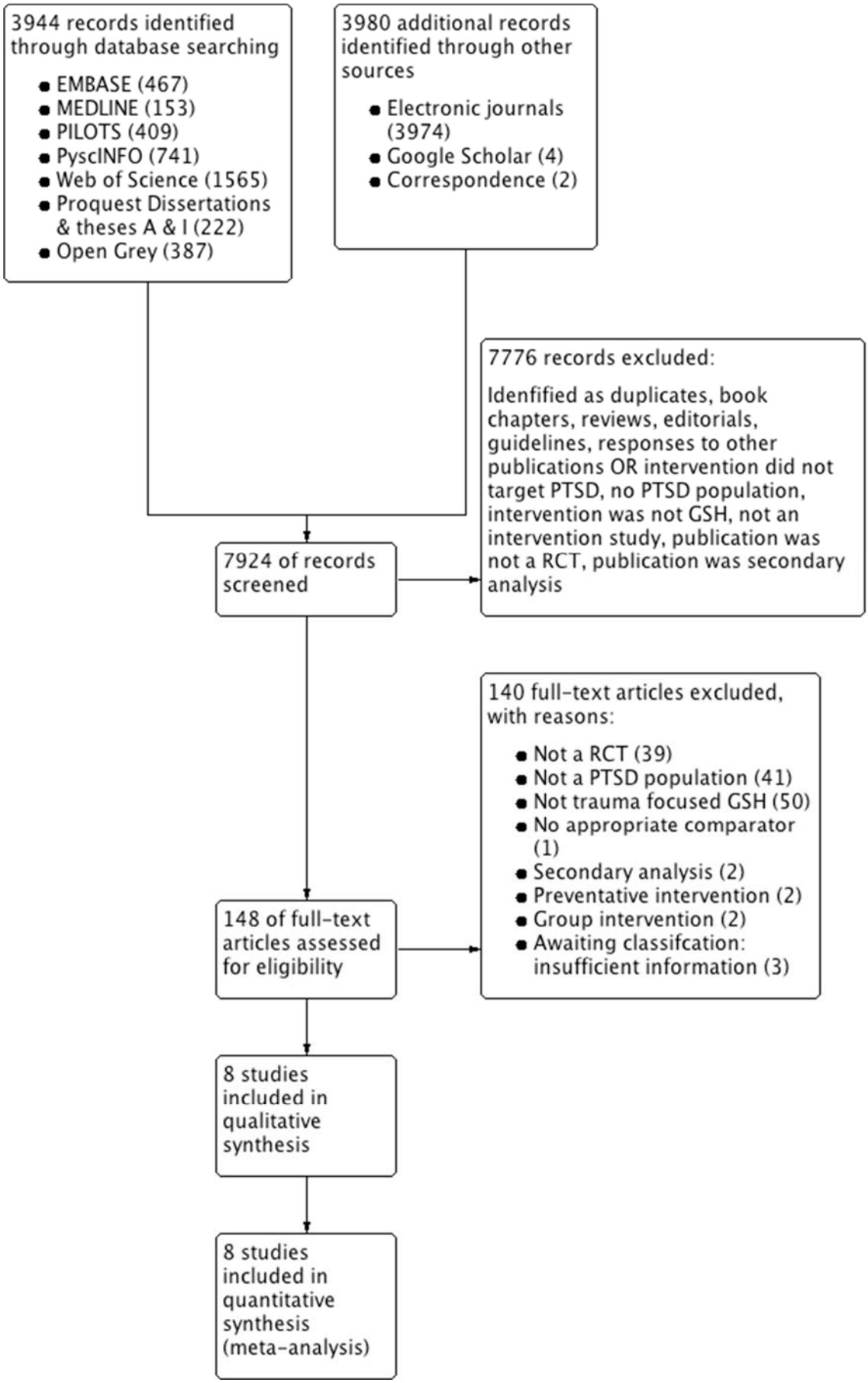

Figure 1. PRISMA Flow diagram of study selection process

control conditions with a total $N = 313$ participants in the intervention groups and $N = 275$ participants in the control groups. Four studies investigated TF-GSH based on Interapy (Knaevelsrud, Brand, Lange, Ruwaard, & Wagner, 2015; Knaevelsrud & Maercker, 2007; Lange et al., 2003; Wagner, Knaevelsrud, & Maercker, 2006), three tested TF-GSH based on CBT modules (Ivarsson et al., 2014; Litz et al., 2007; Spence et al., 2011) and one study tested TF-GSH based on Written Exposure Therapy (WET) (Sloan, Marx, Bovin, Feinstein, & Gallagher, 2012).

3.3.1.1 Types of studies.

All studies were published in scientific journals and were reported in English. All studies employed a parallel group design. Six studies were conducted between the years from 2003 to 2012; for two studies, this information was unavailable (Lange et al., 2003; Wagner et al., 2006).

3.3.1.1.1 Sample sizes.

The sample sizes ranged from $N = 43$ (Litz et al., 2007) to $N = 184$ (Lange et al., 2003), of which six studies had $N < 100$ participants (Ivarsson et al., 2014; Knaevelsrud & Maercker, 2007; Litz et al., 2007; Sloan et al., 2012; Spence et al., 2011; Wagner et al., 2006) and two studies had $N > 100$ participants (Knaevelsrud et al., 2015; Lange et al., 2003).

3.3.1.1.2 Cultural setting.

Seven studies were conducted in a Western society as follows: Two studies in the USA (Litz et al., 2007; Sloan et al., 2012); two studies were conducted by research groups in Switzerland and Germany (Knaevelsrud & Maercker, 2007; Wagner et al., 2006), one study in Australia (Spence et al., 2011), one in Sweden (Ivarsson et al., 2014), one in Amsterdam (Lange et al., 2003). One study was conducted in the Middle East (Knaevelsrud et al., 2015).

3.3.1.2 Participants.

Participants in all the studies were recruited from the general population, i.e. not from clinical settings, via various media adverts and websites.

3.3.1.2.1 Trauma type.

The majority of the studies' participants had experienced civilian trauma such as physical and sexual assault, robbery, motor vehicle accident, loss of/threat to health, and loss of a significant other (Ivarsson et al., 2014; Knaevelsrud & Maercker, 2007; Lange et al., 2003; Sloan et al., 2012; Spence et al., 2011; Wagner et al., 2006). Participants in Knaevelsrud et al. (2015) had experienced war-related violence such as torture, sexual violence, or witnessing bomb attacks, killing of a significant other as their index trauma. Litz et al. (2007) recruited Department of Defense service members in Washington, D.C who had experienced a trauma as a result of the Pentagon attack on September 11th or combat in Irag/Afghanistan.

3.3.1.2.2 Age and gender.

A large proportion of the participants were female with five studies reporting $N >$ 70% females in their total sample (Ivarsson et al., 2014; Knaevelsrud & Maercker, 2007; Knaevelsrud et al., 2015; Spence et al., 2011; Wagner et al., 2006). US service members in the Litz et al. 2007 study were mostly male (78%). One study did not report gender of their sample (Lange et al., 2003). The age range of participants ranged from 18 – 68 across the studies.

3.3.1.2.3 Diagnostic status.

Five studies included participants with levels of PTSD clinical symptoms confirmed by diagnostic screening methods (Ivarsson et al., 2012; Litz et al., 2007; Knaevelsrud et al., 2015; Sloan et al., 2012; Spence et al., 2011). Two studies reported that 70% of participants scored above a cut off threshold of 35 on the IES-R (Knaevelsrud & Maercker, 2007) and on

the IES (Wagner et al., 2006). In Lange et al.'s (2003) study 90% percent of the participants reached a cut off of 28 on the IES, suggesting the presence of PTSD. The IES and IES-R cut-off scores are used as tools for a preliminary diagnosis of PTSD in the literature (Brewin, 2005; Weiss, 2007). The severity of PTSD symptoms ranged from subclinical to extreme.

3.3.1.2.4 Socio-demographic characteristics.

Six studies reported the education level and relationship status of participants. The percentage of participants who had completed a university degree ranged from 31% (Wagner et al., 2006) to 75% (Knaevelsrud et al., 2015). The percentage of participants married or in a partnership ranged from 40% (Knaevelsrud et al., 2015) to 58.1% (Ivarsson et al., 2014). One study did not report any information on socio-demographic characteristics of participants (Lange et al., 2003). Only one study reported the ethnicity of participants (Sloan et al., 2012), which was diverse. The rate of employment ranged from 48% (Knaevelsrud et al., 2015) to 56.5% (Ivarsson et al., 2014) and was reported in four studies.

3.3.1.2.5 Co-morbidity.

The following participant psychiatric co-morbidities were excluded from studies: High risk of suicidal behaviour (Ivarsson et al., 2014; Knaevelsrud & Maercker, 2007; Knaevelsrud et al., 2015; Litz et al., 2007; Sloan et al., 2012; Wagner et al., 2006), psychosis (Knaevelsrud & Maercker, 2007; Knaevelsrud et al., 2015; Lange et al., 2003; Litz et al., 2007; Sloan et al., 2012; Spence et al., 2011; Wagner et al., 2006), substance abuse or dependence (Ivarsson et al., 2014; Knaevelsrud et al., 2015; Lange et al., 2003; Litz et al., 2007; Sloan et al., 2012; Wagner et al., 2006), severe depression (Lange et al., 2003; Spence et al., 2011; Wagner et al., 2006), dissociation (Knaevelsrud & Maercker, 2007; Lange et al., 2003; Spence et al., 2011; Wagner et al., 2006), organic mental disorder, and unmedicated symptomatic bipolar disorder (Sloan et al., 2012).

3.3.1.2.6 Confounding factors.

Four studies stated that participants on medication must be on a stable dose on entry into the study (Ivarsson et al., 2014; Litz et al., 2007; Spence et al., 2011; Sloan et al., 2012) and for this regimen to be maintained during the period of the study intervention. The Lange et al. (2003) study excluded participants taking medication based on type and dosage, although the exclusion criteria upon how these decisions were made is not described. Four studies excluded participants who were currently receiving psychological treatment (Ivarsson et al., 2014; Lange et al., 2003; Sloan et al., 2012; Wagner et al., 2006). Two studies did not make reference to medication or other treatments received elsewhere (Knaevelsrud & Maercker, 2007; Knaevelsrud et al., 2015).

3.3.1.3 Types of TF-GSH interventions.

All studies used manualised treatments and delivered the TF-GSH via the web; apart from one study, which provided GSH material using printed hand-outs (Sloan et al., 2012). Four studies evaluated Interapy, a Dutch internet-based protocol (Lange et al., 2000), for the treatment of PTSD (Knaevelsrud & Maercker, 2007; Knaevelsrud et al., 2015; Lange et al., 2003; Wagner et al., 2006). The same number and frequency of the sessions and treatment duration characterized all Interapy based interventions. Knaevelsrud et al. (2015) translated the manual into Arabic and made cultural adaptations for their study. Three studies investigated GSH based on Internet modular programmes, DESTRESS (Litz et al., 2007) and two that were not specified by name (Ivarsson et al., 2014; Spence et al., 2011). One study (Sloan et al., 2012) investigated WET as a treatment for PTSD.

3.3.1.3.1 Intervention components.

All study interventions included evidence-based principles of TF-CBT such as written exposure exercises (i.e. imaginal exposure) and psychoeducation about PTSD symptoms and the mechanisms of treatment strategies. All study interventions apart from WET (Sloan et al.,

2012) incorporated a cognitive restructuring component. In addition, the modular Internet based interventions delivered in-vivo exposure, relaxation and stress management strategies, and relapse prevention (Ivarsson et al., 2014; Litz et al., 2007; Spence et al., 2011). Of these three studies, two reported delivering homework assignments (Litz et al., 2007; Spence et al., 2011) and one study additionally provided an online discussion forum for each lesson delivered and further resources (Spence et al., 2011). Interapy (Knaevelsrud & Maercker, 2007; Knaevelsrud et al., 2015; Lange et al., 2003; Wagner et al., 2006) included a 'social sharing' treatment phase, where participants were asked to write a letter addressed to themselves or a significant other, although ultimately the letter did not have to be sent. Knaevelsrud et al. (2015) report that their culturally adapted intervention used a more directive therapeutic approach towards participants and "quotes and helpful metaphors from the Koran" were used during the cognitive reappraisal phase.

3.3.1.3.2 Intensity of interventions.

Five studies delivered their intervention over the duration of five weeks: Interapy (Knaevelsrud & Maercker, 2007; Knaevelsrud et al., 2015; Lange et al., 2003; Wagner et al., 2006) and WET (Sloan et al., 2012). The former delivered twice weekly assignments and the latter once weekly. The remaining three delivered 7-8 modules/sessions over an 8-week period (Ivarsson et al., 2014; Litz et al., 2007; Spence et al., 2011). The total hours of treatment received by participants varied from 3.7 hours (Sloan et al., 2012) to a participant average of 23.63 hours "logged on" to the web intervention (*SD* = 17.52) (Litz et al., 2007). All Interapy interventions lasted 7.5 hours (Knaevelsrud & Maercker, 2007; Knaevelsrud et al., 2015; Lange et al., 2003; Wagner et al., 2006). The hours of treatment received was not available for two studies (Ivarsson et al., 2014; Spence et al., 2011).

3.3.1.3.3 Therapist input.

The format of therapist input varied amongst studies including face-to-face contact (Sloan et al., 2012), email (Ivarsson et al., 2014; Wagner et al., 2006), web (Lange et al., 2003), a combination of email and telephone calls (Knaevelsrud et al., 2015; Spence et al., 2011), and face-to-face, email, and telephone calls (Litz et al., 2007). One study did not report the mode of contact (Knaevelsrud & Maercker, 2007). Only three studies explicitly reported the frequency or total duration of therapist contact. Lange et al.'s (2003) study reported at least seven therapist contacts and Ivarsson et al. (2014) reported weekly contact or on demand if needed with an average of 90 minutes of therapist total contact time. Spence et al. (2011) reported an average of 104 minutes (*SD* =9.8). It is presumed that the studies following the Interapy treatment protocol also provided at least seven therapist contacts (Knaevelsrud et al., 2015; Knaevelsrud & Maercker, 2007; Wagner et al., 2006). Knaevelsrud et al. (2015) reported that the therapist time involved in responding to written assignments ranged from 20 to 50 minutes per assignment "depending on the therapist's level of experience with Internet-based therapies".

3.3.1.3.4 Integrity of interventions.

The term *intervention integrity* describes the degree to which interventions are implemented as planned (Dane, 1998). Assessment of the delivery of an intervention can provide information about its feasibility in practice (Dusenbury, Brannigan, Falco, & Hansen, 2003). The qualifications of the therapists delivering the TF-GSH interventions varied across studies and included: Clinical Psychologists, CBT therapists, masters or doctoral level students with prior experience in treating PTSD with exposure based therapies, graduate and post graduate students in clinical psychology, psychotherapists, psychiatrists, and a social worker. All studies reported level of therapist training apart from Litz et al. (2007). Studies reported that supervision was provided for therapists to ensure treatment adherence apart from Spence et al. (2011).

Only two studies did not address participant experience or responsiveness to treatment (Ivarsson et al., 2014; Litz et al., 2007). Three of the seven studies, which employed web-based interventions, reported considerations to Internet or computer access within the participant eligibility criteria (Ivarsson et al., 2014; Knaevelsrud et al., 2015; Spence et al., 2011). Two studies measured the degree of computer and Internet experience, and level of typing skills assessed but did report the results (Lange et al., 2003; Wagner et al., 2006).

Four studies reported participant adherence to the planned intervention within the completer group. The percentage of participants who completed full treatment varied: 39% (Ivarsson et al., 2014), 78% (Spence et al., 2011), 91% (Sloan et al., 2012), and 100% (Knaevelsrud et al., 2015).

3.3.1.3.5 Comparator groups.

Six of the eight studies used a waiting list control design (Knaevelsrud & Maercker, 2007; Knaevelsrud, 2015; Lange et al., 2003; Sloan et al., 2012; Spence et al., 2011; Wagner et al., 2006). The remaining two studies used an active comparison condition. Of these one study delivered general questions on wellbeing and described the control arm as "general support" and "minimum contact" (Ivarsson et al., 2014), and the other used supportive counseling, which incorporated psychoeducation materials about the effects of trauma, and therapist support on "non-trauma-related present-day concerns" (Litz et al., 2007).

3.3.1.4 Types of outcomes.

All studies used reliable and valid outcome measures.

3.3.1.4.1 PTSD.

Most studies assessed PTSD symptoms using self-report measures administered via the Internet, which included the following: Impact of Event Scale-Revised (IES-R; Weiss & Marmar, 1997), Impact of Event Scale (IES; Horowitz et al., 1979; IES Dutch version; Kleber & Brom, 1986), Posttraumatic Diagnostic Scale (PDS; Foa, 1995), PTSD Check List

– Civilian Version (PCL-C; Weathers, Litz, Herman, Huska, & Keane, 1993). One study reported two primary outcome measures of PTSD (Ivarsson et al., 2014). In this instance, the IES-R was included in the analysis rather than the PDS; validity and reliability are comparable, for these measures, but the IES was used more frequently by the other included studies. Two studies (Litz et al., 2007; Sloan et al., 2012) conducted face-to-face clinician administered interviews including the PTSD Symptom Scale- Interview Version (PSSI; Foa & Tolin, 2000) and the Clinician Administered PTSD Scale (CAPS; Blake et al., 1990).

Three studies reported PTSD sum scores only (Litz et al., 2007; Sloan et al., 2012; Spence et al., 2011), three reported subscale scores only (Knaevelsrud & Marcker, 2007; Lange et al., 2003; Wagner et al., 2006), and two studies reported both (Ivarsson et al., 2014; Knaevelsrud et al., 2015).

3.3.1.4.2 Depression and anxiety.

All studies apart from one (Sloan et al., 2011) assessed depression and anxiety symptomology. All measures were self-report instruments administered via the Internet apart from Litz et al., 2007 where assessments were administered face-to-face. Three studies (Ivarsson et al., 2014; Litz et al., 2007; Spence et al., 2011) assessed for depression symptoms using a separate outcome measure which included: Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996), and the Patient Health Questionnaire-9 item (PHQ-9; Kroenke, Spitzer, &Williams, 2001). To measure anxiety, these studies used the following: Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988) and Generalized Anxiety Disorder seven-item scale (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006). Four studies used a single assessment instrument to measure anxiety and depression symptoms on subscales (Knaevelsrud & Maercker, 2007; Knaevelsrud et al., 2015; Lange et al., 2003; Wagner et al., 2006). These included the following: Brief Symptom Inventory

(BSI; Derogatis, 1992), Hopkins Symptom Checklist-25 (HSCL-25; Khuon & Lavelle, 1987), and Symptom Checklist 90 (SCL-90; Derogatis, Lipman, & Covi, 1973).

3.3.1.4.3 Additional outcomes of interest.

Two studies assessed the quality of life of study participants (Ivarsson et al., 2014; Knaevelsrud et al., 2015) using the Quality of Life Inventory (QOLI; Frisch, Cornell, Villanueva, & Retzlaff, 1992) and the European Health Interview Survey-Quality of Life (EUROHIS-QOL; Schmidt, Mühlan, & Power, 2006). One study assessed the working alliance between the therapists and participants (Knaevelsrud & Maercker, 2007) by administering the Working Alliance Inventory (WAI; Horvath & Greenberg, 1989).

Lastly, six out of the eight studies aimed to assess participant satisfaction and treatment experience, which was measured by the Treatment Expectancy Questionnaire (TEQ; Borkovec & Nau, 1972), and the Client Satisfaction Questionnaire (CSQ-8; Larsen, Attkisson, Hargreaves, & Nguyen, 1979) in one study (Sloan et al., 2011) and Knaevelsrud et al. (2015) used the Distress/Endorsement Validation Scale (Devilly, 2004). The remaining four studies administered non-standardized open or scaled questions for participants to evaluate the treatment (Knaevelsrud & Maercker, 2007; Lange et al., 2003; Spence et al., 2011; Wagner et al., 2006)

3.3.1.4.4 Follow-up data.

All studies reported follow up assessments, which ranged from 6 (Lange et al., 2003) to 78 (Knaevelsrud & Maercker, 2009; Wagner & Maercker, 2007) weeks post treatment. Two studies compared the intervention group to the control group at follow up (Litz et al., 2007; Sloan et al., 2012).

3.3.1 Excluded studies.

Studies were excluded if they did not satisfy the eligibility criteria. Studies were excluded on the following bases: Did not employ a RCT design, intervention was aimed at

preventing PTSD, reported secondary analyses of excluded studies, the intervention was not trauma-focused, the intervention was self-help only without therapist guidance, a group based intervention, the study did not use a PTSD outcome measure, the sample was not assessed for PTSD, or participant symptomology did not reach clinical levels. Studies, which examined virtual reality interventions, traditional CBT interventions delivered via teleconferencing, or telehealth interventions delivered by a multi-disciplinary team, were excluded. Studies that were reviewed at the full text process level and excluded are presented in the Characteristics of Excluded Studies table in Appendix G.

3.3.2 Ongoing studies.

Six potentially relevant ongoing interventional RCTs were identified during the search process of this review. These are described in the Details of Ongoing Studies table in Appendix H and would be assessed if this review were to be updated at a later date.

Table 3

Characteristics of Included Studies: Methods and Participants

Author year (Study ID)	Year (s) conducted	Country	Design	Population *N*	Diagnosis/ symptoms	Trauma	Age[1] (*M*, (*SD*), range)	Sex[1] (% Female)	Education level (% university degree/tertiary)
Ivarsson 2014	2012	Sweden	RCT (PG)	GP, 62	CAPS	Diverse	46, (11.7), 21-67	82.3	56.5
Knaevelsrud 2007	2003-2004	Switzerland	RCT (PG)	GP, 96	IES-R (A, I)	Diverse	35, 18-68	90	44
Knaevelsrud 2015	2009-2011	Middle East	RCT (PG)	GP, 159	PDS	War, terror	28.1, (7.43), 18-56	72	75
Lange 2003	NR	Amsterdam	RCT (PG)	GP, 184	IES (A, I)	Diverse	NR	NR	NR
Litz 2007	Ended 2005	USA	RCT (PG)	GP, service members, 43	PSS-I	Combat, terror	39.25, (12.2)	22	NR
Sloan 2012	2009-2010	USA	RCT (PG)	GP, 46	CAPS	MVA	40.65, (13.1)	65	41
Spence 2011	2010	Australia	RCT (PG)	GP, 44	MINI-PTSD	Diverse	42.6, (13.1), 21-68	81	52
Wagner 2006	NR	Switzerland	RCT (PG)	GP, 55	IES (A, I)	Loss	37.0, (10.2), 19-68	93	31

Note. [1] Age and sex of total study participants; A, PTSD avoidance subscale; CAPS, Clinician-Administered PTSD Scale; GP, general population; I, PTSD intrusion subscale; IES, Impact of Event Scale; IES-R, Impact of Event Scale-Revised; *M*, mean; MINI-PTSD, PTSD module of the MINI International Neuropsychiatric; MVA, Motor Vehicle Accident; *N*, total study sample; NR, not reported; PG, parallel-group design; PDS, Posttraumatic Diagnostic Scale; PSS-I, PTSD Symptom Scale-Interview; *SD*, standard deviation.

Table 4

Characteristics of Included Studies: Interventions

Author year	Intervention *N*	Control group *N*	Mode of intervention	Length of intervention (Weeks)	Hours of treatment received (Hours, *M, (SD)*)	Format of therapist input
Ivarsson 2014	8 CBT modules, 31	GS, 31	Web	8	NR	Email
Knaevelsrud 2007	Interapy, 49	WL, 47	Web	5	7.5	NR
Knaevelsrud 2015	Interapy, 79	WL, 80	Web	5	7.5	Email, telephone call
Lange 2003	Interapy, 69	WL, 32	Web	5	7.5	Web
Litz 2007	DESTRESS, 14	SC, 17	Web	8	*23.63, (17.52)*	Face-to-face, email, telephone call
Sloan 2012	Modified WET, 22	WL, 24	Printed hand-outs	5	3.7	Fact-to-face
Spence 2011	7 CBT lessons, 23	WL, 19	Web	8	NR	Email, telephone call
Wagner 2006	Interapy, 26	WL, 25	Web	5	7.5	Email

Note. GS, general support; *M,* mean; *N*, sample size; NR, not reported; *SD,* standard deviation; SC, supportive counseling; WET, Writing Exposure Therapy; WL, waiting list.

Table 5

Characteristics of Included Studies: Outcomes

Author, year	PTSD	Depression	Anxiety	Additional outcomes	Assessment
Ivarsson 2014	IES-R (S, A, I, H)	BDI-II	BAI	QOLI	BL, Post, FU (52)^
Knaevelsrud 2007	IES-R (A, I, H)	BSI (D)	BSI (Ax)	SF-12, WAI, treatment satisfaction questions	BL, Post, FU (12)^
Knaevelsrud & Maercker 2009	IES-R (A, I, H)	BSI (D)	BSI (Ax)	SF-12	FU (78)*
Knaevelsrud 2015	PDS (S, A, I, H)	HSCL-25 (D)	HSCL-25 (Ax)	EUROHIS-QOL SCL-90-R (Sz), DEVS	BL, Post, FU (12)^*
Lange 2003	IES (A, I)	SCL-90 (D)	SCL-90 (A)	Treatment satisfaction questions	BL, Post, FU (6)*
Litz 2007	PSS-I (S)	BDI-II	BAI	Not included	BL, Post, FU (12, 24)^*
Sloan 2012	CAPS (S)	Not included		SAM, TEQ, CSQ-8	BL, Post, FU (18, 30)^
Spence 2011	PCL-C (S)	PHQ-9	GAD-7	LEC, SDS, treatment satisfaction questions	BL, Post, FU (12)^
Wagner 2006	IES (A, I)	BSI (D)	BSI (Ax)	SF-12, BIQ, treatment satisfaction questions	BL, Post, FU (12)*
Wagner & Maercker 2007	IES (A, I)	BSI (D)	BSI (Ax)	SF-12	FU (78)*

Note. A, PTSD avoidance subscale; Ax, anxiety subscale; BAI, Beck Anxiety Inventory; BDI-II, Beck Depression Inventory-II; BIQ, Biographical Information Questionnaire; BL, baseline; BSI, Brief Symptom Inventory; CSQ-8, Client Satisfaction Questionnaire; D, depression

subscale; DEVS, Distress/Endorsement Validation Scale; EUROHIS-QOL, European Health Interview Survey-Quality of Life; FU (xx), follow-up; Follow-up (weeks); GAD-7, Generalized Anxiety Disorder seven-item scale; H, PTSD hyperarousal subscale; HSCL-25; Hopkins Symptom Checklist-25; I, PTSD Intrusion subscale; IES, Impact of Event Scale; IES-R, Impact of Event Scale-Revised; LEC, Life Events Checklist; MINI: Mini International Neuropsychiatric Interview; PCL-C, PTSD checklist-civilian; PDS, Posttraumatic Diagnostic Scale; PHQ-9, Patient Health Questionnaire; Post, post-assessment; PSS-I, PTSD Symptom Scale-Interview; S, PTSD global sum; QOLI, Quality of Life Inventory, SAM, Self-Assessment Manikin; SCL-90; Symptom Checklist-90; SCL-90-R, Symptom Checklist-90-Revised; SDS, Sheehan Disability Scales ; SF-12, Short Form-12; Sz, somatization subscale; TEQ, Treatment Expectancy Questionnaire; WAI, Working Alliance Inventory; ^, analyzed in intention-to-treat analysis; *, analysed in completer-analysis.

3.3.3 Studies awaiting classification.

An inclusion or exclusion decision could not be made for three studies due to insufficient information available for the level of PTSD symptomology of participants (Kersting, 2013; Kersting, 2011; Lange, van de Ven, Schrieken, & Emmelkamp, 2001). Study authors were contacted and if this information is available at a later date, the review will be updated accordingly.

3.4 Risk of Bias in Included Studies

Results of the quality assessment for each individual study are presented in the Risk of Bias tables in Appendix I. This describes study ratings on each criterion on the quality assessment tool. Figure 2 and Figure 3 represent a summary of the risk of bias across included studies and the risk of bias domains.

3.4.1 Selection bias.

3.4.1.1 Random sequence generation.

All studies were judged as low risk of bias on this criterion. In seven studies this was adequately reported and reference was made to using a computer random number generator. Only one study did not sufficiently report the generation of a randomised sequence but through correspondence with the key author it was ascertained that a process of minimization was implemented (Litz et al., 2007).

3.4.1.2 Allocation concealment.

Many of the studies did not address concealment of participant allocations to groups, therefore this criterion was judged as unclear risk of bias. Three studies adequately described concealment procedures, which involved an independent third party (Ivarsson et al., 2014; Sloan et al., 2012; Spence et al., 2011).

3.4.2 Performance and detection bias.

3.4.2.1 Blinding of participants and personnel.

All studies were judged as high risk of bias as it is not possible in trials of psychological therapy for participants and therapists to be blinded to the intervention delivered or received. Lack of blinding risks over-estimating the treatment effects (Cuijpers, et al., 2015).

3.4.2.1 Blinding of outcome assessment.

It is possible for all studies to blind outcome assessors. Five studies adequately described this procedure using computer-automated systems (Lange et al., 2003; Knaevelsrud et al., 2015) or blinded outcome assessors (Ivarsson et al., 2014; Litz et al., 2007; Sloan et al., 2012). The remaining three studies did not address this criterion (Knaevelsrud & Maercker, 2007; Spence et al., 2011; Wagner et al., 2006). Study authors judged that the self-report outcome measures employed by these studies are not likely to be influenced by lack of blinding. All studies were judged as low risk of bias.

3.4.3 Attrition bias.

3.4.3.1 Incomplete outcome data.

All studies provided information on exclusion criteria and the number of exclusions and refusals. Three studies were judged as low risk of bias with adequate dropout analysis and reasons for dropouts reported (Knaevelsrud et al., 2015; Lange et al., 2003). Sloan et al. (2012) reported a 100% retention rate of participants. For the remaining five studies it was not possible to allocate a judgment of low risk or high risk due to insufficient reporting of reasons for dropouts (Ivarsson et al., 2014; Litz et al., 2007) and dropout analysis (Knaevelsrud & Maercker, 2007; Spence et al., 2011; Wagner et al., 2006). Two studies applied completer analyses (Lange et al., 2003; Wagner et al., 2006), four applied Intention-To-Treat (ITT) analyses (Ivarsson et al., 2014; Knaevelsrud & Maercker, 2007; Sloan et al.,

2012; Spence et al., 2011), and two studies applied both methods (Knaevelsrud et al., 2015; Litz et al., 2007).

3.4.4 Reporting bias.

3.4.4.1 Selective reporting

It was not possible to identify any study protocols for the studies. Studies did not explicitly state that all pre-specified outcomes were reported. For six studies an unclear risk of bias judgment was permitted, as all expected outcomes appeared to be reported (Ivarsson et al., 2014; Knaevelsrud & Maercker, 2007; Knaevelsrud et al., 2015; Lange et al., 2003; Spence et al., 2011; Wagner et al., 2006). Litz et al. (2007) reported using an Intention-To-Treat (ITT) analysis, but provided completer analysis results only. One study failed to include results for key outcomes that could be entered into the meta-analysis (Sloan et al., 2012). These latter two studies were judged as at high risk of reporting bias.

3.4.5 Other bias.

All studies appear free from other sources of bias.

3.5 Summary Assessment of Risk of Bias

All domains are presented within a summary assessment of risk of bias across studies, however, it was deliberated that the criterion blinding of participants and personnel is of limited relevance to a psychological intervention and therefore it is not considered within the following overall judgment of risk of bias. Six studies were judged as having an unclear risk of bias for one or more key domains (Ivarsson et al., 2014; Knaevelsrud & Maercker, 2007; Knaevelsrud et al., 2015; Lange et al., 2003; Spence et al., 2011; Wagner et al., 2006). Two studies were judged as high risk of bias on one domain (Litz et al., 2007; Sloan et al., 2012). In summary, most information is from studies judged as unclear risk of bias.

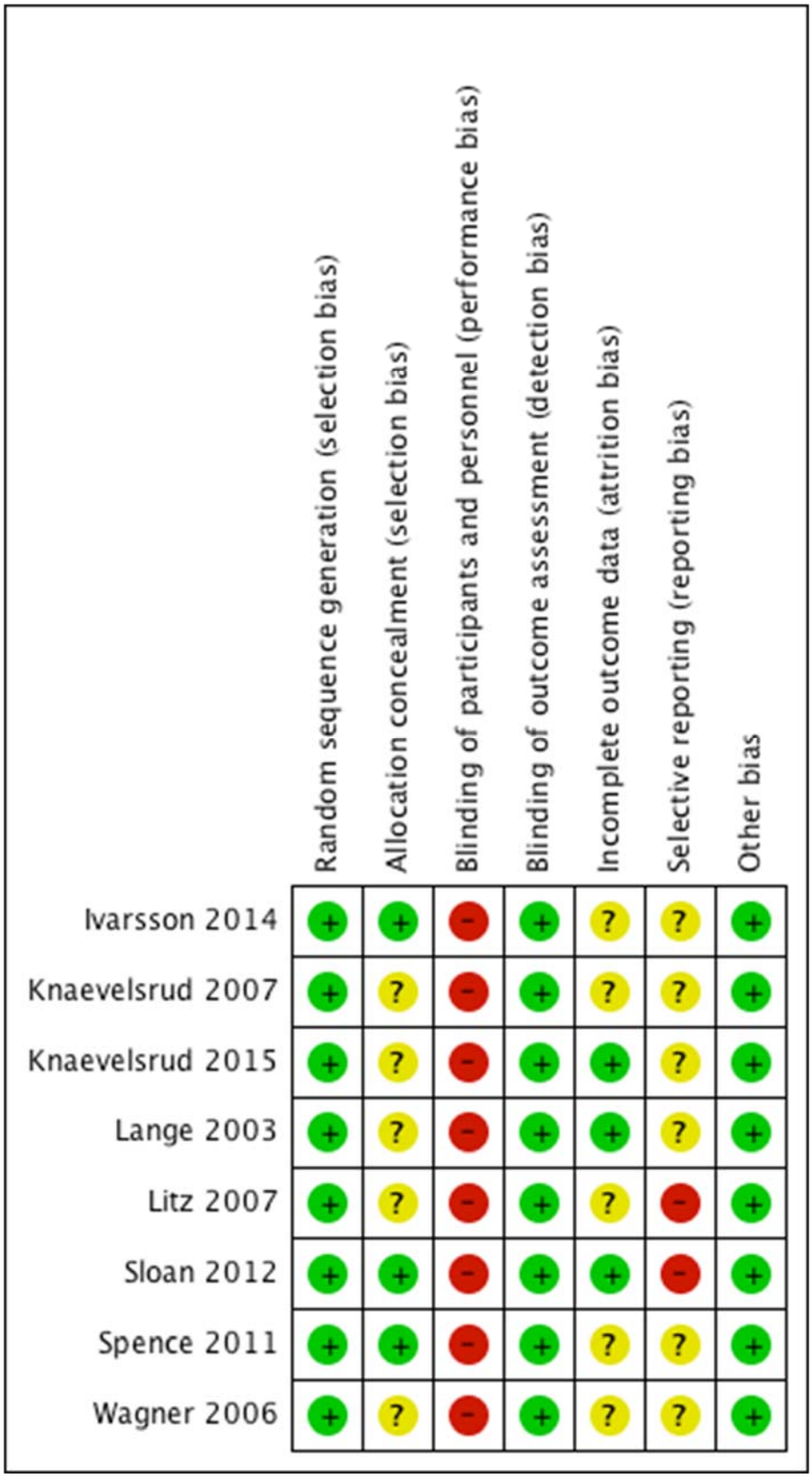

Figure 2. Risk of bias summary: Assessors' judgements about each risk of bias domain for each included study.

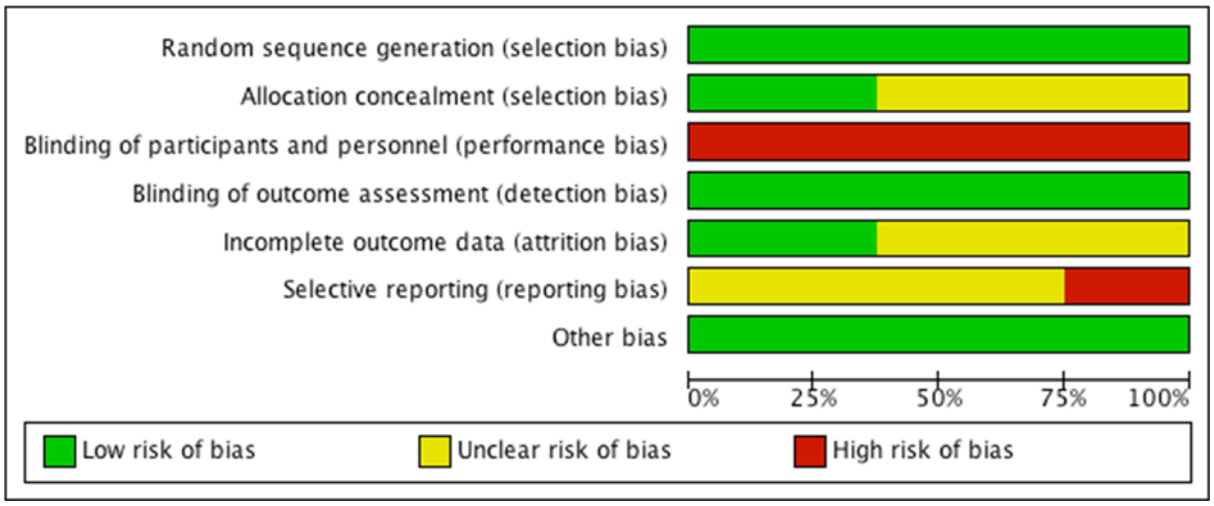

Figure 3. Risk of bias graph: Assessors' judgements about each risk of bias item presented as percentages across all included studies.

3.6 Effects of Interventions for TF-GSH versus Control Conditions

Results are presented for all available outcome measures specified in the methodology in order to address the aim of the review: To determine the effectiveness of TF-GSH for individuals with PTSD. This includes comparisons of interventions with passive and active control conditions for *a priori* PTSD and co-morbid depression symptomology outcomes and *a posteriori* co-morbid anxiety outcomes posttreatment. A random effects model was used with the Standardised Mean Difference (reported as Hedge's *g*) as the measure of effect for each analysis reported below. Confidence intervals (CI) at the 95% level are reported and presented in all analysis figures. An alpha level of 0.10 was adopted to determine statistical significance due to the low power of the chi-squared test when the number of studies included in a meta-analysis is few (Deeks et al., 2011). Additional outcomes and acceptability of the TF-GSH interventions were explored.

For notation purposes *n* refers to the number of participants included in each analysis and *k* refers to the number of studies contributing to the analysis.

3.6.1 Postassessment.

3.6.1.1 PTSD.

For PTSD symptoms posttreatment, the magnitude of effect is large ($k = 8$, $n = 589$, $g = -1.15$, 95% CI -1.59, -0.71) and favours TF-GSH when compared to control conditions (Figure 4). From the data set the null hypothesis that all studies share a common effect size is rejected, $\chi^2 = 32.28$, df = 7, $p < 0.00001$. Results suggest a considerable level of heterogeneity ($I^2 = 82$ %).

Firstly, visual analysis of the forest plot represented in Figure 4, indicates the Sloan et al. (2012) study as an outlier. It is also the only study, which employed a non-web intervention. Its exclusion through sensitivity analysis results in a large effect size ($k = 7$, $n = 543$, $g = -0.93$, 95% CI -1.19, -0.67) favouring TF-CBT. A moderate level of statistically significant heterogeneity was indicated ($\chi^2 = 11.54$, df = 6, $p = 0.07$, $I^2 = 48$ %).

Secondly, studies judged as high risk of bias (Litz et al., 2014; Sloan et al., 2012) were removed resulting in a large effect favouring TF-GSH over control comparators (k = 6, n = 512, g = -0.98, 95% CI -1.24, -0.72) with a statistically significant level of heterogeneity, which may represent moderate heterogeneity (χ^2= 9.27, df = 6, p = 0.10, I^2 = 46 %).

A third sensitivity analysis was conducted where studies, which did not use a 100% clinical PTSD sample, were removed (Knaevelsrud & Maercker, 2007; Lange et al., 2003; Wagner et al., 2006). A large effect favouring TF-CBT remains (k = 5, n =343, g = -1.20, 95% CI -1.94, -0.46) with a statistically significant considerable level of heterogeneity present (χ^2= 33.45, df = 4, p <0.00001, I^2 = 88 %). Repeating this analysis without the identified outlier (Sloan et al., 2012), the results indicate a moderate to large effect (k = 4, n = 296, g = -0.79, 95% CI -1.07, -0.51) favouring TF-CBT. A level of heterogeneity was indicated (χ^2= 3.79, df = 3, p = 0.28, I^2 = 21 %) that might not be important.

Lastly, a further sensitivity analysis indicates that TF-CBT is associated with a moderate to large effect size (k = 2, n = 93, g = -0.77, 95% CI -1.40, -0.15) when compared to active control conditions only (Ivarsson et al., 2014; Litz et al., 2007). This analysis is associated with moderate to substantial heterogeneity (I^2 = 51%).

3.6.1.2 Depression

The magnitude of effect is moderate (k = 7, n =543, g = -0.75, 95% CI -0.96, -0.53) and favours TF-GSH when compared to control conditions for depression posttreatment (Figure 5). The proportion of heterogeneity of effects might not be important (χ^2= 8.31, df = 6, p 0.22, I^2 = 28 %).

A sensitivity analysis revealed a similar effect size (k = 6, n =512, g = -0.77, 95% CI -1.00, -0.54) and level of heterogeneity (I^2 = 34%) when a study at high risk of bias (Litz et al., 2014) was removed.

The effect reduced but remained moderate (g = -0.54, 95% CI -0.96, -0.12) when TF-

GSH was compared to active only control groups (Ivarsson et al., 2014; Litz et al., 2007). The proportion of heterogeneity reduced (I^2 = 0%).

3.6.1.3 Anxiety

At posttreatment, TF-CBT is associated with a moderate effect size (*k* = 6, *n* =543, *g* = -0.62, 95% CI -0.79, -0.44) for symptoms of anxiety (Figure 6). The proportion of heterogeneity of effects (I^2 = 0 %) is interpreted as might not be important. The level of effect and heterogeneity did not change when TF-GSH was compared to active control groups only (Ivarsson et al., 2014; Litz et al., 2007).

Studies judged as high risk of bias were removed (Litz et al., 2007; Sloan et al., 2012) through a sensitivity analysis. The effect remained moderate in favour of TF-GSH (*k* = 6, *n* =512, *g* = -0.64, 95% CI -0.82, -0.46) with the same level of heterogeneity.

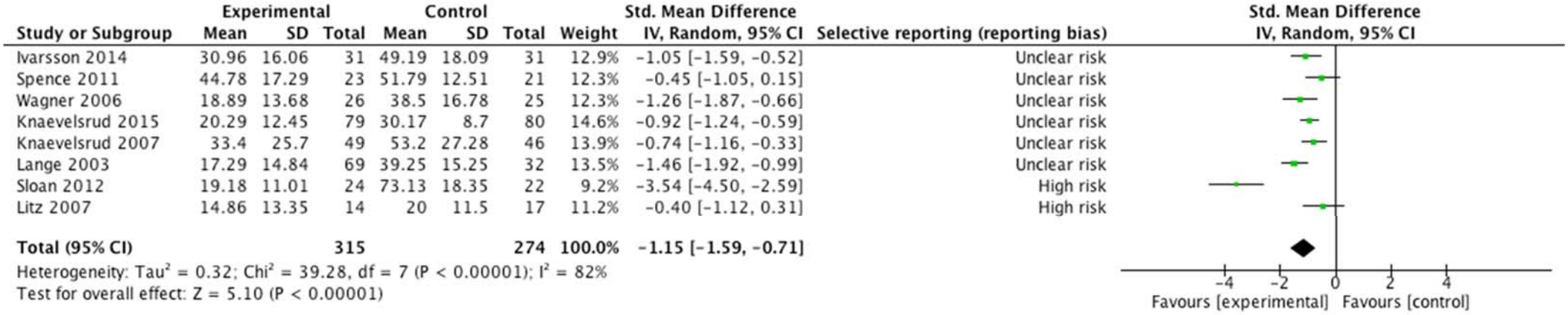

Figure 4. Forest plot of comparison: TF-GSH versus control: PTSD, outcome

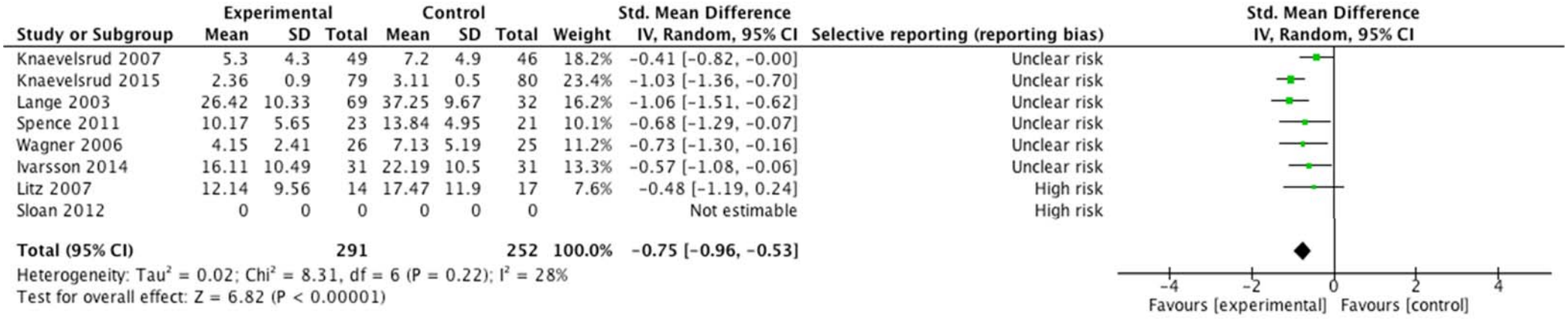

Figure 5. Forest plot of comparison: GSH versus control: Depression, outcome.

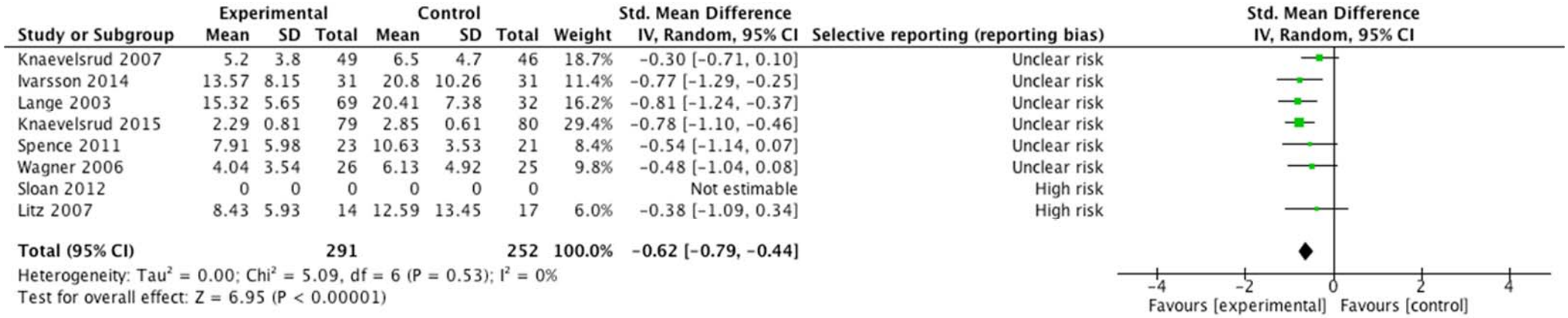

Figure 6. Forest plot of comparison: GSH versus control: Anxiety, outcome.

3.6.2 Follow-up assessment.

All studies reported that treatment gains were maintained at follow-up periods. This includes two studies, which report long-term follow-ups of 18-months (Knaevelsrud & Maercker, 2009; Wagner & Maercker, 2007). There was a lack of consistency amongst studies in assessing outcomes at follow-up periods and the analysis of results (e.g. providing effect sizes for subscales only, or pre to follow-up within-group effect sizes only, or post to follow-up effect sizes only, using clinical reliable change or proportion of participants that met diagnostic status at follow-up to evaluate follow-up outcomes, not reporting effect sizes, and an increase in number of dropouts from post to follow-up assessment) and consequently, synthesising this data was not considered appropriate.

3.6.3 Additional outcomes of interest.

Participants receiving TF-GSH interventions showed a significant increase in quality of life relative to control comparators. A large effect favouring treatment over control was reported in the Knaevelsrud et al. (2015) study, $F1, 157 = 44.20$, $p < 0.001$, $g = 0.84$ and a moderate effect in Ivarsson et al. (2014), $t\ (55) = 2.9$, $p = 0.006$, $g = 0.52$, 95% CI -0.02, 1.06.

Various measures and questionnaires employed within six of the studies indicate levels of treatment satisfaction and experience of participants completing the TF-GSH intervention. The Sloan et al. (2012) results indicate high levels of treatment credibility ($M = 26.61$, $SD = 6.6$, on scale of 3-27) and participant satisfaction ($M = 28.20$, $SD = 3.3$ on a scale of 8-32) with WET treatment.

Spence et al. (2011) reported that 81% of participants rated being either *very satisfied* or *mostly satisfied* with the overall programme of online CBT lessons. No participants rated the programme as *unsatisfactory*. With regards to the treatment modules, 90% rated their quality as *excellent* or *good*. No participants rated the modules as *unsatisfactory*. It was

reported that 95% of participants considered it *worth their time doing the program* and said they would *recommend this program to a friend with PTSD.*

In the Lange et al. (2003) study, participants were invited to rate their feedback of Interapy on a 5-point scale of 1 (*the most negative*) and 5 (*the most positive).* Participants expressed that writing about their feelings was a positive experience (*M* = 4.36, *SD* =0.91) and they had confidence in the therapists and their treatment (M = 4.09, SD = 0.78). An overall evaluation of the Internet treatment was reported as positive (*M* = 3.73, *SD* = 1.28).

Results from the DEVS indicate that 78% of participants considered the duration of Interapy treatment to be *sufficient*, 74% *experienced a marked decrease in their symptom*, 76% would *recommend the treatment to others*, and 87% rated the treatment as *clearly understandable* (Knaevelsrud et al., 2015). High ratings of the working alliance between therapist and participants (participants M = 6.3; therapist = 5.8 on a scale of 1-7) were reported for Interapy treatment in the Knaevelsrud & Maercker, (2007) study. From this study, 86% of participants and 82% in the Wagner et al. (2006) study described the online therapeutic contact as *personal*. Out of these study participants, 60% (Knaevelsrud & Maercker, 2007) and 73% did not miss the face-to-face communication with a therapist (Wagner et al., 2006). With regards to the experience of Internet treatment instead of face-to-face, 76% of participants rated their experience as *pleasant* (Knaevelsrud & Maercker, 2007) and 85% rated the treatments as effective in reducing their complaints as either *a little*, *quite a bit*, or *very strongly* (Wagner et al., 2006).

3.7 Dropout Analysis

Rates of dropouts from TF-GSH ranged from 9% (Sloan et al., 2012; Spence et al., 2011) to 61% (Ivarsson et al., 2014). Dropout rates from passive control conditions ranged from 0% (Sloan et al., 2012; Spence et al., 2011) to 48% (Lange et al., 2003). From active control conditions, 6% dropped out from the Ivarsson et al. (2014) and 19% from Litz et al.

(2007) studies. See Table 6 for individual study dropout rates. Across studies, the estimated dropout rate from the intervention group was 27.2% (95% CI 15.1%, 39.2%). A considerable level of statistically significant heterogeneity was indicated ($I^2 = 88$ %, $p < 0.07$).

Only half of studies reported on the socio-demographic characteristics of completers and dropouts (Ivarsson et al., 2014; Knaevelsrud et al., 2015; Lange et al., 2003; Litz et al., 2007). One study reported no significant association of age with dropouts (Knaevelsrud et al., 2015), whereas Ivarrson et al. (2014) and Lange et al. (2003) found completers to be significantly older than dropouts. Litz et al. (2007) found the reverse. No differences were found based on gender in two studies (Knaevelsrud et al., 2015; Litz et al., 2007), however, completers were more likely to be female in the Lange et al. (2003) study. Education level was not associated with dropout rate (Knaevelsrud et al., 2015; Lange et al., 2003), although Lange et al. (2003) found that completers were less experienced with computers and the Internet. Knaeveslrud et al. (2015) found no differences between completers and dropouts in terms of marital or professional status. Lange et al. (2003) found that completers were more likely to live with a partner and Litz et al. (2007) found completers less likely to be enlisted service members.

Three studies reported no significant association of baseline psychopathology with dropout rate (Ivarsson et al., 2014; Knaevelsrud et al., 2015; Lange et al., 2003). Litz et al. (2007) reported no association of anxiety only with dropout rate, which may suggest that an association existed for PTSD and depression symptoms.

Only two studies provided information on comparisons of trauma related characteristics between completers and dropouts (Knaevelsrud et al., 2015; Lange et al., 2003). No differences were found in the number and type of trauma (Knaevelsrud et al., 2015), or time elapsed since the trauma or degree of prior disclosure about the trauma (Lange et al., 2003).

Reasons for dropouts were provided by six studies (Knaevelsrud & Maercker, 2007; Knaevelsrud et al., 2015; Lange et al., 2003; Sloan et al., 2012; Spence et al., 2011; Wagner et al., 2006). These included the following: Technical problems e.g. network, computer, Internet access, difficulties with electricity (Knaeveslrud & Maercker, 2007; Knaevelsrud et al., 2015; Lange et al., 2003), a preference for face-to-face therapy (Knaeveslrud et al., 2015; Lange et al., 2003; Wagner et al., 2006), or the participant felt better (Sloan et al., 2012).

The following reasons for dropouts may be associated with adverse effects of treatment: Intervention was too much of a commitment (Lange et al., 2003; Spence et al., 2011), induced emotional distress (Knaevelsrud & Maercker, 2007; Sloan et al., 2012), was too soon after the death of a significant other (Wagner et al., 2006), relapse in depressive symptoms (Wagner et al., 2003), hospitalization, or referral to local psychiatrists (Knaevelsrud et al., 2015).

3.8 Publication Bias

An exploratory visual inspection of the funnel plot (See Figure 7) shows the smallest study (Sloan et al., 2012) towards the bottom of the graph. This study reported a larger effect associated with TF-GSH and has been identified as an outlier in the forest plot above (Figure 4). The remaining seven studies cluster more symmetrically around the mean effect size for PTSD, depression (Figure 8), and anxiety outcomes (Figure 9). This suggests an absence of publication bias. However, this statement should be received with caution due to the few studies included within the review and the limitations associated with visual inspections of funnel plots in accurately detecting publication bias (Lau, Ioannidis, Terrin, Schmid, & Olkin, 2006).

Funding sources were clearly stated for all of the included studies apart from Wagner et al. (2006) and did not raise any suspicions of publication bias (Bhandari, 2004).

Table 6

Dropout Analyses

Author, year (Study ID)	Dropout rates % Intervention: control	Completers' characteristic in comparison to dropouts' characteristic	Reasons for drop outs
Ivarsson (2014)	61.29: 6.45 (AC)	-No differences on psychopathology (NOS) -Completers older	-Not reported
Knaevelsrud (2007)	16.33:2.13	-Not reported	-Technical problems (network/computer) -Emotional distress due to the writing about their stressful events
Knaevelsrud (2015)	40.51:41.25	-No differences on demographics (age, gender, educational level, marital status, professional status) -No differences on psychopathology (PTSD, anxiety, depression) -No differences on trauma (type, number)	-Difficulties with electricity/internet access -Hospitalization -Referral to local psychiatrists -Preference for face-to-face therapy
Lange (2003)	36.06:48.39	-No differences on level of education -No differences on trauma (time since trauma, degree of disclosure) -No differences on psychopathology (PTSD, anxiety, depression, somatization, sleep problems). -Completers more likely to be female -Completers older -Completers more likely to live with a partner -Completers less experienced with computers/ Internet	-Technical problems (network/ computer) -Preference for face-to-face contact -Experiencing the writing assignments "as too much of a burden"
Litz (2007)	41.67:19.05 (AC)	-No differences on gender, minority status -No differences on baseline anxiety -Completers younger -Completers less likely to be enlisted service members	-Not reported
Sloan (2012)	9.09:0	-Not reported	-Thinking about trauma felt "unpleasant" -Feeling better

Spence (2011)	8.67:0	-Not reported	-Competing time commitments -Relapse of depressive symptoms
Wagner (2006)	10.34:3.85	-Not reported	-Preference for face-to-face contact -Treatment too soon after the death of significant other

Note. AC, active control condition.

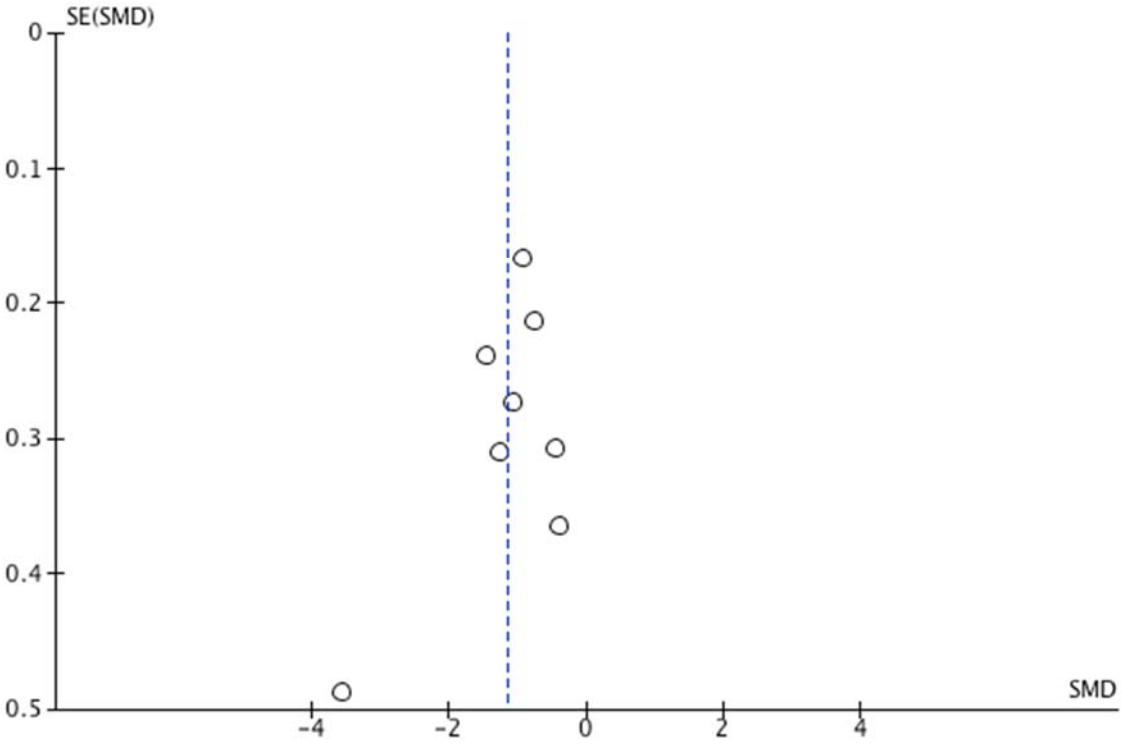

Figure 7. Funnel plot of comparison: TF-GSH versus control: PTSD, outcome

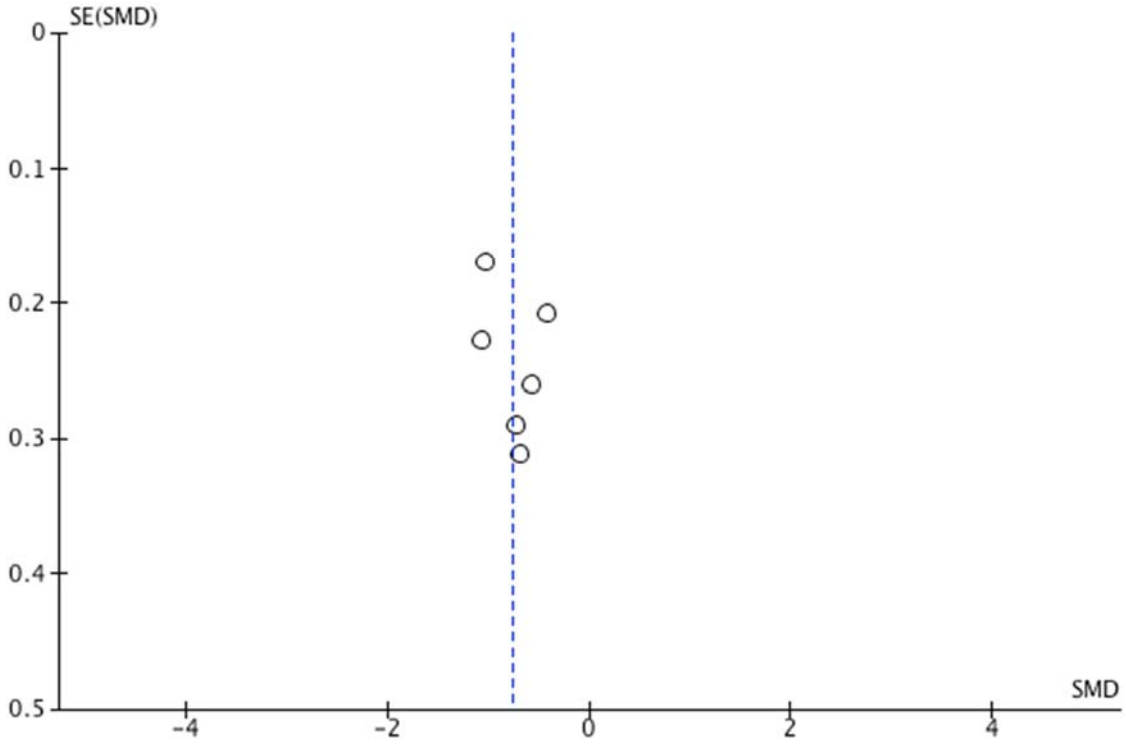

Figure 8. Funnel plot of comparison: TF-GSH versus control: Depression, outcome

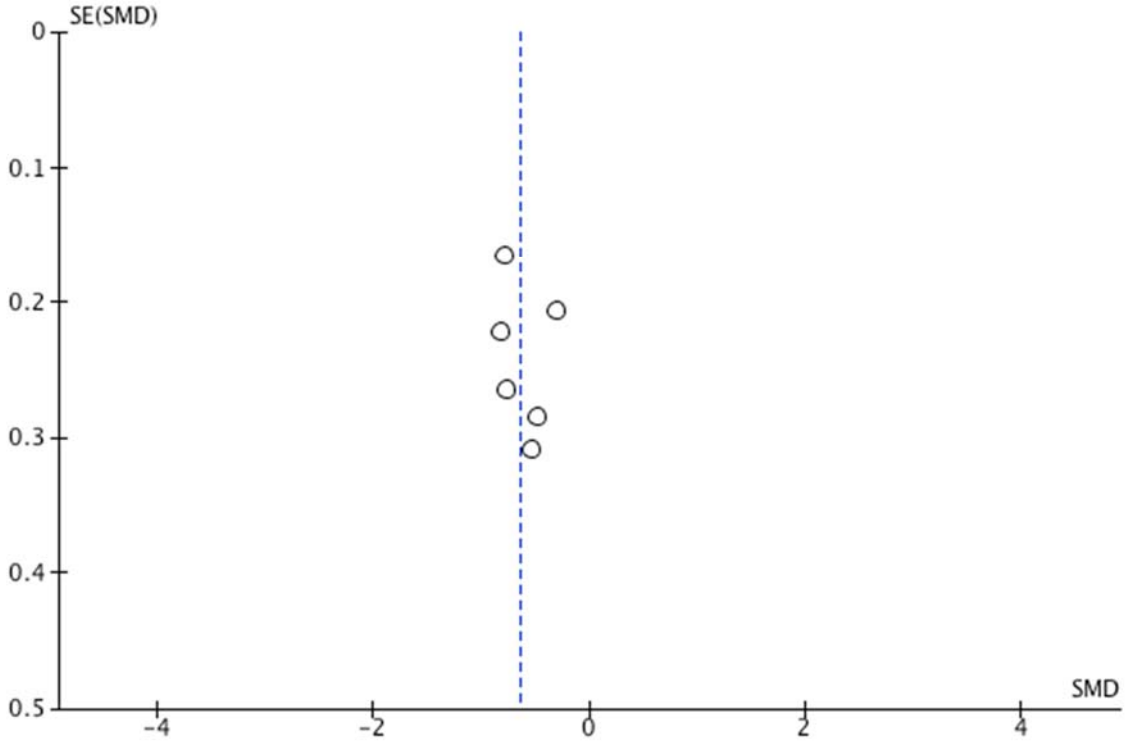

Figure 9. Funnel plot of comparison: TF-GSH versus control: Anxiety, outcome

Table 7

Summary of Findings for TF-GSH compared with Controls for PTSD

Outcomes	**Intervention effect in favour of TF-GSH (95% CI)**	**No of Participants (studies)**	**Quality of the evidence (GRADE)**	**Comments**
PTSD Self-report or clinician administered interview	-0.98 (-1.24, -0.72)	512 (6) [1]	⊕⊕⊖⊖ **low**[2]	Primary analysis restricted at unclear risk of bias
DEPRESSION Self-report	-0.77 (-1.00, -0.54)	512 (6)	⊕⊕⊖⊖ **low**	Primary analysis restricted at unclear risk of bias
TREATMENT SATISFACTION	Not estimable	496 (6)	⊕⊕⊖⊖ **low**	Feedback from intervention completers was positive overall
DROPOUT RATE	Not estimable	589 (8)	⊕⊕⊖⊖ **low**	Dropout rate summary: 27% Range: 9%-61% Reasons for dropout: Technical problems & preference for face-to-face therapy reported in 3 studies
ADVERSE EFFECTS[3]	Not estimable	589 (8)	⊕⊕⊖⊖ **low**	Incidents of dropouts due to commitment required by intervention, emotional distress provoked by intervention, relapse of symptoms

Note. CI: Confidence Interval; GRADE: GRADE Working Group grades of evidence (see explanations below).
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1]Summary of intervention effect is based upon studies assessed as unclear risk of bias. Two studies judged as high risk of bias were excluded from the summary intervention effect.

[2]The quality level was downgraded due to: Unclear risk of bias across many studies for incomplete outcome data, selective reporting, and allocation concealment domains, comparators used (e.g. waiting list), unexplained heterogeneity, imprecision of results (reflected in wide confidence intervals). A factor that increased the quality level was the moderate to large magnitude of effect.

[3]No studies explicitly addressed adverse effects, but reported incidents of individual participants dropping out of the intervention for the reasons described.

3.9 Chapter Summary

A total of 7776 records were identified through the study selection procedure. Reasons for excluding studies were reported and several ongoing studies were documented. Results from data synthesis and analysis were based upon a final total of eight included studies, comprising eight comparisons comparing TF-GSH with either active or passive control groups. All included studies employed RCT parallel group designs and recruited participants from the general population via the media. The type of trauma was diverse. Seven of the eight studies employed a web-based intervention, and format and intensity of therapist input varied. Most information was from studies judged as unclear risk of bias.

For PTSD outcomes, post treatment results suggest that TF-CBT is associated with a large effect with the presence of significant and clinical heterogeneity. A moderate to large effect was indicated for symptoms of anxiety and depression post treatment, with a level of heterogeneity that might not be considered important. Levels of effect and heterogeneity did not reduce when two studies judged at high risk of bias were removed through sensitivity analyses. Treatment gains appeared to be maintained at follow-up at multiple time points up to 18 months post treatment. TF-GSH was associated with a significant improvement in quality of life and feedback from participants on the intervention they received was mainly positive. The average rate of dropouts across studies was 28% and the reasons provided by participants were mainly technical difficulties and a preference for face-to-face contact. Adverse effects of the intervention included an increase in emotional distress. Finally, publication bias was explored and a summary of findings is presented where summary intervention effects are based upon studies judged as unclear risk only.

4 Discussion

4.1 Chapter Outline

The main findings of the review are summarised, followed by an evaluation of the clinical and statistical heterogeneity of included studies. The external validity and relevance of the evidence to the review questions are explored, as well as its methodological quality. Strengths and limitations in relation to potential bias within the review process are discussed. The results from this review are explored in light of other evidence and reviews, and implications for clinical practice and future research are outlined within the conclusions.

4.2 Summary of Main Findings

The review identified eight RCTs comparing a TF-GSH intervention with a control group comparator for individuals with PTSD. These studies were designed to reduce symptoms of PTSD and evaluated TF-GSH programmes that comprised elements of TF-CBT including written exposure exercises (i.e. imaginal exposure), psychoeducation about the disorder and the mechanisms of treatment strategies.

The evidence available suggests that TF-GSH had a greater effect than waiting list, supportive counselling, and general support comparators in reducing PTSD symptomology at posttreatment. These effects were demonstrated across a range of PTSD outcome measures. The treatment effect was large and this magnitude of effect remained when one study (Sloan et al., 2012), identified as an outlier (with the greatest effect in favour of TF-GSH), was removed from the analysis. This study was the only one, which delivered TF-GSH materials in printed handouts, where the therapists initially read the instructions face-to-face with the participants, checked their understanding and answered any questions. All subsequent therapist contact was face-to-face. The study also had a low dropout rate (9%). This may suggest that face-to-face therapist guidance is associated with greater treatment adherence and treatment gains.

Additionally, the magnitude of effect was unchanged when a further study judged at high risk of bias was removed, and secondly when analysis was based on those studies which used a 100% clinical PTSD sample. A moderate to large effect size was found when TF-GSH was compared to active control comparators only (e.g. supportive counselling and general support). The magnitude of effect appears robust to the differential decisions made during the review process.

Follow-up analysis was limited due to the majority of studies using a waiting list control group, which received treatment within the follow-up periods. Studies reported within group effect sizes, which indicated treatment gains were maintained for the TF-GSH group during follow-up periods ranging from 6 weeks to 18-months.

Out of the eight studies, seven assessed co-morbid symptoms of depression and anxiety using a number of outcome measures. Evidence supported beneficial effects of TF-GSH for depression and anxiety, although the magnitude of effects was not as great compared to PTSD symptoms. Additionally, six of the eight studies that included participant ratings reported high levels of treatment satisfaction of participants completing the TF-GSH interventions.

Across studies, the dropout rate was estimated as 27%, with individual study dropout rates ranging from 9-61%. Evidence of age, gender, and marital status, as factors associated with dropouts was variable across studies. Differences of education level were not found between those that completed treatment compared to dropouts, and one study found that dropouts were more experienced with computers and the Internet. Baseline psychopathology and trauma related characteristics were not associated with dropout rate. However, only half of the studies included an analysis of characteristics of completers and dropouts, and data for each variable are limited. Primary reasons for dropouts were technical problems e.g. network, computer, Internet access, electricity, and a preference for face-to-face therapy.

Reasons for dropouts which may indicate adverse effects of TF-GSH included: Induced emotional distress, the intervention was too much of a commitment, too soon after the death of a significant other, and relapse in depressive symptoms, hospitilization during the intervention phase, referral to local psychiatrist.

4.3 Heterogeneity

There was evidence of clinical and statistical heterogeneity within the included studies for PTSD outcomes.

4.3.1 Clinical heterogeneity.

There was insufficient data to consider sources of heterogeneity using moderator and sub-group analyses. However, narrative synthesis allows an exploration of some of the factors that may have contributed to the considerable levels of heterogeneity. Although all the studies delivered TF-GSH with the aim of reducing symptoms of PTSD there was diversity amongst interventions. Intervention components, which varied among studies, included in-vivo exposure, cognitive restructuring, relaxation and stress management techniques, and relapse prevention. The hours of treatment received by participants varied considerably from 3.7 to an average of 24 hours. The format of therapist input was mixed and information regarding the intensity of therapist contact was not provided by many of the studies. The qualifications of the therapists delivering the intervention were diverse.

Moreover, there were differences in the clinical samples used within studies, with a heterogeneous range of trauma types. One study (Litz et al., 2007) included service members who had experienced combat related traumas, and one study (Wagner et al., 2006) included only participants who had experienced the loss of a significant other. This study did not confirm a diagnosis of PTSD as part of their screening of participants. Within DSM-5 (APA, 2013) criterion A specifies that the death of a significant other must have been violent or accidental. The study does not provide any information with regards to nature of death. With

regards to the diagnostic status of participants, only five studies included participants with a confirmed PTSD diagnosis. Remaining studies used a specified cut-off on an outcome measure to indicate clinical levels of PTSD symptomology and their samples included participants whose PTSD symptoms were assessed as subclinical levels. Furthermore, the cut-off specified on the outcome measures used was not uniform across those studies. A sensitivity analysis was applied with the aim to address this potential source of heterogeneity. Lastly, the exclusion criteria applied to participants entering the studies varied with regards to co-morbidities and use of medication.

4.3.2 Statistical heterogeneity.

Statistically significant levels of heterogeneity were found for PTSD outcomes indicating that the included studies did not share a common effect size. The I^2 statistic demonstrated a moderate to considerable level of heterogeneity in a number of analyses. The application of sensitivity analyses revealed that the level of heterogeneity might not be important when the summary of effects combined studies that used a sample of participants with a diagnostic status of PTSD and the study outlier was removed (Sloan et al., 2012). The level of heterogeneity amongst study effect sizes means that caution should be applied in interpreting the summary effect size (Deeks et al., 2011).

4.4 Generalisability and Applicability of the Evidence

The evidence is from trials that recruited participants from the general population via various media advertisements and websites. Whilst this may have increased accessibility to treatment, the participants who applied to take part in the research may not be representative of individuals who present in clinical settings (Egger, Smith, Schneider, & Minder, 1997). However, advertising and signposting to primary care services such as IAPT in England, that may potentially offer low-intensity interventions for PTSD in future, may be an important

factor in encouraging self-referrals and increasing the representation of individuals with PTSD within such services.

The severity of PTSD symptoms at baseline was diverse. The majority of participants experienced clinical levels of PTSD symptomology within the moderate to severe range. Unlike previous reviews (e.g. Kuester et al., 2016), which included studies of non-clinical samples, the evidence from this review is relevant to address the effectiveness of GSH for individuals with PTSD. Moreover, the types of trauma experienced amongst participants were diverse, and outcomes did not appear to be associated with trauma type. This suggests that TF-GSH may be an acceptable treatment for a range of traumas.

The age of participants ranged from 18-68 years representing an adult population, and therefore there is no evidence of the effectiveness of TF-GSH for children and adolescents, and older adults with PTSD. Therefore, the results are limited to an adult PTSD population. With regards to gender, apart from one study (Litz et al., 2007) that recruited service members only, females were over-represented within the studies' civilian samples. However, this is in line with prevalence data that show that PTSD is twice as common among women, compared to men in civilian populations (Friedman, Resick & Keane, 2014).

The majority of studies excluded participants with psychiatric co-morbidities such as severe depression, psychosis, substance abuse or dependence, and half of studies excluded those individuals with dissociation. The evidence suggests that TF-GSH based interventions may be effective for reducing symptoms of PTSD and co-morbid depression for individuals with mild to moderate depression. This clinical population is representative of individuals treated within IAPT services within primary care (Clark, 2011). However, studies within this review are insufficient in addressing whether individuals with severe depression and additional psychiatric conditions commonly associated with PTSD, may benefit from TF-GSH. Only one study (Knaevelsrud et al., 2015) was conducted in an Eastern society and the

remaining studies took place in a Western Society, where results may be more relevant for UK health care settings such as the NHS.

The results are based primarily on TF-GSH materials delivered via the web, which reflects the advances in technology and the direction of current research. Computers and the Internet appear ubiquitous, and a survey conducted in 2015 found that 72% of adults in Great Britain used a computer every day. However, 10% of adults had never used a computer. Of those adults aged 16 to 24, only 1% had never used a computer compared to 32% of adults aged 65 and over (Office for National Statistics, 2015). This suggests that web based interventions may be less accessible for older adults with PTSD.

It must be acknowledged that the number of participants with a university degree or tertiary education was overrepresented within samples of the six studies that provided this data. A study assessing the reading age and readability of self-help books for depression showed that: "A significant proportion of the UK population would struggle" to access the information due to the complexity of language (Martinez, Whitfield, Dafters, & Williams, 2008). Whilst participants in the included studies were coached and guided alongside using the self-help materials, the evidence may not support the use of the interventions with individuals with a lower level of literacy or additional learning needs. Only one study reported the reading level of their intervention, which was for ages 12-14 (Ivarsson et al., 2014). Tailoring the readability of self-help materials to the literacy level of the individual or community is an essential consideration for treatment (Baguley et al., 2010). Additionally, Knaevelsrud et al. (2015) adapted their intervention to the language and cultural representation of their participant sample.

The length of study interventions (5-8 weeks), excluding follow-up, is in line with the NICE definition of GSH (2011). The evidence suggests that a low intensity intervention of less than 10 hours was sufficient in producing a large treatment effect. However, two studies

did not report this data, and therefore this statement should be considered with caution. A range of professionals varying in experience and qualifications delivered the interventions, suggesting a wide applicability of the GSH materials within services.

Reasons for dropouts indicate that TF-GSH via the web may introduce different barriers for individuals seeking treatment. Whilst this format of intervention may afford increased anonymity and reduce the barrier associated with stigma (Pietrzak et al., 2009), technological access may present an inequity of treatment access and delivery.

4.5 Quality of the Evidence

The evidence is summarised from a total sample of 588 participants. The majority of information incorporated within this review is taken from studies judged as unclear risk of bias. Lack of clarity of methods used is restricted to allocation concealment, incomplete outcome data, and selective reporting. A key methodological limitation was that five studies failed to report reasons for dropouts or provide a dropout analysis, therefore attrition bias may have influenced study results. Additionally, insufficient reporting of participant allocation to groups occurred in five of the eight studies. Low risk of bias and methodological strength was associated with random sequence generation, blinding of outcome assessment, and other bias. Two studies were deemed as high risk of bias due to factors associated with selective reporting of results.

The quality of evidence using the GRADE approach was graded as low. This was due to methodological quality of studies, unexplained heterogeneity amongst included studies, and imprecision of results reflected by wide within study confidence intervals. Additionally, six of the eight studies used a waiting list control group, which is less effective than standard treatment in clinical settings and six studies relied on self-report measures of PTSD symptoms. These factors impact upon the directness of evidence. Furthermore, the use of a waiting list control restricted analysis of follow-up data to produce between group effects. A

factor that increased the quality level was the magnitude of effect found for PTSD symptoms.

A low grade of evidence according to GRADE suggests "further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate". However, criticisms have been raised towards the GRADE approach to define the quality of evidence. The assessment criteria have been described as "narrow", and the value placed on RCT designs may not suitably capture the complexity of human change associated with research of psychotherapy (Holmgvist & Persson, 2012). The application of the GRADE approach ensures high standards of evidence; however, there is a risk that potentially beneficial interventions are not implemented within healthcare (Holmgvist & Persson, 2012). It has been emphasised that the evidence for the effectiveness of public health interventions requires a multiplicity of research methods to encompass complexity (Krantz, 2008).

Of the total number of studies, six used samples of less than 100 participants. *Small study effects* is a phenomenon whereby treatment effects in small trials tend to be more beneficial compared to larger trials (Nüesch et al., 2010). The few number of trials included within the review restricted analytic exploration of small study effects. It is advised that results from meta-analyses including mainly small trials should be interpreted with care (Nüesch et al., 2010).

4.6 Potential Biases in the Review Process

This review adopted the Cochrane Collaboration guidelines, therefore the review process aimed to reduce potential bias, such as incorporating a grey literature search and including non-English language studies. The range of search terms employed led to a sensitive search strategy and it is considered likely that all relevant data was obtained. The study selection process was performed independently by two assessors and incorporated a third person if any disagreements occurred.

In retrospect, the inclusion and exclusion criteria could have been clearer with regards to the PTSD diagnosis or symptomology of participants. Various cut-off scores were used by studies using symptom outcome measures to assess PTSD and in some studies not all participants reached clinical levels of PTSD symptoms. Restricting studies to those that used clinical diagnostic tools to screen participants may have reduced heterogeneity, although it would have reduced the number of eligible studies. Moreover, the eligibility criteria did not stipulate a definition of trauma. Some studies included participants whose experienced traumatic event would not have fulfilled the definition of a trauma outlined in diagnostic criteria (5th ed.,; DSM-V; APA, 2013).

Full data was not available for all studies and only some of this information was made available through personal contact with authors. Further information may have provided a more reliable judgment of risk when assessing study methodology, and may have led to the appropriate inclusion or exclusion of three further studies within the study selection process.

4.7 Comparisons of Findings with Other Studies or Reviews

Although this review did not restrict the format of GSH materials, the results indicate that Internet based treatment may be the future of the dissemination of low intensity treatments. The large effect size found in favour of TF-GSH is in line with studies that have investigated Internet and telehealth based treatments for PTSD.

Kuester et al. (2016) found moderate to large effect sizes for CBT-IBIs in treating PTSD symptom severity when comparing to passive control conditions. Similarly, the Sloan et al. (2011) meta-analysis found a large effect of telehealth treatments for reducing symptoms of PTSD when compared to waitlist controls. However, when compared to active control conditions such as supportive counselling or psychoeducation, neither reviews evidenced the superiority of their treatments in the reduction of PTSD symptoms, in contrast to this current review. Moreover, Sloan et al. (2011) found an inferior effect of their

treatment compared to face-to-face comparators. However, currently, it is considered of limited value to directly compare the findings to these reviews where study treatments are principally high-intensity and do not conform to the definition of GSH. It may be useful to consider the results of this current review in the future in context of ongoing reviews assessing the efficacy of Internet-based CBT for PTSD with and without therapist guidance (Lewis et al., 2013; Fricke et al., 2014).

Sloan et al., (2011) found a large effect in favour of telehealth treatment for depression symptoms compared to waiting list comparators, in line with the findings of this review. Contrary to PTSD symptoms, in the Sloan et al., (2011) review, there was no significant difference between telehealth and face-to-face conditions suggesting a comparability of treatment effects. A previous meta-analysis has shown that GSH is comparable to face-to-face psychotherapy in treatment effects for depression and anxiety disorders (Cuijpers et al., 2010). The current review has demonstrated a paucity of research comparing GSH for PTSD to face-to-face treatment.

The dropout rate (27%) from this review is equivalent to those found in other studies investigating treatments for PTSD. Kuester et al. (2016) reported a dropout rate of 23.23% for Internet based CBT and Bisson et al. (2007) found that up to 30% of participants did not complete face-to-face treatment in some studies. Furthermore, Cuijpers et al. (2010) did not find a significant difference in dropout rate between face-to-face treatment and GSH for depression and anxiety disorders.

4.8 Conclusions

4.8.1 Implications for practice.

The review aimed to analysis and synthesis research in the context of the NICE (2005) research recommendations for “newly developed guided self-help materials based on trauma-focused psychological interventions” to assess efficacy in the treatment of PTSD. The

evidence from this review suggests that TF-GSH is associated with favourable treatment effects in reducing symptoms of PTSD and co-morbid anxiety and depression symptoms. Treatment benefits were demonstrated across a range of trauma types and severity of PTSD symptoms, suggesting that TF-GSH may be an effective and appropriate intervention for a range of individuals presenting with PTSD. Moreover, based upon self-reports, the majority of participants who completed the TF-GSH interventions reported a positive experience and was satisfied with the treatment received. However, the estimate of this effect must be interpreted with caution based on the current availability of evidence. It is considered that further research is necessary to increase the level of confidence in the potential benefits of TF-GSH as a low-intensity intervention for individuals with symptomatic PTSD.

The review provides limited evidence with regards to the maintenance of treatment benefits. Additionally, with reference to the NICE (2005) research recommendations this review is not able to address the question of the efficacy or cost effectiveness of TF-GSH compared with current evidence-based trauma-focused psychological interventions for PTSD.

The form and components of TF-GSH including therapist input varied across studies, and it is not clear which are the key ingredients associated with a favourable treatment effect to suggest a standardised TF-GSH intervention that could be introduced into the delivery of routine care. The variation of therapist experience and level of qualification suggests that TF-GSH could be delivered by a range of professionals, enhancing the feasibility of such an intervention within care services.

The future direction of dissemination of PTSD treatments via the Internet is highlighted. It is important to acknowledge that this mode of treatment may not be appropriate for everyone and may introduce new barriers to accessing treatment. Furthermore, person-centred care would provide a choice of therapeutic contact, as preference for face-to-face therapy was reported by some participants as a reason for their

dropout from treatment.

4.8.2 Implications for research.

Further well-designed RCTs of TF-GSH as an intervention for individuals with PTSD are required. This review consisted predominantly of small studies and there was not a sufficient number to fully explore and therefore explain the levels of heterogeneity. There is a need for comparison studies of TF-GSH with evidence-based treatment, such as TF-CBT. It would be beneficial for future studies to include active control comparators to provide further evidence for the long-term effects of TF-GSH.

Future research should aim to include information about the intensity of therapist input, such as total time and frequency. This would allow for the time and cost effectiveness to be evaluated alongside the clinical effectiveness of TF-GSH. Additionally, it would be useful to know the total duration of treatment received by participants in addition to treatment delivered. This would help to consider the dose of therapy required for any potential treatment gains, necessary to guide any future treatment recommendations.

Previous reviews have included studies that have used a non-clinical sample. It is considered that at this stage of research into TF-GSH, future research should focus on clinical samples. Many of the studies included in this review relied on self-report measures. Multi-modal measures of PTSD symptoms such as clinical interviews along with self-report measures may provide a more reliable assessment of PTSD presentations amongst participants. Additionally, evidence is limited to participants recruited from the general population. Research should be directed towards individuals presenting in clinical settings to identify the effectiveness and feasibility of TF-GSH within care services.

The education level of participants is an important factor to consider within future studies. A representative sample of the local population may provide further information as to whether TF-GSH materials are accessible to the majority. Many of the studies within this

review did not provide comprehensive information on the socio-economic status of participants. Including this information may provide a greater understanding of whom this treatment may potentially benefit.

It would be beneficial for future research to sufficiently report methodologies employed within an RCT, such as the allocation of participants to groups. This information is important in reviewing the quality of evidence, and some well-designed studies may be disadvantaged by the lack of information provided within their reports. Additionally, information and analysis regarding dropouts is essential in assessing attrition bias and the acceptability of TF-GSH.

RCTs are considered the gold standard of research (Akobeng, 2005). The inclusion of RCTs only within this review aimed to evaluate the highest levels of research in determining the effectiveness of TF-GSH. However, the superiority associated with RCTs in regards to public health interventions has been met with skepticism, described as "too simplistic", with sole reliance on such study designs cautioned (Rychetnik, Frommer, Hawe, & Shiell, 2002; Krantz, 2008; Holmqvist & Persson, 2012). It is deemed necessary to consider study designs and reviews such as this one in context with other valuable research methodologies such as qualitative designs to encompass the complexity of the real world. This highlights the complexity of the decision making process within healthcare and difficulties associated with research into psychological interventions.

4.9 Chapter Summary

TF-GSH as a low-intensity intervention for adults with PTSD and co-morbid symptoms of depression and/or anxiety is associated with a favourable treatment effect. The rate of dropouts is comparable to other intervention studies for PTSD. Reasons provided by participants for dropping out of treatment were primarily related to technical problems experienced with accessing the web based interventions, and a preference for face-to-face

therapy.

Significant and considerable statistical and clinical heterogeneity was associated with diverse range of TF-GSH interventions and therapist input, as well as the studies' clinical samples. The evidence presented may not be applicable to individuals with additional co-morbid mental disorders or those presenting in clinical settings. It is not clear whether the interventions would be accessible for individuals with lower educational levels or additional learning needs. The Internet appears an important vehicle for the dissemination of PTSD interventions, although this may be associated with new barriers to accessing treatment for some individuals.

The body of evidence provided within this review is graded as low, with a recommendation that future research is required to impact upon the level of confidence in the estimate of the treatment effect. The review was deemed comprehensive of the available research in this area, however, eligibility criteria for including or excluding studies could have been more clearly defined. The majority of studies within this review are small which may threaten the reliability of the treatment effect estimate.

The evidence suggests that TF-GSH may be beneficial for a range of trauma types and severity of symptom levels. However, there is no evidence available with regards to the long-term effects of the interventions. It is not clear which are the key components necessary to include within TF-GSH, although imaginal exposure and psychoeducation were incorporated in all study interventions.

Future research may aim to compare TF-GSH with face-to-face evidence based TF-CBT to establish relative effectiveness. It is recommended that future studies include information regarding the intensity of therapist input and intervention to establish cost and time effectiveness as well as the ideal therapeutic dose within a low-intensity intervention. Additionally, the importance of reporting sufficient information in relation to the study's

methodologies is essential in accurately assessing its quality is highlighted. It is advised that this review and future RCTs are considered in the context of other study methodologies to gain a sense of the evidence base necessary to guide future health care decision-making processes.

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Appendix A: PROSPERO Web Links and Registration

- PROSPERO web site

http://www.crd.york.ac.uk/PROSPERO/

- Proposal registered with PROSPERO

http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42015026026

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Guided Self-Help (GSH) interventions for post-traumatic stress disorder: a meta-analysis

Camilla Loveridge, Richard Meiser-Stedman

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Review question(s)
How effective is GSH in reducing symptoms of PTSD?

How effective is GSH in reducing symptoms of co-morbid depression?

How acceptable is GSH as an intervention for PTSD, i.e. drop out rates?

Searches
Studies will be identified by systematic searches of the following bibliographic databases: EMBASE, MEDLINE, PILOTS, CINAHL and PsycINFO. Database searches will be limited from 1980 with no restrictions on language, publication status, or age of participants.

Further search strategies will be employed in addition to database searching and relevant sources will be used to identify "grey" literature.

The detailed search strategy can be found in the accompanying PDF document (link below).

Link to search strategy
http://www.crd.york.ac.uk/PROSPEROFILES/26026_STRATEGY_20150807.pdf

Types of study to be included
As research in this area remains in its infancy, thresholds for eligibility of study design criteria will be less restrictive. Studies which use a Randomised Controlled Trial (RCT) or Controlled Clinical Trial (CCT) design will be included in the review. Cluster and parallel RCT designs will be included. Following guidance from the Cochrane Handbook (Lefebvre, Manheimer, Glanville, 2011; chapter 6.3.a) if the author of the study states explicitly that a random allocation procedure was used then the trial will be classified as a RCT. If no explicit statement regarding randomisation is included, but its use as a procedure cannot be ruled out, or the trial uses a quasi-method of allocation, it will be classified as a CCT.

Condition or domain being studied
Previously, PTSD has been categorised as an anxiety disorder within The Diagnostic and Statistical Manual of Mental Disorders (DSM). Now, in the DSM-5 it falls under a new category, “trauma and stressor-related disorders”. The DSM conceptualises PTSD as occurring when an individual has been exposed to a traumatic event in which they experienced, witnessed, or was confronted with an event or events that involved “actual or threatened death, serious injury, or sexual violence”. The diagnostic criteria that response to the event involved, namely intense fear, helplessness, or horror have been removed from DSM-5 (APA, 2013).

Within the DSM, symptoms include the traumatic event being persistently re-experienced through recurrent and intrusive distressing recollections of the event, and intense psychological distress at exposure to cues that resemble an aspect of the traumatic event. The disorder is characterised by persistent avoidance of external and internal stimuli and increased arousal and reactivity associated with the traumatic event. DSM-5’s PTSD construct includes the

presence of negative mood and cognitions. PTSD is diagnosed when symptoms are present for more than 1 month. The onset of PTSD can be immediately after the stressor or with delayed expression, at least 6 months after the event. The disorder is associated with clinically significant distress and impairment in social and occupational functioning (APA, 2013).

Participants/ population

Studies will be included where individuals have a diagnosis of PTSD given by a qualified clinician or by the administration of standardised diagnostic assessment, or where the presence of PTSD symptoms (mild to severe) is determined by the administration of a PTSD symptom outcome measure. Individuals with co-morbid depression and psychosis will also be included within the review.

Studies will be excluded where participants have additional diagnoses of mental disorder including, personality disorder, neurodevelopmental disorder, and learning disability. Participants with severe depression where their symptoms preclude suitability for psychological intervention (e.g. high risk of suicide, and/or substance dependency, which would interfere with the effectiveness of intervention) will not be considered within this review. Studies where interventions are aimed at carers, professionals, or family of the individual with PSTD will be excluded.

No limits will be placed on gender, setting (e.g. community, hospital, military), the nature of the trauma; the time elapsed since the traumatic event, or the chronicity of PTSD.

Intervention(s), exposure(s)

Studies will be included if they define and employ GSH materials based on trauma-focused CBT, delivered by a trained practitioner.

All other interventions will be excluded. Any studies, which combine the intervention of interest with another intervention e.g. psychotropic medication, will also be excluded. This review will exclude studies, which aim to prevent the onset of PTSD, rather than treat PTSD. The current evidence for GSH for PTSD is minimal and therefore no limit will be set on the variations of GSH (e.g. duration and frequency of GSH intervention, timing of delivery, intensity of therapist input, mode of delivery.), however these factors will be explored through subsequent moderator analyses if appropriate. Modes of intervention delivery include any electronic materials or paper formatted books or manuals. Modes of therapist contact include: telephone calls, texts, emails, letters, videoconference, and face-to-face.

Comparator(s)/ control

The use of randomised comparator groups includes inactive control (e.g. placebo, no treatment, waitlist, treatment as usual, placebo) and active control interventions (e.g. supportive counselling, standalone psycho-education, pharmacotherapy, different model of psychological therapy). If a study includes multiple interventions, such as non-trauma focused CBT and trauma-focused CBT, then only trauma focused CBT will be compared with the control group to create a single pair-wise comparison.

Context

No restrictions will be placed on setting. Both civilian and military populations will be included.

Outcome(s)

Primary outcomes

Inclusion of studies, which use a clinical diagnostic interview or at least one validated outcome measure of PTSD symptomology pre and post- intervention, e.g. the Impact of Events Scale-Revised (IES-R), the Post-traumatic Stress Disorder Checklist (PCL), Post-traumatic Diagnostic Scale (PDS).

Secondary outcomes

No limits will be set on secondary outcomes. Data from studies, which include outcome measures assessing depression, will be included in a meta-analysis. Outcomes assessing the quality of life, therapeutic alliance, and patient satisfaction, will be of interest and incorporated into the discussion of the review. In addition, information regarding drop out rates will be extracted to explore acceptability of the intervention.

Data extraction, (selection and coding)

Selection:

1. Search results will be merged using EndNote software, and duplicate records of reports removed.

2. The primary researcher will examine titles and abstracts of the studies and those studies that are apparently irrelevant will be removed.

3. Full texts of potentially relevant reports will be retrieved.

4. Multiple reports of the same study will be linked together.

5. The primary researcher and collaborator will independently examine and apply eligibility criteria to full-text reports. If the assessors know the names of the study authors, institutions, journal of publication, or results at the time of applying the eligibility criteria, this will be recorded and considered within the review.

6. The primary researcher and collaborator will correspond to clarify study eligibility and to resolve any disagreements that arise through discussion.

7. Study authors will be contacted for further information, such as a request for missing data where necessary.

8. Final decisions will be made on study inclusion before proceeding to data collection.

Coding:

Data will be extracted using a data extraction form with coding instructions. The primary researcher and a collaborator will carry out data extraction independently. Disagreements will be addressed by discussion. If this is not sufficient, the disagreement may necessitate mediation by another person (e.g. another member of the department or supervisor).

The following information will be extracted: year of publication; type of report; group descriptors, e.g. intervention format, comparators, intensity of treatment; sample descriptors, number and characteristics of participants, e.g. mean age and gender; design descriptors, e.g. method of allocation, outcome measures used; and effect size data.

Risk of bias (quality) assessment

The Cochrane Collaboration's tool for assessing risk of bias will be used with judgements categorised as 'Low risk' of bias, 'High risk' of bias or 'Unclear risk' of bias for included studies within the review.The primary researcher and collaborator will carry out the assessment. Forest plots stratified according to risk will be used to explore the likely impact of risk of bias on results. Meta-regression will be employed to compare intervention effects of studies at 'High risk', 'Unclear risk' and 'Low risk' studies. If appropriate, this review intends to stratify studies according to risk of bias producing at least three estimates of the intervention effect: from studies at 'High risk', at 'Low risk', and from all studies. The three estimates would be clearly presented in the abstract of the review.

Strategy for data synthesis

A meta-analysis will be conducted for PTSD data using the Review Manager software (RevMan Version 5.3, 2014). A separate meta-analysis will be also conducted for depression outcome measures. The random-effects (DerSimonian and Laird) model (DerSimonian, 1986) will be used based on the assumption that there will be heterogeneity amongst the intervention effects across studies.

Heterogeneity will be assessed using the I-squared statistic.

Analysis of subgroups or subsets

If appropriate, this review will aim to investigate the following potential effect modifiers: intensity (frequency and duration) of therapist input and intervention, modality of intervention, and sample (military versus civilian).

Dissemination plans

This review will be conducted as part as a doctoral thesis. The aim is to disemminate findings within selected

conferences and journals.

Contact details for further information
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Organisational affiliation of the review
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Review team
Miss Camilla Loveridge, University of East Anglia
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Collaborators
Miss Verity Chester, Partnerships In Care Learning Disabilities

Anticipated or actual start date
11 September 2015

Anticipated completion date
01 March 2016

Funding sources/sponsors
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Conflicts of interest
None known

Other registration details
University of East Anglia, UK

Language
English

Country
England

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Health Behavior; Humans; Stress Disorders, Post-Traumatic

Stage of review
Ongoing

Date of registration in PROSPERO
08 September 2015

UNIVERSITY of York
Centre for Reviews and Dissemination

NHS
National Institute for Health Research

Date of publication of this revision
08 September 2015

DOI
10.15124/CRD42015026026

Stage of review at time of this submission	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Appendix B: Web Links for Search Sources

EMBASE: https://www.elsevier.com/solutions/embase-biomedical-research

MEDLINE: http://www.ncbi.nlm.nih.gov/pubmed

PILOTS: http://www.proquest.com/products-services/pilots-set-c.html

PsycINFO: http://www.apa.org/pubs/databases/psycinfo/

Web of Science: http://ipscience.thomsonreuters.com

ProQuest Dissertation & Theses A&I: http://www.proquest.com/products-services/pqdtglobal.html

OpenGrey: http://www.opengrey.eu

The Cochrane Library: http://www.cochranelibrary.com

Centre for Reviews & Dissertations: https://www.york.ac.uk/crd/

NICE Evidence Search Engine: https://www.evidence.nhs.uk

International Clinical Trials Registry Platform: http://apps.who.int/trialsearch/

Google Scholar: https://scholar.google.co.uk

Appendix C: Search Strategies

EMBASE

1. posttraumatic stress OR posttraumatic stress disorder OR "posttraumatic stress disorder (PTSD)" [EMTREE Terms: major descriptors]
2. ("posttraumatic stress disorder" OR "post-traumatic stress disorder" OR "PTSD" OR "post traumatic stress disorder" OR "posttraumatic" OR "post-traumatic" OR "traumatic event") [Title, Abstract]
3. self-help OR self care [EMTREE Terms: major descriptors]
4. ("web*" OR "comput*" OR "internet" OR "online" OR "bibliotherapy" OR "videotape" OR "audiotape" OR "etherapy" OR "cybertherapy" OR "e-health" OR "videoconferenc*" OR "videoteleconferenc*" "interapy" OR "tele*" OR "electronic" OR "skype" OR "instant messaging" OR "mobile" OR "tape" OR "DVD*" OR "CD*" OR "self-help" OR "self-care" OR "self-directed" OR "self-change" OR "self-management" OR "self-administ*" OR "guided self-help" OR "guided self-change" OR "guided" OR "self-exposure" OR "minimal contact" OR "minimal therapist contact" OR "reduced contact" OR "reduced therapist contact" OR "limited contact" OR "limited therapist contact" OR "therapist assisted") [Title, Abstract]
5. crossover procedure OR double blind procedure OR randomized controlled trial OR single blind procedure OR controlled clinical trial [EMTREE Terms: not 'exploded']
6. ("random*" OR "factorial" OR "crossover*" OR "cross over*" OR "cross-over" OR "placebo" OR (doubl* blind*) OR (singl* blind*) OR "assign*" OR "allocate*" OR "volunteer*") [Title, Abstract]
7. 1 OR 2
8. 3 OR 4
9. 5 OR 6
10. 7 AND 8 AND 9 [Limit to: Publication Year 1980-2015]

MEDLINE

1. stress disorders, post-traumatic/ OR stress disorders, traumatic/ OR combat disorders/ [MeSH Terms: major descriptors]
2. ("posttraumatic stress disorder" OR "post-traumatic stress disorder" OR "PTSD" OR "post traumatic stress disorder" OR "posttraumatic" OR "post-traumatic" OR "traumatic event") [Title, Abstract]
3.bibliotherapy OR telemedicine [MeSH Terms: major descriptors]
4. ("web*" OR "comput*" OR "internet" OR "online" OR "bibliotherapy" OR "videotape" OR "audiotape" OR "etherapy" OR "cybertherapy" OR "e-health" OR "videoconferenc*" OR "videoteleconferenc*" "interapy" OR "tele*" OR "electronic" OR "skype" OR "instant messaging" OR "mobile" OR "tape" OR "DVD*" OR "CD*" OR "self-help" OR "self-care" OR "self-directed" OR "self-change" OR "self-management" OR "self-administ*" OR "guided self-help" OR "guided self-change" OR "guided" OR "self-exposure" OR "minimal contact" OR "minimal therapist contact" OR "reduced contact" OR "reduced therapist contact" OR "limited contact" OR "limited therapist contact" OR "therapist assisted") [Title, Abstract]
5. clinical trials as topic [MeSH Term: not 'exploded']
6. ("random*' OR "placebo" OR "trial" OR "group*") [Title, Abstract]
7. controlled clinical trial or randomized controlled trial [Publication Type]

8. 1 OR 2
9. 3 OR 4
10. 5 OR 6
11. 8 AND 9 AND 10
12. 11 [Limit to: Publication Year 1980-2015]

PsycINFO

1. posttraumatic stress disorder [Subject Term: major descriptor]
2. ("posttraumatic stress disorder" OR "post-traumatic stress disorder" OR "PTSD" OR "post traumatic stress disorder" OR "posttraumatic" OR "post-traumatic" OR "traumatic event") [Title, Abstract]
3. self management OR self help techniques [Subject Terms: major descriptors]
4. ("web*" OR "comput*" OR "internet" OR "online" OR "bibliotherapy" OR "videotape" OR "audiotape" OR "etherapy" OR "cybertherapy" OR "e-health" OR "videoconferenc*" OR "videoteleconferenc*" "interapy" OR "tele*" OR "electronic" OR "skype" OR "instant messaging" OR "mobile" OR "tape" OR "DVD*" OR "CD*" OR "self-help" OR "self-care" OR "self-directed" OR "self-change" OR "self-management" OR "self-administ*" OR "guided self-help" OR "guided self-change" OR "guided" OR "self-exposure" OR "minimal contact" OR "minimal therapist contact" OR "reduced contact" OR "reduced therapist contact" OR "limited contact" OR "limited therapist contact" OR "therapist assisted") [Title, Abstract]
5. clinical trials [Subject Term: not 'exploded']
6. ("random*" OR "factorial" OR "crossover*" OR "cross over*" OR "cross-over" OR "placebo" OR (doubl* blind*) OR (singl* blind*) OR "assign*" OR "allocate*" OR "volunteer*" OR "control*" OR (clinical trial)) [Title, Abstract]
7. 1 OR 2
8. 3 OR 4
9. 5 OR 6
10. 7 AND 8 AND 9

PILOTS

1. ("self help techniques" OR "computer assisted psychotherapy" OR "bibliotherapy" OR "telemedicine") [Subject Terms: exact]
2. "clinical trial" OR "randomized clinical trial" [Subject Terms: exploded]
3. 1 AND 2 [Limit to: Publication Year 1980-2015]

Web of Science

1. ("posttraumatic stress disorder" OR "post-traumatic stress disorder" OR "PTSD" OR "post traumatic stress disorder" OR "posttraumatic" OR "post-traumatic" OR "traumatic event") [Topic]
2. ("web*" OR "comput*" OR "internet" OR "online" OR "bibliotherapy" OR "videotape" OR "audiotape" OR "etherapy" OR "cybertherapy" OR "e-health" OR "videoconferenc*" OR "videoteleconferenc*" "interapy" OR "tele*" OR "electronic" OR "skype" OR "instant messaging" OR "mobile" OR "tape" OR "DVD*" OR "CD*" OR "self-help" OR "self-care" OR "self-directed" OR "self-change" OR "self-management" OR "self-

administ*" OR "guided self-help" OR "guided self-change" OR "guided" OR "self-exposure" OR "minimal contact" OR "minimal therapist contact" OR "reduced contact" OR "reduced therapist contact" OR "limited contact" OR "limited therapist contact" OR "therapist assisted") [Topic]
3. ("random*" OR "factorial" OR "crossover*" OR "cross over*" OR "cross-over" OR "placebo" OR (doubl* blind*) OR (singl* blind*) OR "assign*" OR "allocate*" OR "volunteer*" OR "control*" OR (clinical trial)) [Topic]
4. 1 AND 2 AND 3

Proquest Dissertation

1. ("posttraumatic stress disorder" OR "post-traumatic stress disorder" OR "PTSD" OR "post traumatic stress disorder" OR "posttraumatic" OR "post-traumatic" OR "traumatic event") [Title, Abstract]
2. ("web*" OR "comput*" OR "internet" OR "online" OR "bibliotherapy" OR "videotape" OR "audiotape" OR "etherapy" OR "cybertherapy" OR "e-health" OR "videoconferenc*" OR "videoteleconferenc*" "interapy" OR "tele*" OR "electronic" OR "skype" OR "instant messaging" OR "mobile" OR "tape" OR "DVD*" OR "CD*" OR "self-help" OR "self-care" OR "self-directed" OR "self-change" OR "self-management" OR "self-administ*" OR "guided self-help" OR "guided self-change" OR "guided" OR "self-exposure" OR "minimal contact" OR "minimal therapist contact" OR "reduced contact" OR "reduced therapist contact" OR "limited contact" OR "limited therapist contact" OR "therapist assisted") [Title, Abstract]
3. ("random*" OR "factorial" OR "crossover*" OR "cross over*" OR "cross-over" OR "placebo" OR (doubl* blind*) OR (singl* blind*) OR "assign*" OR "allocate*" OR "volunteer*" OR "control*" OR (clinical trial)) [Title, Abstract]
4. 1 AND 2 AND 3

OpenGrey

"Posttraumatic stress disorder" OR "post-traumatic stress disorder" OR "PTSD" OR "post traumatic stress disorder" OR "posttraumatic" OR "post-traumatic" OR "traumatic event" [Abstract]

Appendix D: List of Authors for Correspondence

Lisa Beatty, Jessica Bomyea, Suzanne Chambers, Leonard Egede, Michiyo Hirai, Anette Kersting, Britt Klein, Christine Knaevelsrud, Alfred Lange, Brett Litz, Leslie Morland, Frank Neuner, Kyle Possemato, Matthew Price, Jeroen Ruwaard, Denise Sloan, Birgit Wagner, Zhiyun Wang, Kitty Wu, and Yinyin Zang.

Appendix E: Data Extraction Form

Data Extraction Form
Review author ID: *Circle*
VC
CL

Source

Study ID: Authors (*surnames*) Year (*four digits*)
Year: Four digits **(***the year the study was conducted*)
Country of origin: *Text*
Data source: *Circle*
1. Published data only (unpublished not sought)
2. Published & unpublished data
3. Unpublished data only
4. Published data only (unpublished sought but not used)

Identifiers: *Enter text as applicable*
DOI:
ISRCTN:
Clinical Trials.gov:
Other:

Reference type: *Circle*
1. Journal article
2. Book
3. Section of book
4. Conference proceedings
5. Correspondence
6. Unpublished data
7. Cochrane review
8. Cochrane protocol
9. Other (*specify)*

Citation: *Enter text as applicable*
Authors:
English Title:
Original Title:
Journal/Book/Source: Edition:
Date of Publication: Editor(s):
Volume: Publisher Name:
Issue: Pages:

Confirm eligibility: *Circle*
1. Included
2. Excluded (*give reason for exclusion)*

Methods

1. **Study design:** *Circle*
   1.Randomised Control Trial
      a. Parallel-group
      b. Cross Over
      c. Cluster
   2. Clinical Controlled Trial
   3. Unclear

** Following guidance from the Cochrane Handbook (Lefebvre, Manheimer, Glanville, 2011) if the author of the study states explicitly that a random allocation procedure was used then the trial will be classified as a RCT. If no explicit statement regarding randomisation is included, but its use as a procedure cannot be ruled out, or the trial uses a quasi-method of allocation, it will be classified as a CCT.*

Risk of bias
**See Table 8.5.d: Criteria for judging risk of bias in the 'Risk of bias' assessment tool (Higgins, Altman, & Sterne, 2011)*

2. **Random sequence generation (selection bias):** *Circle*
   Low
   Unclear
   High

   Support for judgement: *Text (include quotes and comments)*

3. **Allocation concealment (selection bias):** *Circle*
   Low
   Unclear
   High

   Support for judgement: *Text (include quotes and comments)*

4. **Blinding of participants and personnel (performance bias):** *Circle*
   Low
   Unclear
   High

   Support for judgement: *Text (include quotes and comments)*

5. **Blinding of outcome assessment (detection bias):** *Circle*
   Low
   Unclear
   High

   Support for judgement: *text (include quotes and comments)*

6. **Incomplete outcome data (attrition bias):** *Circle*
   Low
   Unclear
   High

   Support for judgement: *Text (include quotes and comments)*

7. **Selective reporting (reporting bias):** *Circle*
   Low
   Unclear
   High

   Support for judgement: *Text (include quotes and comments)*

8. **Other bias:** *Circle*
   Low
   Unclear
   High

   Support for judgement: *Text (include quotes and comments)*

Participants

9. **Total number of study (at baseline):** *Digits*

10. **Setting:** *Text*

11. **Diagnostic criteria:** *Circle*
    1. DSM-III
    2. DSM-IV
    3. DSM-V
    4. CAPS
    5. CAPS-CA
    6. CAPS-5
    7. PCL-5
    8. SPTSS
    9. PDS
    10. MPSS-SR
    11. IES
    12. IES-R
    13. TSI
    14. TSC-40
    15. Penn Inventory
    16. Other: *(please state)*

12. **Age of whole study:** *Digits*
    Means, standard deviations:
    Ranges:
    Summary details:

13. **Age of intervention group:** *Digits*
    Means, standard deviations:
    Ranges:
    Summary details:

14. **Age of control group:** *Digits*
    Means, standard deviations:
    Ranges:
    Summary details:

15. **Sex of whole study:** *Digits*

	Male	Female
Percentage		
Whole counts		

16. **Sex of intervention group:** *Digits*

	Male	Female
Percentage		
Whole counts		

17. **Sex of control group:** *Digits*

	Male	Female
Percentage		
Whole counts		

18. **Presence of co-moribidity:** *Circle*

1. Mild to moderate depression
2. Severe depression
3. Substance misuse/ addiction
4. Anxiety condition *(please state)*
5. Psychosis
6. Other *(please state)*

19. **Trauma type:** *Text*
    1. Community violence (e.g., mugging, burglary, physical or sexual assault)
    2. Sexual and/or physical abuse
    3. Natural disaster (e.g., earthquake, hurricane)
    4. Serious injury, major surgery, or life-threatening illness
    5. Domestic or family violence, war or political violence (e.g., civil war, terrorism)
    6. Road traffic accident
    7. Sudden unexpected or violent death of someone (e.g. suicide, accident)
    8. Other (please specify)

20. **Socio-demographics (e.g. Education level, Income level, Occupation, Religion):** *Text*

21. **Ethnicity:** *Text*

Interventions

22. **Intervention description:** *Text (sufficient for replication, if feasible)*

23. **Was GSH based on a manual?**
    1. No
    2. Yes
    3. Unclear

24. **GSH material format:** *Circle*
    1. Web
    2. Booklet
    3. Book
    4. Leaflet/hand outs
    5. Audiotape
    6. Videotape
    7. CD-ROM
    8. Mobile Phone (e.g. apps)
    9. Other (please specify)

25. **Length of intervention:** *Digits + text*

26. **Mean hours of treatment received:** *Digits*

27. **Therapist qualifications and training:** *Circle*
    1. Clinical Psychologist
    2. CBT therapist
    3. Mental Health Practitioner
    4. Counselor
    5. Student
    6. Other *(please specify)*

28. **Therapist contact format:** *Circle*
    1. Email
    2. Telephone call
    3. Skype
    4. Face-to-face
    5. Letters
    6. Other *(please specify)*

29. **Number of therapist contact hours offered:** *Digits*

30. **Number of therapist contacts offered:** *Digits*

31. **Number of therapist contact hours received:** *Digits*

32. **Number of therapist contacts received:** *Digits*

33. **Additional comments regarding therapist input:** *Text (e.g. therapist supervision, evidence that specified intervention components were delivered as described)*

34. **Format of control groups** *Circle (Add any additional information of content of control group)*

    1. Treatment as usual
    2. Wait list
    3. Supportive Counseling
    4. Psychoeducation
    5. Other *(please state)*

Additional information:

Outcomes

35. **Outcome measure for PTSD symptoms:** *Circle*
    1. SCID: DSM-III
    2. SCID: DSM-IV
    3. SCID: DSM-V
    4. CAPS
    5. CAPS-CA
    6. CAPS-5
    7. PCL-5
    8. SPTSS
    9. PDS
    10. MPSS-SR
    11. IES
    12. IES-R
    13. TSI
    14. TSC-40
    15. Penn Inventory
    16. Other: *(please state and check validity)*

36. **Outcome measure for depressive symptoms:** *Circle*
    1. SCID: DSM-III
    2. SCID: DSM-IV
    3. SCID: DSM-V
    4. BDI
    5. BDI-II
    6. PHQ-2
    7. PHQ-9
    8. HADS
    9. Other *(please specify and check validity)*

37. **Outcome measure for anxiety symptoms:** *Circle*
    1. BAI
    2. GAD-7
    3. STAI
    4. Other *(please specify and check validity)*

Outcome data key

38. **Outcome report**
    1. Self report
    2. Clinician report
    3. Informant report
39. **Cut off scores/ severity thresholds included:**
    1. No
    2. Yes
    3. Unclear
40. **Unit of measurement:**
    1. Continuous
    2. Dichotomous
41. **Upper limit of measure:** *Digits*
42. **Lower limit of measure:** *Digits*
43. **Is a low score favorable?**
    1. No
    2. Yes
    3. Unclear

	Outcome measure PTSD	**Outcome measure depression**	**Outcome measure anxiety**
39. Outcome report			
40. Cut off score/severity thresholds			
41. Unit of measurement			
42. Upper limit of measure			
43. Lower limit of measure			
44. Is a low score favourable?			

44. **Additional Outcomes of interest:** *Text (These may include measures of quality of life, therapeutic alliance, and patient satisfaction)*

Results

45. **Total number of intervention group (at baseline):** *Digits*

46. **Total number of control group (at baseline):** *Digits*

47. **Sample size of intervention group:** *Digits*

48. **Sample size of control group:** *Digits*

49. **Baseline Group differences:** *Circle*
    1. Not assessed
    2. Assessed, Negligible Differences
    3. Assessed, Some Difference, Judged Unimportant
    4. Assessed, Some Difference, Judged Important (significant differences across several variables/ significant difference on a major variable, e.g. age)

50. **Number of dropouts from intervention group:** *Digits (please give information regarding stage of dropout)*

51. **Number of dropouts from comparator group:** *Digits (please give information regarding stage of dropout)*

52. **Completers' characteristic in comparison to dropouts' characteristic:** *Text*

53. **Reasons for dropouts:** *Text*

Effect Size (ES) Data Key

If more than one relevant outcome variable is used, code effect size data separately for each outcome variable. All of the following items should be coded for each individual effect size using additional columns in the table below

54. **Outcome measure:** Text; Description of outcome variable
55. **Effect size type**
    1**.** Immediately post intervention
    2**.** Follow up
56. **Analysis:**
    1. Completer
    2. Intention-to-treat
57. **Intervention group mean:** Digits
58. **Control group mean:** Digits
59. **Intervention group standard deviation:** Digits
60. **Control group standard deviation:** Digits

	ES 1	**ES 2**	**ES 3**	**ES 4**	**ES 5**	**ES 6**
54. Outcome Measure						
55. ES type						
56. Analysis						
57. Intervention Group Mean						
58. Control Group Mean						
59. Intervention Group SD						
60. Control Group SD						

Miscellaneous

- **Funding source**
- **Key conclusions of the study authors**
- **Miscellaneous comments from the study authors**
- **References to other relevant studies**
- **Correspondence required**
- **Miscellaneous comments by the review author**

Tips!

- Record the source of each key piece of information collected, including where it was found in the report (highlight data in hard copy), or if information was obtained from unpublished sources of personal communications.

- Collect data in the format, which they were reported (then transform).

- Put 'Not stated' or 'Not applicable' rather than leave any items blank.

References

Higgins, J.P.T., Altman, D.G., Sterne, J.A.C. (editors). Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Lefebvre, C., Manheimer, E., Glanville, J. Chapter 6: Searching for studies. In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Appendix F: The Cochrane Collaboration's Risk of Bias Assessment Tool

Show

Table 8.5.d: Criteria for judging risk of bias in the 'Risk of bias' assessment tool

RANDOM SEQUENCE GENERATION **Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.**	
Criteria for a judgement of 'Low risk' of bias.	The investigators describe a random component in the sequence generation process such as: • Referring to a random number table; • Using a computer random number generator; • Coin tossing; • Shuffling cards or envelopes; • Throwing dice; • Drawing of lots; • Minimization*. *Minimization may be implemented without a random element, and this is considered to be equivalent to being random.
Criteria for the judgement of 'High risk' of bias.	The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: • Sequence generated by odd or even date of birth; • Sequence generated by some rule based on date (or day) of admission; • Sequence generated by some rule based on hospital or clinic record number. Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example: • Allocation by judgement of the clinician; • Allocation by preference of the participant; • Allocation based on the results of a laboratory test or a series of tests; • Allocation by availability of the intervention.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information about the sequence generation process to permit judgement of 'Low risk' or 'High risk'.
ALLOCATION CONCEALMENT **Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.**	
Criteria for a judgement of 'Low risk' of bias.	Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: • Central allocation (including telephone, web-based and pharmacy-controlled randomization);

	• Sequentially numbered drug containers of identical appearance; • Sequentially numbered, opaque, sealed envelopes.
Criteria for the judgement of 'High risk' of bias.	Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: • Using an open random allocation schedule (e.g. a list of random numbers); • Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); • Alternation or rotation; • Date of birth; • Case record number; • Any other explicitly unconcealed procedure.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.
BLINDING OF PARTICIPANTS AND PERSONNEL **Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.**	
Criteria for a judgement of 'Low risk' of bias.	Any one of the following: • No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; • Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; • Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgement of 'Low risk' or 'High risk'; • The study did not address this outcome.
BLINDING OF OUTCOME ASSESSMENT **Detection bias due to knowledge of the allocated interventions by outcome assessors.**	
Criteria for a judgement of 'Low risk' of bias.	Any one of the following: • No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; • Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • No blinding of outcome assessment, and the outcome measurement is likely to

	be influenced by lack of blinding; • Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.
Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgement of 'Low risk' or 'High risk'; • The study did not address this outcome.

INCOMPLETE OUTCOME DATA

Attrition bias due to amount, nature or handling of incomplete outcome data.

Criteria for a judgement of 'Low risk' of bias.	Any one of the following: • No missing outcome data; • Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); • Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; • Missing data have been imputed using appropriate methods.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; • 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization; • Potentially inappropriate application of simple imputation.
Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: • Insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided); • The study did not address this outcome.

SELECTIVE REPORTING

Reporting bias due to selective outcome reporting.

Criteria for a judgement of 'Low risk' of bias.	Any of the following: • The study protocol is available and all of the study's pre-specified (primary and

	secondary) outcomes that are of interest in the review have been reported in the pre-specified way; • The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • Not all of the study's pre-specified primary outcomes have been reported; • One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; • One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); • One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; • The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. It is likely that the majority of studies will fall into this category.
OTHER BIAS **Bias due to problems not covered elsewhere in the table.**	
Criteria for a judgement of 'Low risk' of bias.	The study appears to be free of other sources of bias.
Criteria for the judgement of 'High risk' of bias.	There is at least one important risk of bias. For example, the study: • Had a potential source of bias related to the specific study design used; or • Has been claimed to have been fraudulent; or • Had some other problem.
Criteria for the judgement of 'Unclear risk' of bias.	There may be a risk of bias, but there is either: • Insufficient information to assess whether an important risk of bias exists; or • Insufficient rationale or evidence that an identified problem will introduce bias.

Appendix G: Characteristics of Excluded Studies Table

Study	Reason for Exclusion
Aguado 2012	Not a PTSD population. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Alghamdi 2015	Not trauma-focused guided self-help.
Applebaum 2012	Used data from Duhamel et al., 2010.
Baikie 2012	Not a PTSD population. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Basoglu 2003	Not a RCT
Basoglu 2005	Not trauma-focused guided self-help.
Beatty 2009	Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms.
Beatty 2010	Not trauma-focused guided self-help.
Beatty 2011	Not a RCT. Not trauma-focused guided self-help.
Beatty 2015	Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms.
Bernard 2011	Not trauma-focused guided self-help.
Beyer 2010	Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms
Bichescu 2007	Not trauma-focused guided self-help.
Boals 2012	Not trauma-focused guided self-help.
Bomyea 2015	Not trauma-focused guided self-help.
Bomyea 2014	Not trauma-focused guided self-help.
Boscarino 2006	Not a RCT.
Brief 2011	Not a RCT.
Bugg 2009	Preventative study.
Callinan 2011	Not a RCT.
Carpenter 2014	Not a PTSD population. Not trauma-focused guided self-help.
Cernvall 2015	Not trauma-focused guided self-help.
Chambers 2014	Not a PTSD population. Not trauma-focused guided self-help.
Collins 2014	Not a RCT.
Connolly 2011	Not trauma-focused guided self-help.
Cox 2010	Not trauma-focused guided self-help.
Craske 2009	Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms.

Deitsch 2000	Not a RCT.
DuHamel 2015	Not trauma-focused guided self-help.
Duncan 2007	Not a RCT.
Dunn 2007	Not individual trauma-focused guided self-help.
Echeburua 1997	Not a RCT.
Egede 2015	Not a PTSD population. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Ehlers 2003	Not trauma-focused guided self-help.
Eisma 2015	Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms.
Elbers 2013	Not a PTSD population. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Engel 2015	Not trauma-focused guided self-help.
Epstein 2012	Not a RCT.
Erbes 2014	Not a RCT. Not a PTSD population. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Ferdos 2007	Not a RCT. Not trauma-focused guided self-help.
Foa 2006	Not trauma-focused guided self-help.
Ford 1997	Not a RCT. Not trauma-focused guided self-help.
Frueh 2007	Not trauma-focused guided self-help.
Germain 2009	Not trauma-focused guided self-help.
Germain 2014	Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Gillespie 2002	Not a RCT.
Goenjian 1997	Not a RCT. Not trauma-focused guided self-help.
Goenjian 2005	Not a RCT. Not trauma-focused guided self-help.
Gros 2011	Not a RCT. Not trauma-focused guided self-help.
Harned 2013	Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms.
Hedman 2015	Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms.
Held 2015	Not trauma-focused guided self-help.
Hernandez Tejada 2014	Not trauma-focused guided self-help.
Hijazi 2014	Not trauma-focused guided self-help.
Hirai 2005	Not trauma-focused guided self-help.
Hirai 2012	Not a PTSD population. Not trauma-focused guided self-help.
Ho 2014	Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms.
Hobfoll 2015	Not trauma-focused guided self-help.
Ironson 2013	Not a PTSD population. Not trauma-focused guided self-help.

Irvine 2011	Not a PTSD population. Not trauma-focused guided self-help.
Jaber 2012	Not trauma-focused guided self-help.
Jain 2012	Not trauma-focused guided self-help.
Joesch 2012	Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Klein 2009	Not a RCT.
Klein 2010	Not a RCT.
Klein 2011	Not a RCT.
Klinitzke 2013	Not a RCT. Not a PTSD population.
Knaevelsrud 2006	Not a RCT.
Knaevelsrud 2014	Not a RCT.
Lang 2009	Not a PTSD population. Not trauma-focused guided self-help.
Lange 2000	Not an RCT.
Laurette 2007	Not a PTSD population. Not trauma-focused guided self-help.
Le 2013	Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Lewis 2013	Not a RCT.
Litz 2004	Not a RCT. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Litz 2007	Not a RCT.
Litz 2014	Not a PTSD population. Not trauma-focused guided self-help.
Loizzo 2010	Not a PTSD population. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Marsac 2013	Preventative study.
Martino 2012	Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms.
McDevitt-Murphy 2014	Not a PTSD population. Not trauma-focused guided self-help.
Mitchell 2009	Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms.
Mohr 2011	Not a PTSD population. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Morland 2004	Not individual trauma-focused guided self-help.
Morland 2014	Not trauma-focused guided self-help.
Morland 2015	Not trauma-focused guided self-help.
Neuner 2008	Not trauma-focused guided self-help.
Neuner 2004	Not trauma-focused guided self-help.
Nosen 2014	Not trauma-focused guided self-help.
Olthius 2014	Not a PTSD population. Not trauma-focused guided self-help.
Possemato 2010	Not a PTSD population.

Possemato 2011	Not trauma-focused guided self-help.
Possemato in press	Not trauma-focused guided self-help.
Price 2012	Not a RCT. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Price 2015	Not a PTSD population. Not trauma-focused guided self-help.
Proctor 2008	Not trauma-focused guided self-help.
Resnick 2007	Not a PTSD population. Not trauma-focused guided self-help.
Rosen 2013	Not trauma-focused guided self-help.
Rothbaum 2012	Not trauma-focused guided self-help.
Ruggiero 2015	Not trauma-focused guided self-help.
Ruzek 2014	Not a PTSD population. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Salciouglu 2010	Not original study.
Salemink 2014	Did not include measures aimed at assessing PTSD symptoms.
Santacroce 2010	Not a PTSD population. Not trauma-focused guided self-help.
Sayer 2015	Not a PTSD population. Not trauma-focused guided self-help.
Scholes 2007	Not a PTSD population. Not trauma-focused guided self-help.
Schreiber 2001	Not a RCT.
Seal 2012	Not a PTSD population. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Seitz 2014	Not a RCT. Not a PTSD population.
Shalev 2012	Not a PTSD population. Not trauma-focused guided self-help.
Sloan 2011	Not trauma-focused guided self-help.
Sloan 2004	Not trauma-focused guided self-help.
Smyth 2003	Not a RCT. Not a PTSD population. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Somer 2005	Not a RCT. Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms
Spence 2014	No relevant comparator group.
Stanton 2005	Not a PTSD population. Not trauma-focused guided self-help.
Stecker 2014	Not trauma-focused guided self-help.
Steinmetz 2012	Not trauma-focused guided self-help.
Stockton 2014	Not a PTSD population.
Stubbings 2013	Not a PTSD population. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Tuerk 2010	Not a RCT.
Turpin 2005	Not trauma-focused guided self-help.
Van 2012	Not a RCT.

Van der Houwen 2010	Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms.
Verwoerd 2012	Not a PTSD population. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Wagner 2007	Not trauma-focused guided self-help.
Wagner 2012a	Not a RCT. Not trauma-focused guided self-help. Did not include measures aimed at assessing PTSD symptoms.
Wagner 2012b	Not a RCT.
Wang 2013a	Not trauma-focused guided self-help.
Wang 2014	Not a RCT. Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms.
Wang 2013b	Not trauma-focused guided self-help.
Williams 2010	Not a RCT. Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms.
Woud 2013	Not a PTSD population. Did not include measures aimed at assessing PTSD symptoms.
Wu 2014	Not trauma-focused guided self-help.
Yuen 2015	Not trauma-focused guided self-help.
Zang 2013	Not trauma-focused guided self-help.
Zang 2013	Not trauma-focused guided self-help.

Appendix H: List of Ongoing Studies

Study 1	
Register	ANZCTR
Main ID	ACTRN12614001213639
Public title	Internet treatment for Posttraumatic Stress Disorder (PTSD)
URL	http://www.anzctr.org.au/ACTRN12614001213639.aspx
Study 2	
Register	ANZCTR
Main ID	ACTRN12606000401550
Public title	The efficacy of an Internet-based therapy (Interapy) for posttraumatic stress: a randomized controlled trial
URL	http://www.anzctr.org.au/ACTRN12606000401550.aspx
Study 3	
Register	ANZCTR
Main ID	ACTRN12608000259347
Public title	Evaluation of a cognitive-behavioral writing therapy (Integrative testimonial therapy –ITT) of traumatised war children of the II. World War: A randomized trial
URL	http://www.anzctr.org.au/ACTRN12608000259347.aspx
Study 4	
Register	ChiCTR
Main ID	ChiCTR-TRC-12002940
Public title	Resilience and implications from writings of children traumatised by the earthquake: A study of Guided Narrative Technique
URL	http://www.chictr.org.cn/showproj.aspx?proj=6615
Study 5	
Register	ChiCTR
Main ID	ChiCTR-TRC-12002941
Public title	The effect of a Guided Narrative Technique among children traumatised by the earthquake: Pilot study
URL	http://www.chictr.org.cn/showproj.aspx?proj=6614
Study 6	
Register	ClinicalTrials.gov
Main ID	NCT02556645
Public title	A Comparison of Web-Prolonged Exposure (Web-PE) and Present-Centered Therapy
URL	https://clinicaltrials.gov/show/NCT02556645

Appendix I: Within Study Risk of Bias Assessment Results

Study ID: Ivarsson 2014

Type of bias	Entry	Judgment	Support for judgment
Selection bias	Random sequence generation	Low risk	Quote (from report): "Randomization was conducted…using an online true random-number service (www.random.org).
Selection bias	Allocation concealment	Low risk	Quote (from report): "randomization was conducted by an individual who was not otherwise involved in the research project". Comment: Assumed that study investigators could not forsee assignment due to the above.
Performance bias	Blinding of participants and personnel	High risk	Comment: Blinding of participants and personnel not possible for studies of psychological intervention.
Detection bias	Blinding of outcome assessment (self-report measures)	Low risk	Quote (from report): "The post-treatment interviewers were blind to participant status (i.e. treatment or control). Quote (from report): "Blinding was not possible at the 1 year-year follow up due to a lack of a control condition. Comment: The assessors believe that the outcome measures are not likely to be influenced by lack of blinding for post assessment data.
Attrition bias	Incomplete outcome data	Unclear risk	Comment: 3 missing from intervention group and 5 missing from control group. No reasons for dropouts provided. Quote (from report): "The proportion of missing data did not significantly differ between conditions at post-treatment".

			Quote (from report): "Given…the small amount of missing data, we relied on full information maximum likelihood estimation, which provides unbiased estimates under standard data missing assumptions of ignorable missing (i.e., missing at random; e.g., Salim et al., 2008).
Reporting bias	Selective reporting	Unclear risk	Comment: Three outcome measures listed in Methods repeated at post treatment and follow up. No protocol available.
Other bias	Bias due to problems not covered elsewhere in the table	Low risk	Comment: Assessors believe that potential sources of bias are not important and these are discussed within the narrative section of the results.

Study ID: Knaevelsrud & Maercker 2007

Type of bias	Entry	Judgment	Support for judgment
Selection bias	Random sequence generation	Low risk	Quote (from report): "Randomization was based on a computer generated randomization list."
Selection bias	Allocation concealment	Unclear risk	Comment: Not explicitly addressed. Probably done based upon the above.
Performance bias	Blinding of participants and personnel	High risk	Comment: Blinding of participants and personnel not possible for studies of psychological intervention.
Detection bias	Blinding of outcome assessment (self-report measures)	Low risk	Comment: Not addressed by study authors. Assessors judge that self-report measures are not likely to be influenced by lack of blinding.
Attrition bias	Incomplete outcome data	Unclear risk	Comment: 8 dropouts from intervention group and 1 from control group. Quote (from report): "Most frequent reported reasons for dropping out were technical problems (network and computer) and emotional distress due to writing about their stressful events". Comment: No dropout analysis included within the report.
Reporting bias	Selective reporting	Unclear risk	Comment: Four outcome measures listed in Methods repeated at post treatment and follow up. All results reported. No protocol available.
Other bias	Bias due to problems not covered elsewhere in the table	Low risk	Comment: Assessors believe that potential sources of bias are not important and these are discussed within the narrative section of the results.

Study ID: Knaevelsrud 2015

Type of bias	Entry	Judgment	Support for judgment
Selection bias	Random sequence generation	Low risk	Quote (from report): "Randomization was conducted based on a computer – generated randomization list"
Selection bias	Allocation concealment	Unclear risk	Comment: Not described. Probably done based upon the above.
Performance bias	Blinding of participants and personnel	High risk	Comment: Blinding of participants and personnel not possible for studies of psychological intervention. Quote (from report): " Researchers and psychotherapists were not masked to the intervention."
Detection bias	Blinding of outcome assessment (self-report measures)	Low risk	Quote (from report): " a fully automated computerized assessment battery including all outcome measures in the trial". Comment: All assessments were completed using an online system. It is not clear whether scoring was automated. Assessors judge that self-report measures are not likely to be influenced by lack of blinding.
Attrition bias	Incomplete outcome data	Low risk	Comment: 32 participants dropped out of the treatment group. Quote (from report): "The treatment group did not differ from the control group in terms of attrition rate". "At baseline, there were no differences in their posttraumatic stress symptoms, anxiety, or depression levels". Quote (from report): " We ascertained that three participants were lost due to difficulties with electricity and Internet access. Two patients had to terminate the treatment due to hospitalization and were referred to local psychiatrist. Two

			participants preferred face-to-face therapy, whereas another three patients completed the treatment but not the posttreatment and assessment." Comment: Reasons for missing outcome data unlikely to be related to true outcome.
Reporting bias	Selective reporting	Unclear risk	Comment: All expected outcomes reported. No protocol available.
Other bias	Bias due to problems not covered elsewhere in the table	Low risk	Comment: Assessors believe that potential sources of bias are not important and these are discussed within the narrative section of the results.

Study ID: Lange 2003

Type of bias	Entry	Judgment	Support for judgment
Selection bias	Random sequence generation	Low risk	Quote (from report): " The computer assigned participants randomly"
Selection bias	Allocation concealment	Unclear risk	Comment: Not described. Probably done based upon the above.
Performance bias	Blinding of participants and personnel	High risk	Comment: Blinding of participants and personnel not possible for studies of psychological intervention.
Detection bias	Blinding of outcome assessment (self-report measures)	Low risk	Quote (from report): " The Interapy system automatically analysed the answers of the participants". Comment: Assessors judge that self-report measures are not likely to be influenced by lack of blinding.
Attrition bias	Incomplete outcome data	Low risk	Comment: 44 participants in the treatment group did not complete the treatment. Reasons included technical problems (network and computer), a preference for face-to-face contact, and experiencing the writing assignments "as too much of a burden". 30 participants dropped out of the control group as "they did not wish to wait or had decided on at the therapy". Quote: No differences were found in…general psychological functioning measured with the IES and the SCL-90. Comment: Reasons for missing outcome data unlikely to be related to true outcome.
Reporting bias	Selective reporting	Unclear risk	Comment: All expected outcomes reported. No protocol available.
Other bias	Bias due to problems not covered elsewhere	Low risk	Comment: Assessors believe that potential sources of bias are not

in the table		important and these are discussed within the narrative section of the results.

Study ID: Litz 2007

Type of bias	Entry	Judgment	Support for judgment
Selection bias	Random sequence generation	Low risk	Comment: Not described within the report. Quote (from correspondence): "Randomization will use a process of minimization (Pocock, 1983) stratified on gender, co-morbidity (depression indexed by BDI-2), and severity of PTSD."
Selection bias	Allocation concealment	Unclear risk	Comment: Not described within the report. Quote (from correspondence): "Allocation was done by my staff here in Boston (the trial occurred at Walter Reed Army Medical Center)."
Performance bias	Blinding of participants and personnel	High risk	Comment: Blinding of participants and personnel not possible for studies of psychological intervention.
Detection bias	Blinding of outcome assessment (self-report measures)	Low risk	Quote (from report): "Clinicians blind to the study arm conducted the follow-up evaluations". Comment: Assessors judge that self-report measures are not likely to be influenced by lack of blinding.
Attrition bias	Incomplete outcome data	Unclear risk	Quote (from report): " seven dropped out during treatment". Quote (from report): " There were no differences in dropouts between the two study arms overall" Comment: No information provided on the reasons for dropouts. Hierarchical linear modeling analysis model was used

			with an expectation-maximization algorithm for full maximum likelihood estimation of missing data. There is not enough information to permit a judgment about whether the reason for missing outcome data is likely to be related to true outcome.
Reporting bias	Selective reporting	High risk	Comment:. Only completer results presented although ITT analysis conducted. No protocol available.
Other bias	Bias due to problems not covered elsewhere in the table	Low risk	Comment: Assessors believe that potential sources of bias are not important and these are discussed within the narrative section of the results.

Study ID: Sloan 2012

Type of bias	Entry	Judgment	Support for judgment
Selection bias	Random sequence generation	Low risk	Quote (from report): " Computer generated random sequence…"
Selection bias	Allocation concealment	Low risk	Quote (from report):" …of concealed slips, opened in agreement to participate by a person other than the assessors".
Performance bias	Blinding of participants and personnel	High risk	Comment: Blinding of participants and personnel not possible for studies of psychological intervention.
Detection bias	Blinding of outcome assessment (self-report measures)	Low risk	Quote (from report): "Clinicians, who were unaware of condition assignment and study assessment period, conducted the diagnostic assessments". Comment: Assessors judge that self-report measures are not likely to be influenced by lack of blinding.
Attrition bias	Incomplete outcome data	Low risk	Quote (from report): " one participant indicated that the reason she dropped out of WET (after three sessions) was because the treatment was making her "think too much" about her car accident, which she found unpleasant. The other participant reported that he dropped out of WET (after two sessions) because he was feeling better." Quote (from correspondence): " we had 100% retention at follow-up assessment (including the two people who dropped out prematurely from treatment)
Reporting bias	Selective reporting	High risk	Comment: The study did not report results from the 30-week follow-up. No results were available in a table to calculate effect sizes. No protocol available.

Other bias	Bias due to problems not covered elsewhere in the table	Low risk	Comment: Assessors believe that potential sources of bias are not important and these are discussed within the narrative section of the results.

Study ID: Spence 2011

Type of bias	**Entry**	**Judgment**	**Support for judgment**
Selection bias	Random sequence generation	Low risk	Quote (from report): " randomised via a true randomisation process (www.random.org)…"
Selection bias	Allocation concealment	Low risk	Quote (from report): " … generated by an independent person".
Performance bias	Blinding of participants and personnel	High risk	Comment: Blinding of participants and personnel not possible for studies of psychological intervention.
Detection bias	Blinding of outcome assessment (self-report measures)	Low risk	Comment: Not addressed by study authors for primary outcome measures. Assessors judge that self-report measures are not likely to be influenced by lack of blinding.
Attrition bias	Incomplete outcome data	Unclear risk	Comment: Data missing at follow up for 2 participants in the intervention group. No dropout analysis reported. Quote (from report): "five participants did not complete the program: one for unknown reasons; three because of competing time commitments; and one because of a relapse of depressive symptoms. There were no formal dropouts during the treatment program".
Reporting bias	Selective reporting	Unclear risk	Comment: All expected outcomes were reported. No protocol available.
Other bias	Bias due to problems not covered elsewhere in the table	Low risk	Comment: Assessors believe that potential sources of bias are not important and these are discussed within the narrative section of the results.

Study ID: Wagner 2006

Type of bias	Entry	Judgment	Support for judgment
Selection bias	Random sequence generation	Low risk	Quote (from report): " the computer assigned participants randomly to the (immediate) treatment condition or to the waiting list condition."
Selection bias	Allocation concealment	Unclear risk	Comment: Not addressed within the report.
Performance bias	Blinding of participants and personnel	High risk	Comment: Blinding of participants and personnel not possible for studies of psychological intervention.
Detection bias	Blinding of outcome assessment (self-report measures)	Low risk	Comment: Not addressed by study authors for primary outcome measures. Assessors judge that self-report measures are not likely to be influenced by lack of blinding.
Attrition bias	Incomplete outcome data	Unclear risk	Comment: No dropout analysis reported. Quote (from report): " 8% (*n*= 4) did not complete the first phase and were considered dropouts: one participant would have preferred faced-to-face contact; two said it was too soon after the death; one participant did not give any reasons."
Reporting bias	Selective reporting	Unclear risk	Comment: All expected outcomes were reported. No protocol available.
Other bias	Bias due to problems not covered elsewhere in the table	Low risk	Comment: Assessors believe that potential sources of bias are not important and these are discussed within the narrative section of the results.