Posttraumatic Stress Disorder and Psychological Therapies

Submitted by Samantha Gerdes, to the University of Exeter
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LITERATURE REVIEW

A Review of Psychological Therapies for Sleep Disturbances in Sufferers of PTSD

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Abstract

The current review presents a recent review of the effectiveness of psychological therapies to treat sleep difficulties (such as insomnia and nightmares) in sufferers of posttraumatic stress disorder (PTSD). The review also aimed to investigate whether there are differences in the effectiveness of specific psychological therapies to treat sleep disturbances in PTSD, such as between the different types of psychological therapies such as cognitive behavioural therapy for insomnia (CBT-I) and imagery rehearsal therapy (IRT). Eleven studies were included in the review that met the inclusion and exclusion criteria. Results are presented in tables and a descriptive account is included. The review demonstrates that psychological therapies are effective for the treatment of insomnia and other sleep difficulties such as nightmares. However, firm conclusions cannot be drawn about the effectiveness of different types of psychological therapies as studies predominantly used CBT and only one non-CBT study was included in the review. Comparisons between the effectiveness of different CBT approaches is also not possible as there was a large range of diversity in the study characteristics and also there were only a small number of studies for each intervention, which therefore limits the generalisability of results in the current review. It may be that different CBT interventions such as CBT-I or EERT and IRT may be better suited to treat insomnia and nightmares respectively, but further research needs to be conducted into which of these approaches are beneficial for different PTSD specific sleep difficulties.

Keywords: Sleep disturbance, insomnia, PTSD

Introduction

Rationale

Post-traumatic Stress Disorder (PTSD) affects between 7-12% in the general population (Kessler, et al., 2005) and sleep difficulties form part of the DSM-5 diagnostic criteria for PTSD (American Psychological Association, 2013). Problems with sleep can have a large impact on health and quality of life as well as daily functioning (DeViva, Zayfert, & Mellman, 2004). Sleep disturbances are arguably some of the most distressing symptoms of PTSD, due to exacerbating other symptoms and leading to daytime impairment (Nappi, Drummond, & Hall, 2012). Studies have shown that sleep difficulties affect a high proportion of people suffering from PTSD, as 70-91% of patients with PTSD have trouble falling or staying asleep and between 19-71% of patients report nightmares (Maher, Rego, & Asnis, 2006).

Polysonograpic studies have demonstrated that people with PTSD have objective sleep abnormalities (e.g., less slow wave sleep and greater rapid-eye-movement density) compared with people without PTSD (Kobayashi, Boarts, & Delahanty, 2007). Whilst it was originally thought that sleep difficulties were a symptom of PTSD, it is now generally accepted that sleep is largely implicated in PTSD development and maintenance (Picchioni, et al., 2010; Gehrman, Harb & Ross, 2016). Disturbed sleep prior to trauma exposure and also after trauma exposure can increase vulnerability to development of PTSD (e.g., Gehrman et al., 2013; Mellman, Bustamante, Fins, Pigeon, & Nolan, 2002) and studies have demonstrated the impact that sleep has on the severity of PTSD symptoms, even after the effect of other factors such as trauma characteristics and alcohol use are controlled for (Belleville, Guay, & Marchand, 2009). Additionally, in patients that no longer met diagnostic criteria for PTSD following treatment with psychological

therapy, approximately 50% had residual sleep disturbances (residual insomnia) (Zayfert, & DeViva, 2004). This suggests that sleep difficulties tend to become independent of PTSD over time, rather than being a symptom of PTSD which would resolve after successful treatment for PTSD (Gehrman et al., 2016).

Sleep Disturbances in PTSD

Differences exist in the symptom expression of PTSD sufferers, especially in regard to comorbid sleep difficulties (Wallace, Iyengar, Bramoweth, Frank, & Germain, 2015). For example, some may present with insomnia whereas others may also experience nightmares or other PTSD specific sleep difficulties (Maher, et al., 2006). Past reviews have often focused on sleep difficulties such as insomnia and sleep quality but have neglected to include findings on nightmares and PTSD specific sleep difficulties (e.g., Ho et al., 2016). Nightmares form a significant component of the PTSD symptom presentation (Maher, et al., 2006) therefore these symptoms are important to consider when examining evidence for suitable treatment approaches.

Therefore, in the current review, sleep difficulties in PTSD sufferers will be operationalised in four ways: ‘insomnia’, ‘sleep quality’, ‘PTSD specific sleep difficulties’ (such as nightmares, episodes of terror during sleep or acting out dreams such as kicking running or screaming; Germain, Hall, Krakow, Shear, & Buysse, 2005) and ‘nightmares’. Conceptualising sleep difficulties in this way may also highlight differences in treatment effectiveness for different PTSD presentations.

Treatment for Sleep Disturbances in PTSD

As sleep disturbances in PTSD can be debilitating, they can further contribute to the development and maintenance of PTSD and can also remain after PTSD treatment (Zayfert, & DeViva, 2004), it is important to offer sleep specific treatments

to PTSD suffers (Gehrman et al., 2016) as improving sleep can improve daytime functioning as well as PTSD symptoms (Margolies, 2011).

Pharmacological and psychological therapies are two common approaches used to treat insomnia in people with PTSD and have been used independently or in conjunction with one another (Nappi et al., 2012). Pharmacotherapy is the most common treatment for insomnia (e.g., Edinger et al., 2009) despite limited evidence of the effectiveness to treat insomnia in PTSD sufferers. A recent review suggests that aside from Prazosin (an adrenergic inhibiting agent), few pharmacological treatments demonstrate efficacious results (Lipinska, Baldwin, & Thomas, 2016).

Psychological therapies on the other hand, have demonstrated promising results in the treatment of insomnia in PTSD sufferers, including approaches such as relaxation (e.g., Edinger, et al., 2001), stimulus control (e.g., Riedel et al., 1998) and cognitive-behavioural therapy (CBT) (e.g., Ho, Chan, & Tang, 2016). Commonly used psychological therapies for insomnia include Cognitive Behavioural Therapy for insomnia (CBT-I), Imagery Rehearsal Therapy (IRT) or a combination of the two (Ulmer, Edinger, & Calhoun, 2011), and treatment is delivered individually or in group sessions (Talbot et al., 2014; Krakow et al., 2001). Novel treatments are also emerging, such as using yoga (e.g., Jindani, Turner, & Khalsa, 2015) or mind-body bridging (MBB) (e.g., Nakamura, Lipschitz, Landward, Kuhn & West, 2011).

CBT-I comprises four main techniques including stimulus control and sleep restriction (known as the sleep scheduling component), sleep hygiene and cognitive restructuring (Morin, 1993). The approach utilises behavioural techniques such as breaking habitual behaviours and associations that are not fundamental to sleep, e.g., association of the bedroom and wakefulness. Sleep is restricted to consolidate sleep over a shorter amount of time in bed, and behavioural and environmental

changes are encouraged to facilitate a good night's sleep. Cognitive restructuring aims to change the maladaptive cognitions that people may hold about sleep (Morin, 1993).

IRT is a manualised approach used for the treatment of insomnia in PTSD sufferers (Rose, 2013), that focuses on sleep hygiene, relaxation, exposure of nightmare content and rewriting and rehearsal of rewritten nightmare content (Davis & Wright, 2006). A meta-analysis has demonstrated that studies using this approach had a large effect on reductions of nightmare frequency, sleep quality and PTSD symptoms, and effects were sustained through 6 to 12-month follow-up (Casement & Swanson, 2012).

Rationale

Previous reviews have also investigated psychological therapies to treat sleep disturbance in PTSD sufferers and the current review builds on these in the following ways. Firstly, past reviews demonstrate that sleep-specific cognitive behavioural therapy (CBT) is efficacious and feasible in remediating PTSD symptoms and depression, as well as insomnia severity and sleep quality (Ho, et al., 2016), however despite identifying studies that treat insomnia, they report overall PTSD severity as the outcome rather than insomnia. In contrast, the current review focuses on identifying studies that specifically target sleep disturbances in PTSD sufferers and assess sleep-specific variables such as insomnia, nightmares, PTSD specific sleep difficulties and sleep quality in PTSD sufferers.

In addition, the current review is original as firstly, no review has been conducted that specifically examines the effect of sleep-focused psychological treatments on sleep outcomes and secondly, past reviews that did include sleep-focused psychological treatments, have neglected sleep-specific outcomes such as

insomnia (e.g., Casement & Swanson, 2012), nightmares and PTSD specific sleep difficulties (e.g., Ho et al., 2016). Arguably this is a significant oversight, as nightmares and PTSD specific sleep disturbances[1] are significant components of the PTSD symptom presentation (Maher, et al., 2006) and often comprise the residual symptoms following trauma-focused CBT (TF-CBT) (Zayfert, & DeViva, 2004). Therefore, it is fundamental to present all sleep-specific outcomes in a review that investigates treatments for PTSD sufferers and the current review achieves this by including all types of sleep disturbances, i.e., 'insomnia', 'sleep quality', 'PTSD specific sleep difficulties' and 'nightmares', whilst other reviews do not.

Additionally, until this point, no review has investigated the differences between the effectiveness of different therapies in treating insomnia in PTSD sufferers. Psychological therapies use different therapeutic components and significant variability often exists even within one approach e.g., between CBT-I and IRT. The current review also adds to past reviews, as original and broader search terms are used in order to identify both CBT and non-CBT studies that treat sleep disturbances in PTSD sufferers, whereas past reviews such as Ho et al., 2016, have been limited to CBT studies only.

Although evidence supports the use of psychological therapy in the treatment of sleep difficulties in PTSD sufferers, there is a paucity of randomised controlled trails and there has not been a recent review of the evidence i.e., Ho, et al., (2016) searched databases in 2014, therefore, the current review will search databases for articles over an additional period of 3.5 years. Cochrane Guidance (2017) recommends that reviews are updated every two years in order to provide the most

[1] (such as nightmares, episodes of terror during sleep or acting out dreams such as kicking running or screaming; Germain, Hall, Krakow, Shear, & Buysse, 2005)

up to date evidence on the effects of an intervention to inform healthcare decisions (Higgins, Green & Scholten, 2011; Cochrane Guidance, 2017). Therefore, an updated review of the effectiveness of psychological therapies to treat sleep difficulties in PTSD sufferers is overdue.

Finally, an update in this field is vital, given that there has been increasing clinical and theoretical interest in addressing sleep disorders in trauma survivors with PTSD. For example, draft NICE Guidance (2018) for the treatment of PTSD suggests symptom-specific CBT interventions (e.g., for sleep disturbance) should be used for those who are unable or willing to engage in a trauma focused intervention or have residual symptoms after a trauma-focused intervention.

Objectives

The aims of the current review are firstly, to present a recent review of the effectiveness of psychological therapies to treat sleep disturbances (such as insomnia and nightmares) in PTSD sufferers. To our knowledge, a recent review has not been completed that includes studies published since 2014, nor one that presents all facets of sleep disturbances for PTSD sufferers (including nightmares) and in addition, focuses on sleep disturbances as a primary outcome rather than focusing on PTSD outcomes. The second aim of the study, is to investigate whether there are differences in the effectiveness of specific psychological therapies to treat sleep disturbances in PTSD sufferers, including the differences within specific therapy modalities, such as different CBT approaches i.e., CBT-I and IRT.

Method

Protocol and Registration

In order to support transparency of the systematic review process (Kirkham, Altman, & Williamson, 2010), a protocol was written for the current systematic

review, though this was not registered on a systematic review protocol database such as PROSPERO. However, no post hoc changes were made to the planned methodology and analysis. The PRISMA statement (Appendix A) (Moher, Liberati, Tetzlaff, & Altman, 2009) and Cochrane Handbook for Systematic Review of Interventions (Higgins & Green, 2011) were followed in order to structure the review.

Eligibility Criteria

Population, Intervention, Comparator, Outcomes, Study Design (PICOS)

Population. Participants were aged 16 or over, with insomnia or sleep difficulties as indicated by valid and reliable insomnia measures such as Insomnia Severity Index (ISI; Morin, 1993) or meeting research diagnostic criteria for insomnia (Edinger et al., 2004) and who also have a diagnosis of PTSD or, participants who have been assessed for PTSD symptomology in non-clinical populations using a PTSD measure such as the PTSD Checklist for DSM-5 (PCL-5) (Weathers, et al., 2013). No limitations were placed on the severity of PTSD or insomnia symptoms, and populations with comorbid mental health problems were eligible for inclusion.

Intervention. Psychological or psychosocial interventions to treat sleep disturbances were identified as the intervention target. Studies that treated insomnia as a secondary outcome measure or used an intervention to treat a comorbid mental health problem whilst measuring the impact on insomnia were excluded from the review. No limitations were placed on type of health professional delivering the psychological or psychosocial intervention nor the setting of treatment delivery.

Comparator. Only studies that used a control or comparison group were included in the current review, as per the guidance by Cochrane Handbook for Systematic Review of Interventions, which recommends to only include rigorous studies e.g., randomised trials (O'Connor, Green, & Higgins, 2011).

Outcome. Studies using primary outcome measurements of sleep difficulties using standardised, validated self-report or clinician administered measures producing continuous data were included in the review, such as the Pittsburgh Sleep Quality Index Addendum for PTSD (PSQI-A; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989).

Study Design. Study designs were included that are randomised controlled trials (RCT) that used active and inactive controls. To include inactive controls, the study enabled the effect of the psychological intervention to be isolated, such as 'psychological intervention vs control' (no-treatment control, wait-list control, treatment as usual) and studies were excluded if a different methodology was used, such as pre-post designs without a comparison or control group. Both published and unpublished studies were included in the review, including unpublished doctoral dissertations.

Information Sources

Eligible studies were identified through a search of relevant databases (EMBASE, Medline, PsychInfo) and by scanning the reference lists of previous systematic reviews and meta-analyses.

Search Strategy

Databases were searched on 13th January 2018 and full details of the search strategy can be found in Appendix B. Key search terms included 'Post Traumatic Stress Disorder' intersected with 'Psychological Therapy' AND 'Randomised controlled trial'.

Study Selection

Studies were selected on the basis of meeting the PICOS criteria and initial assessment was by title and abstract. A full text screen was then completed for

potentially eligible studies, which were further assessed against the inclusion/exclusion criteria.

A second rater also reviewed six studies at the full text screening stage making an independent yes/no decision regarding whether the study should be included or excluded from the review based on PICOS criteria. The second rater and author agreed on all six of the studies selected for second review.

Data Collection Process

In order to extract data from the included studies, a data extraction form was used, based on the guidance from the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Deeks, 2011). Data was extracted by the lead researcher and a summary of the extracted data is available in Table 1.

Data Items

Information was extracted for each study including the identification features of the study (title and authors); the study design and setting; participant characteristics such as diagnosis, age, sex and country; description of the interventions and comparisons (control method, individual/group, length of treatment, frequency of sessions); primary outcome measurements (quality of outcome measurements) and main results.

Risk of Bias in Individual Studies

Risk of bias was assessed for all studies included in the review, by using the Cochrane Collaboration's tool (Higgins & Altman, 2008). Studies were judged on their risk of bias and assigned a score of either low, medium, high or unclear risk. Risk of bias in included studies will be summarised in the results section including allocation, blinding, incomplete outcome data, selective reporting, and other potential sources of bias. Studies with a high risk of bias will be excluded from the review. The

quality of studies was assessed using the Quality Assessment Tool (QAT) for Quantitative Studies from the Effective Public Health Project was used (Armijo-Olivo, Stiles, Hagen, Biondo, & Cummings, 2012; Appendix C) and is reported in the summary of findings table (Table 2). An independent rater reviewed three studies at random and an inter-rater reliability of $r = 1.0$ was calculated, indicating that the criteria has been adhered to.

Synthesis of Results

A summary of the main findings of the effects is presented as well as a descriptive account of the results, which includes descriptions of the characteristics of included studies such as study participants, setting, interventions, comparisons and outcome measures, as well as key differences among the studies (Schunemann et al., 2011).

Results

Search Results

In the initial search, 443 articles were identified, of which 76 were duplicates, leaving 367 articles to screen. Six further articles were identified by scanning the reference lists of existing systematic reviews and meta-analyses. A total of three-hundred and seventy-three articles were screened by their title and abstract against the inclusion and exclusion criteria, using the process described in the PRISMA guidelines (Appendix A). This resulted in the exclusion of 325 records, leaving 48 for full-text review. Forty-eight full-text articles were screened and 37 were excluded, leaving 12 to be included in the review (Figure 1). During the data extraction process it became apparent that one of the 12 studies did not include results of primary outcomes due to a large attrition rate. Therefore, due to methodological and bias concerns, this study was excluded from the review at this stage. A total of 11 studies

were included in the synthesis. A second rater screened a random sample of studies (n = 6) and an inter-rater reliability was computed (*r = 1.0).*

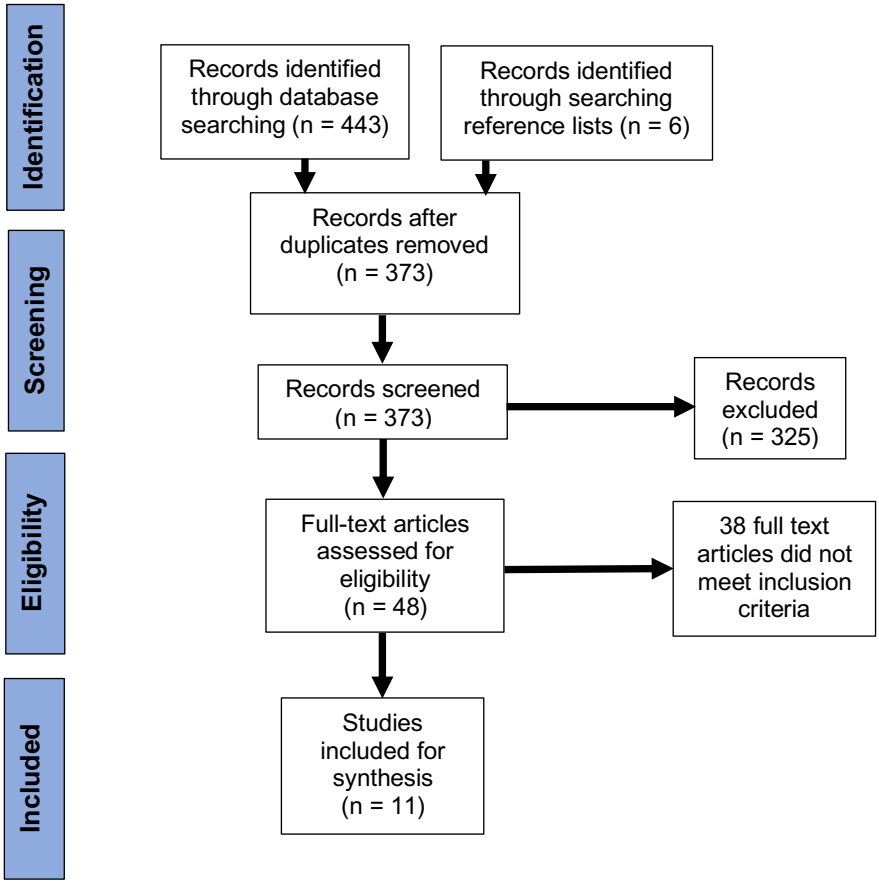

Figure 1. PRISMA Flow Diagram.

Study Characteristics

A total of 11 studies were included in the current review and study characteristics are included in Table 1.

Table 1. *Summary of Articles under Review*

Number	Study	Methods	Participants	Intervention/ Control Groups	Outcomes
1	Ulmer, et al., (2011)	Randomised Controlled Trial	N = 22 Setting: Clinical (Veterans Affairs Hospital) Health Status: PTSD Diagnosis and insomnia disorder with nightmares. Age: M = 45.96 (SD = 11.06) Sex: 15 men and 7 women Country: US	Intervention: CBT-I/IRT Received 6 bi-weekly 1 hour individual intervention sessions over 12 weeks, including 3 sessions of CBT for insomnia and 3 sessions of Imagery Rehearsal Therapy (IRT). Also eligible to receive same elements as usual care. Usual Care Control Group: Treatment by primary care provider, consisting of psychotropic medication.	Sleep measures: ISI, PSQI, PSQI-A PTSD: PCL-M Timepoints**:** Baseline and then after 6th session (12 weeks).
2	Talbot, et al., (2014).	Randomised Controlled Trial	N = 45 Setting: Non-clinical Health status: Chronic PTSD or partial PTSD and persistent insomnia. Age: M = 37.2 (SD = 10.5). Sex: 31 women; 14 men Country: US	Intervention: CBT-I 8 week group CBT-I treatment. Control: 8 week monitor only waitlist control.	Sleep measures: ISI, ESS, PSQI, PSQI-A PTSD: PCL Timepoints: Self-report measures at baseline, after 4 weeks and after 8 weeks.
3	Margolies et al., (2013)	Randomised Controlled Trial	N = 40 Setting: Clinical (Veterans Affairs clinic) Health status: PTSD and current sleep disturbance Age: M = 37.7 (9.1) Sex: 90% Male; 10 % Female Country: US	Intervention: CBT-I/IRT 4 x 60 min weekly individual sessions of CBT-I/IRT and posttreatment assessment. Wait-list Control: Six-week waitlist period where participants were contacted weekly, a follow-up assessment and the option to participate in treatment.	Sleep measures: ISI, DBAS-16, PSQI, PSQI-A PTSD: PSS-SR Intervention condition completed baseline questionnaires and completed again two weeks after 4th session. Participants in control group completed baseline questionnaires, 6 week waitlist period where they were contracted weekly, and follow up assessment including baseline measures.
4	Krakow et al., (2001)	Randomised Controlled Trial	N = 168 Setting: Non-clinical Health status: 95% had moderate-severe PTSD; 5% had mild PTSD. Age: Completer control group (N = 60; M = 36; SD = 9.3) Completer treatment group (N = 54; M = 40; SD = 11.2). Sex: Female Country: US	Intervention: IRT 3 x weekly group sessions (two 3-hour sessions and 1-hour follow up 3 weeks later). Wait list control: No details of input.	Sleep measures: PSQI, PSQI-A, NES, NDQ PTSD: PSS, CAPS The NFQ, PSQI, and PSS were administered at 3 points. All others were at baseline and 6 month follow up.

Number	Study	Methods	Participants	Intervention/ Control Groups	Outcomes
5	Davis et al., (2011)	Randomised Clinical Trial	N = 47 Setting: Non-clinical Health status: PTSD diagnosis (37% moderate; 14% severe; 25% extreme symptoms of PTSD); and sleep difficulties. Age: Treatment group (M =38.80; SD = 38.49); Control group (M =38.17, SD = 38.49). Sex: Mixed (75% female) Country: US	Intervention: ERRT 2 hours weekly over 3 weeks. Wait list control (delayed treatment) Initial assessment then not contacted for 3 weeks apart from phone call to schedule time for re-assessment.	Sleep measures: PSQI, TRNS PSTD: CAPS, TSI
6	Germain et al., (2012)	Randomised Controlled Trial - placebo and Prazosin controlled	N = 50 Setting: Armed Forces Veterans; Clinical and Non-clinical Health status: Mild to moderate daytime PTSD symptom severity and clinically meaningful sleep disturbances. 58% met all DSM-IV criteria for current PTSD, whereas 42% endorsed sub threshold symptoms. 30% met diagnostic criteria for comorbid insomnia. Age: M = 40.9 (SD = 13.2) Sex: 90% were men Country: US	Intervention: Behavioural Sleep Intervention (BSI) 8 x sessions weekly over 8 week period, including at least 5 weekly in-person sessions and up to 3 telephone contacts. All individual sessions were 45 mins. Comparison: Prazosin took oral dose of 4 capsules each night or placebo.	Sleep measures: ISI; PSQI; PSQI-A PTSD: PCL Completed at baseline, post-treatment and 4 month follow up. Four months posttreatment, measures of clinical improvement and self-report measures of sleep and psychiatric symptoms were obtained.
7	Davis & Wright (2007)	Randomised Clinical Trial	N = 27 Setting: Non-clinical Health status: Mean number of traumatic events, M = 4.6 (DS = 2.0) and sleep difficulties - 67.3% had PTSD diagnosis. Age: M = 40 (SD = 12) Sex: Men (18.4%); Women (81.6%) Country: US	Intervention: ERRT 2 hours a week for 3 consecutive weeks. Control: No input.	Sleep measures: PSQI, TRNS PTSD: TAA, SCID, MPSS-SR. Baseline and 1 week post-treatment. Also follow up analysis on N = 19 completers.
8	Germain et al., (2014)	Preliminary Randomised Controlled Trial	N = 40 Setting: Clinical - Veterans Health status: PTSD (50% had current symptoms) and primary or comorbid insomnia. Age: Mean = 38.4 (SD = 11.69)	Intervention: Brief Behavioural Treatment of Insomnia - military version (BBTI-MV) 4 weeks: Two in-person visits (week 1= 45 mins & week 3 = <30 mins) and two telephone contacts (week 2 & 4 = <20 min each).	Sleep measures: ISI; PSQI; PSQI-A PSTD: CAPS; PCL-C ISI, PSQI completed at baseline, post-treatment and 6 month follow up.

Number	Study	Methods	Participants	Intervention/ Control Groups	Outcomes
			Sex: Men (85%) Country: US	Information Control: 4 weeks: 1 individual in-person visit (approx. 30 mins), brief telephone appointments during weeks 2 and 4 (<20 mins each) and a booster in-person visit at week 3 (<20 mins). Received two brochures on insomnia and health sleep practices at week 1.	Sleep and psychiatric outcomes at baseline, 10 days posttreatment and 6 month follow up.
9	Mack (2013)	Pilot study with control conditions	N = 34 Setting: Clinical (Combat Veterans enrolled in Veterans Association Medical Centre PTSD clinic). Health status: Diagnosis of PTSD and met criteria for chronic insomnia Age: M = 58.91 (SD = 9.02) Sex: 97.1% Male Country: US	Intervention: CBT-I/IRT 6 x 90 minute combined CBT-I and IRT over 6 weeks. (7 groups in total). Waitlist control. Participants were called bi-weekly to keep them engaged.	Sleep measures: ISI; PSQI; PSQI-A; DBAS-16 PTSD:PSS; PSS-SR, ITEQ (only administered posttreatment).
10	Ustinov (2013)	Randomised Controlled Trial	N = 65 Setting: Clinical (Veterans Affairs Medical Centres - residential and outpatient). Health status: PTSD diagnosis and subthreshold PTSD and sleep difficulties. Age: M = 53.60 years (SD = 10.76). Sex: Men = 92.9% Country: US	Intervention: CBT-I 4 x 60 min weekly group treatment sessions of CBT-i. Waitlist control: 5 weeks of treatment as usual.	Sleep measures: ISI, DBAS-16 PTSD: PCL-M CBT-I completed assessments at baseline and posttreatment. Participants in WL completed assessments at time intervals matched to the CBT-I group (at baseline and 5 weeks after baseline).
11	Nakamura et al., (2011)	Pilot Randomised Controlled Trial	N = 63 Setting: Clinical (Veterans Affairs Primary Care Clinic) Health status: PTSD symptoms and sleep disturbance Age: M = 51.85 (SD = 10.35) Sex: Men = 95.2% Country: US	Intervention: Mind-body bridging (MBB) (Non-CBT) 2 x 1.5 hour weekly sessions Waitlist: Sleep Hygiene 2 x 1 hour weekly sessions	Sleep measures: MOS-SS PTSD: PCL-M Completed 1 week prior to the first session and at least 7 days after the second session. MOS-SS was also completed at Week 1 prior to the start of the second session.

Notes: CAPS = PTSD Clinician-Administered PTSD Scale; DBAS-16 = Dysfunctional Beliefs and Attitudes about Sleep Scale*;* ESS = Epworth Sleepiness Scale; ISI = Insomnia Severity Index; ITEQ = Insomnia Treatment Evaluation Questionnaire; MOS-SS = Medical Outcomes Study – Sleep Scale; MPSS-SR = The Modified PTSD Symptom Scale Self Report; NDQ = Nightmare Distress Questionnaire*;* NES = Nightmare Effects Survey*;* NM = Nightmares*;* PCL = PTSD Checklist; PCL-C = PTSD Checklist (Civilian Version)*;* PCL-M = PTSD Checklist-Military Version; PSQI = Pittsburgh Sleep Quality Index; PSQI-A = Pittsburgh Sleep Quality Index-Addendum; PSS = PTSD Symptom Scale; PSS-SR = PTSD Symptom Scale-Self Report; SCID = The Structured Clinical Interview for DSM-IV: PTSD Module; TAA = Trauma Assessment for Adults; TRNS = Trauma Related Nightmare Survey; TSI = Trauma Symptom Inventory.

Design. All of the studies in the review used a randomised controlled trial design and all included a control or comparison group. Randomisation to groups was explicitly detailed in seven of the studies (2, 4, 5, 6, 8, 9, 11). The other four studies did not include details of random sequence generation (1, 3, 7, 10)

Sample sizes. Sample sizes mostly ranged between 22 to 65 participants, though one study had a large sample of 168 participants (4).

Participants. Approximately half of the studies conducted the trial in a clinical setting such as a hospital or mental health clinic (1, 3, 8, 9, 10, 11), whereas four conducted the study in non-clinical settings (2, 4, 5, 7) and one conducted the group in both a clinical and non-clinical setting (6).

In approximately half of the studies, all of the participants were assessed for PTSD through rigorous clinical assessment as indicated by the Clinician-Administered PTSD Scale (CAPS) (Blake et al., 1995) or the Structured Clinical Interview for DSM-IV (SCID; First, Spitzer, Williams, & Gibbon, 1996) (1, 2, 4, 6, 7, 8). Two studies recruited participants from PTSD treatment clinics, but no details were given regarding how PTSD diagnoses were established (3, 5). One study recruited participants from a PTSD treatment clinic and required participants to score over 53 on the PCL-M and also met DSM criteria for PTSD (9). Two studies relied on self-report of PTSD symptoms using the PCL-M (10, 11), and in one of the studies, those that didn't fully meet criteria were included if they scored over 45 on the PCL-M (10) whereas the other study placed no emphasis on PCL-M score (11).

Studies included only participants who had a diagnosis of PTSD (1, 3, 4, 9), those with PTSD or subthreshold PTSD symptoms (6), those with PTSD or partial PTSD operationalised by past diagnosis and symptoms in cluster B and either C or D (DSM-IV) (2) or whose PTSD was in partial remission or controlled with

medication, or with symptoms that did not meet full diagnostic criteria, but were included if they met clinical cut-off of 45 or greater on the PCL-M (10). In one study (11) the level of PTSD in participants was unclear. Some studies included a mixed sample including PTSD and those with other anxiety disorders (5, 7, 8).

All of the studies apart from one (6), included only participants who had insomnia or symptoms of insomnia. Insomnia was established by meeting diagnostic criteria for Insomnia Disorder as per Duke Structured Sleep Interview (1), or research diagnostic criteria e.g., Edinger et al., 2004 (2, 3) or criteria for comorbid or primary insomnia as defined by the International Classification of Sleep Disorders (Hauri & Sateia, 2005) (8). Others used diagnostic screening criteria adapted from the Diagnostic and Statistical Manual of Mental Disorder, Fourth Edition, Text Revision (DSM-IV-TR; American Psychiatric Association, 2000) and who also scored above the suggested clinical cut-off on the Insomnia Severity Index (ISI) (10). Some studies used self-report symptoms of insomnia (3, 4, 11) or a combination of self-report insomnia and nightmares (5, 7). One study included participants of which 70% did not meet diagnostic criteria for insomnia (6).

Participants mean age in included studies ranged from M = 36 years (SD = 9.3) (5) to M = 58.91 (SD = 9.02) (9). Some studies had all female participants (4) whereas most studies were mixed gender (1, 2, 5, 6, 7, 8, 9, 10, 11), although some of these had mostly male participants 85% - 97.1% (6, 8, 9, 10, 11). Seven out of the 11 studies included Armed Forces Veterans (1, 3, 5, 5, 8, 9, 10, 11) who had experienced combat in areas of conflict. All 11 studies were conducted in the United States.

Interventions. Only interventions that used MBB and CBT were identified, and used either just one therapeutic approach (e.g., MBB (11), CBT-I (2, 10), IRT

(4)) or a combination of both CBT-I and IRT (1, 3, 9). Two of the studies used exposure, relaxation and rescripting therapy (ERRT) (5, 7) and there were two other behavioural variants: Behavioural Sleep Intervention (BSI) (6) and Brief Behavioural Treatment of Insomnia – Military Version (BBTI-MV) (8).

The interventions were delivered in either an individual session format (1, 2, 3, 6, 8) or in group sessions (4, 9, 10). Information was not provided about whether EERT was provided in a group or individual format in three of the studies (5, 7, 11).

The number of intervention sessions varied and studies delivered the intervention over 2 sessions (11), 3 sessions (4, 7), 4 sessions (3, 8, 10), 6 sessions (1, 3, 9), and 8 sessions (2, 6). The duration of intervention sessions ranged from brief 20-minute telephone contacts between longer face-to-face sessions (8), 45-minute sessions (6), 1-hour sessions (1, 3), 1.5-hour sessions (11), and 2-hour group sessions (4, 5, 7, 9). One study did not report the duration of each treatment session (2). All of the treatment sessions were delivered on a weekly (2, 3, 4, 5, 6, 7, 8, 9, 10, 11) or bi-weekly basis (1).

The control groups varied across the studies and included treatment as usual (1, 10), sleep and symptom monitoring (2), wait-list control (3, 4, 5, 7, 9), a sleep hygiene program (11), Prazosin or Placebo control (6) and an information control group where people were given brochures with information on insomnia and health sleep practices to review (8).

Outcomes. All of the studies used outcome measures with well-established psychometric properties as a measure of insomnia such as the Insomnia Severity Index (ISI) or Pittsburgh Sleep Quality Index (PSQI).

Excluded Studies

Studies were excluded from the current review due to reasons such as the primary outcome measure being PTSD, the treatment was not an evidence-based psychological therapy intervention (i.e., hypnosis), the treatment was targeting PTSD rather than insomnia and insomnia was measured as a secondary outcome or the study was not an RCT. Following the data extraction process, one further study was excluded (Rose, 2013) due to a large attrition rate which meant that the hypothesis for the study could not be empirically evaluated and as well, there were concerns about the methodological and reporting quality and therefore the study was deemed to have a high risk of bias.

Risk of Bias in Included Studies

Risk of bias in the included studies was assessed using the Cochrane collaboration tool (Higgins & Altman, 2008) and results are presented in Table 2. For three of the studies there was an ‘unclear’ risk of bias, due to a lack of information about the study procedure, especially with regards to blinding of participants and study personnel to conditions (9, 10, 11). The other eight studies included in the review had a ‘low’ risk of bias.

Table 2. *Risk of Bias in Included Studies*

Study	Authors	Random sequence generation	Allocation concealment	Blinding of participants/ personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other sources of bias
1	Ulmer, et al., (2011)	Unclear	Unclear	Unclear	Unclear	Low	Low	Low
2	Talbot, et al., (2014)	Low	Low	Low	Low	Low	Low	Low
3	Margolies, et al., (2013)	Unclear	Unclear	Unclear	Unclear	Low	Low	Low
4	Krakow et al., (2001)	Low	High	High	Low	High	Low	Low
5	Davis et al., (2011)	Low	High	Low	High	Low	Low	High
6	Germain et al., (2012)	Low	Low	Unclear	Unclear	Low	Low	Low
7	Davis & Wright (2007)	Unclear	Low	Unclear	Low	Low	Low	Low
8	Germain et al., (2014)	Low	Unclear	Unclear	Unclear	Low	High	Low
9	Mack (2013)	Low	Unclear	Unclear	Unclear	Unclear	Low	High
10	Ustinov (2013)	Unclear	Unclear	Unclear	Unclear	High	Low	Low
11	Nakamura et al., (2011)	Low	Unclear	Unclear	Unclear	Low	Unclear	Low

Effects of Interventions/ Synthesis of Results

The results of the studies can be found in Table 3, including main findings, test statistics, effect size and main conclusions.

Insomnia. Seven studies (1, 2, 3, 6, 8, 9, 10) specifically measured insomnia using the Insomnia Severity Index (ISI), and there were improvements in the treatment groups of six of the seven studies. Effect sizes were large in four studies (1, 2, 3, 9). In one study where a CBT-I group treatment approach was adopted, there were no improvements in insomnia (10), whereas the others used a combined CBT-I/IRT approach (1, 3, 9), pure CBT-I (2), BSI (6), or BBTI-MV (8) which all found a significant reduction in insomnia in the treatment condition following intervention. One study that used MBB measured insomnia using the MOS-SS and found a significant improvement in sleep with a large effect size (11).

Overall CBT approaches including CBT-I/IRT, pure CBT-I, and behavioural interventions (BSI and BBTI-MV) and a non-CBT approach i.e., MBB were successful in improving insomnia following the intervention, however one study that used CBT-I in a group format did not find a reduction in insomnia.

Sleep Quality. Sleep quality was assessed in nine studies using the PSQI which focuses on insomnia symptoms but also ‘bad dreams’, ‘having pain’, and the impact of sleep difficulties on daily functioning (Buysse, et al., 1989). Seven of the nine studies found significant improvements in sleep quality in the intervention condition (1, 2, 3, 4, 5, 8, 9) and found large effect sizes (1, 2, 3, 5, 9) or a medium effect size (4). Of the studies that found an increase in sleep quality in the treatment condition, three of the interventions used a combined CBT/IRT approach (1, 3, 9), one used a pure CBT-I approach (2), one used a pure IRT approach (4), one used BBTI-MV (8) and another used EERT (5). In two of the studies, interventions

targeted nightmares specifically (4, 5), two focused purely on insomnia (2, 8) and three provided a combination of CBT-I and IRT to target both insomnia and nightmares (1, 3, 9). Two studies did not find an improvement in sleep quality for the treatment groups, which used BSI (6) to target insomnia and EERT which provided sleep hygiene and also targeted nightmares (7). The ESS was also used by one study (2) to assess daytime sleepiness and there was a significant reduction in the treatment group.

Overall, studies found improvements in sleep quality following intervention, which included CBT-I/IRT, pure CBT-I, pure IRT and behavioural and exposure interventions (EERT and BBTI-MV).

PTSD Specific Sleep Difficulties. PTSD specific sleep difficulties[2] were measured using the PSQI-A in seven of the studies. There was a significant reduction in the intervention condition in only three studies (2, 3, 4); one of which used a CBT-I approach in a pure format which unlike IRT did not include a focus on nightmares. Despite this, they found a moderate effect of CBT-I in reducing PTSD specific sleep difficulties. The other two studies found a significant reduction in nightmares, either through combined CBT-I and IRT (3), or pure IRT (4). Both studies found a moderate (3) and large effect size (4) for nightmare improvements in the treatment group.

Two studies that combined CBT-I and IRT and therefore included a nightmare element in the intervention, did not find reductions in PTSD specific sleep difficulties compared to control groups (1, 9). Additionally, the study that used a Brief Behavioural Treatment of Insomnia - military version (BBTI-MV) (8) did not find

[2] such as nightmares, episodes of terror during sleep or acting out dreams such as kicking running or screaming (Germain, Hall, Krakow, Shear, & Buysse, 2005)

reductions in PTSD sleep specific difficulties, nor did a Behavioural Sleep Intervention (BSI) (6) both of which integrated techniques such as stimulus control and sleep restriction.

Overall, only a small proportion of the studies that measured PTSD specific sleep difficulties (approximately 40%) found a significant reduction post intervention.

Nightmares. Nightmares were measured as an outcome in three out of the eleven studies and all three studies found a reduction in nightmares following the intervention (4, 5, 7). The two studies that measured nightmares using the TRNS (5, 7) both found significant reductions in the treatment group compared with the control group, for 'nights per week with nightmares' and 'nightmare severity', however there was not a reduction for the 'number of nightmares per week'. This may be due to the lack of internal reliability of the TRNS, as the 'frequency of nightmares' item has a test-retest coefficient of $r = .64$ which may explain the discrepancy in findings. Nightmares were also assessed in Krakow et al., (2001) (4) by the NES and NDQ, which found significant reductions in 'nightmare effects' and 'nightmare distress' in the treatment group. All three studies specifically targeted nightmares as part of the intervention, using interventions consisting of IRT (4) and EERT (5, 7).

Overall, all three of the studies that targeted nightmares in the treatment intervention and measured nightmares as an outcome found a reduction in nightmares following the intervention condition. However, for two of the studies (5, 7) findings were mixed as there was a reduction of nights per week with nightmares and nightmare severity, but not for number of nightmares per week, which may suggest that although the number of nights experiencing nightmares decreased, the frequency of nightmares did not.

Overall

In summary, CBT approaches for sleep difficulties were successful in reducing insomnia and improving sleep quality in PTSD suffers with comorbid insomnia. Most of the studies found a reduction in insomnia following the intervention (1, 2, 3, 6, 8, 9) and an improvement in sleep quality (1, 2, 3, 4, 5, 8, 9). One study that used a non-CBT approach (i.e., MBB) (11), was also successful in reducing symptoms of insomnia after only two treatment sessions.

There were mixed findings for the reduction of PTSD specific sleep difficulties. Three studies using CBI-I, CBT-I/IRT or IRT found a reduction in PTSD specific sleep difficulties (2, 3, 4), whereas others that used BSI (6), BBTI-MV (8) and CBT-I/IRT (1, 9) did not find reductions following intervention. This suggests that treatments that had a cognitive component, were more successful in reducing PTSD specific sleep difficulties, than those that only used behavioural techniques.

Treatments that are tailored specifically for nightmares such as IRT and EERT, were successful for the treatment of nightmares in PTSD sufferers with comorbid sleep difficulties (4, 5, 7). However, despite the frequency of nightmares reducing in two studies, sleep quality did not improve following the intervention (5, 7).

Table 3. *Results of Studies.*

Number	Study	Outcomes	Results	Effect size	Key Findings	QAT Ratings
1	Ulmer, et al., (2011)	ISI	Significant condition x time (baseline, post-intervention) interaction, F (1, 21) = 11.80, p = 0.003	d = -2.15	Veterans with PTSD and comorbid insomnia had a reduction in insomnia and increase in sleep quality following a combined CBT-I/IRT intervention delivered on an individual basis, compared to a usual care control group. However, there was no reduction in specific PTSD sleep difficulties such as nightmares, or episodes of terror during sleep. Conclusions: Support for combined CBT-I/IRT individual treatment to reduce insomnia, and improve sleep quality. No evidence to support CBT-I/IRT to reduce PTSD-related sleep quality.	A: Strong B: Weak C: Strong D: Moderate E: Strong F: Strong Global: Moderate
		PSQI	Significant condition x time (baseline, post-intervention) interaction, F (1, 21) = 17.31, p = 0.0005	d = -1.60		
		PSQI-A	No significant difference for condition x time (baseline, post-intervention) interaction, F (1, 21) = 0.76, p > 0.05 (Intent to treat analysis)	d = -0.30		
2	Talbot, et al., (2014)	ISI	Significant condition x time (baseline, mid treatment, posttreatment) interaction, F (2, 80) = 19.75, p < 0.001	η_p^2 = 0.33	Adults with PTSD and comorbid insomnia had a reduction in insomnia, daytime sleepiness and specific PTSD sleep difficulties and an increase in sleep quality following a CBT-I group treatment compared with a monitor only waitlist control group. Conclusions: Support for group CBT-I treatment to reduce symptoms of insomnia, daytime sleepiness and specific PTSD sleep difficulties and increase sleep quality for individuals with PTSD and comorbid insomnia.	A: Strong B: Strong C: Strong D: Strong E: Strong F: Strong Global: Strong
		PSQI	Significant condition x time (baseline, mid treatment, posttreatment) interaction F (2, 80) = 22.13, p = 0.001	η_p^2 = 0.36		
		ESS	ESS Significant condition x time (baseline, mid treatment, posttreatment) interaction F (2, 70) = 5.74, p = 0.005	η_p^2 = 0.14		

		PSQI-A	Significant condition x time (baseline, mid treatment, posttreatment) interaction F (2, 80) = 9.74, p = 0.001	η_p^2 = 0.19		
3	Margolies, et al., (2013)	ISI	Significant condition x time (baseline, posttreatment) interaction, F (1, 35) = 16.24, p < .001	η_p^2 = 0.32	Veterans with PTSD and sleep disturbances had a reduction in insomnia and PTSD current insomnia, and an increase in sleep quality following a CBT-I intervention delivered on an individual basis, compared with a waitlist control group. However there was not a reduction of dysfunctional beliefs and attitudes about sleep. Conclusions: Individual CBT-I is effective in reducing insomnia and PTSD specific sleep difficulties, and increasing sleep quality in Veterans with PTSD and comorbid insomnia, but does not reduce dysfunctional beliefs and attitudes about sleep.	A: Strong B: Weak C: Strong D: Moderate E: Strong F: Moderate Global: Moderate
		PSQI	Significant condition x time (baseline, posttreatment) interaction F (1, 35) = 25.28, p < .001	η_p^2 = 0.42		
		PSQI-A	Significant condition x time (baseline, posttreatment) interaction F (1, 24) = 7.32, p = 0.01	η_p^2 = 0.24		
		DBAS-16	Non-significant condition x time (baseline, posttreatment) interaction, F (1, 34) = 3.42, p = 0.07 (Intent to treat analysis)	η_p^2 = 0.09		
4	Krakow et al., (2001)	PSQI	Significant condition x time (baseline, endpoint = 3 or 6 month follow up) interaction, F (1, 109) = 8.10, p = 0.001	d = 0.67	Sexual assault survivors with PTSD and chronic nightmares who received a group IRT treatment, had an increase in sleep quality, decrease in PTSD specific sleep difficulties and nightmare effects and distress, compared with a waitlist control group. Conclusions: Group IRT is effective in reducing	A: Strong B: Weak C: Strong D: Moderate E: Moderate F: Moderate Global: Moderate
		PSQI-A	Significant condition x time (baseline, endpoint = 3 or 6	d = 1.15		

			month follow up) interaction, F (1, 109) = 23.75, p = 0.001		PTSD specific sleep difficulties and nightmare effects and distress and increasing sleep quality.	
		NES	Significant condition x time (baseline, endpoint = 3 or 6 month follow up) interaction, F (1, 110) = 19.85, p < 0.001	d = 1.07		
		NDQ	Significant condition x time (baseline, endpoint = 3 or 6 month follow up) interaction, F (1, 92) = 18.33, p , 0.001	d = 1.31		
5	Davis et al., (2011)	PSQI	Significant condition x time (baseline, 1 week posttreatment) interaction, F (1,47) = 13.68, p < 0.001	d = 0.92	Adults with PTSD (37% moderate; 14% severe; 25% extreme symptoms of PTSD) and sleep difficulties (nightmares) had an increase in sleep quality, and a decrease in number of nights per week with nightmares and nightmare severity following an EERT intervention, compared with a waitlist control group. Conclusions: EERT was effective in increasing sleep quality, and reducing number of nights per week with nightmares and nightmare severity, but not for reducing the number of nightmares per week.	A: Moderate B: Strong C: Strong D: Weak E: Strong F: Moderate Global: Moderate
		TRNS Nights per week with NM	Significant condition x time (baseline, 1 week posttreatment) interaction, F (1,47) = 4.10, p < 0.05	d = 0.68		
		NM per week	Non-significant condition x time (baseline, 1 week posttreatment) interaction, F (1,47) = 0.49, p > 0.05	d = 0.21		
		NM Severity	Significant condition x time (baseline, 1 week posttreatment) interaction, F (1,47) = 8.05, p < 0.01	d = 0.87		

6	Germain et al., (2012)	ISI	Significant condition x time (baseline, 1 week posttreatment) interaction for BSI and prazosin, F (2, 37.0) = 6.06, $p < 0.01$	Not available	Veterans (58% with PTSD; 42% subthreshold PTSD) with clinically meaningful sleep disturbance had a decrease in insomnia following individual BSI treatment compared to control groups (prazosin or placebo). However there was not difference for sleep quality or PTSD specific sleep difficulties. Conclusions: BSI shows some indication that it can be effective in reducing insomnia in Veterans with PTSD or subthreshold PTSD and comorbid sleep disturbance. However, BSI was no more effective at improving sleep quality or reducing PTSD specific sleep difficulties. Follow up worth reporting	A: Strong B: Strong C: Strong D: Moderate E: Moderate F: Moderate Global: Strong
		PSQI	No significant condition x time (baseline, 1 week posttreatment) interaction, F (2, 37.0) = 2.38, p = 0.11			
		PSQI-A	No significant condition x time (baseline, 1 week posttreatment) interaction, F (2, 37.0) = 0.83, p = 0.44			
7	Davis & Wright (2007)	PSQI	No significant condition x time (baseline, 1 week posttreatment) interaction F (1, 41) = 1.62, $p > 0.05$	d = 0.24	Trauma exposed adults with sleep difficulties had a reduction in nights per week with nightmares and nightmare severity following an EERT intervention compared with the control group. However, there was no improvement in sleep quality or number of nightmares per week. Conclusions: EERT shows some evidence of being effective to reduce number of nights per week with nightmares and nightmare severity. However, EERT was not effective in improving sleep quality or number of nightmares per week.	A: Moderate B: Moderate C: Strong D: Moderate E: Strong F: Moderate Global: Strong
		TRNS Nights per week with NM	Significant condition x time (baseline, 1 week posttreatment) interaction F (1, 41) = 9.26, $p < 0.01$	d = 0.84		
		NM per week	No significant condition x time (baseline, 1 week posttreatment) interaction F (1, 41) = 2.17, $p > 0.05$	d = 0.50		
		NM Severity	Significant condition x time (baseline, 1 week posttreatment) interaction, F (1, 41) = 6.92, $p < 0.05$ (Intent to treat analysis)	d = 0.64		

8	Germain et al., (2014)	ISI	Pre to post treatment improvements were significantly greater in the BBTI-MV condition compared to the information control, t (47) = 2.22, *p* = 0.03	Not available	Veterans with insomnia (50% had current PTSD) who received a BBTI-MV intervention had a reduction in insomnia and improvement in sleep quality compared with an information control group. However, there was no change in PTSD specific sleep difficulties. Conclusions: BBTI-MV is effective in reducing insomnia and improving sleep quality in Veterans with insomnia and some who have both PTSD and insomnia. However, BBTI-MV was not effective in reducing PTSD specific sleep difficulties.	A: Weak B: Strong C: Weak D: Moderate E: Weak F: Strong Global: Moderate
		PSQI	Pre to post treatment improvements were significantly greater in the BBTI-MV condition compared to the information control, t (45) = 2.34, *p* = 0.02			
		PSQI-A	There was no significant different in pre to post scores in the BBTI-MV condition compared to the information control, t (46) = -0.48, *p* > 0.05			
9	Mack (2013)	ISI	Significant condition x time (pretreatment, posttreatment) interaction, *F* (1, 32) = 13.62, *p* = 0.001	ηp^2 = 0.299	Veterans with PTSD and insomnia, who received a combined CBT/IRT group treatment had a reduction in insomnia and an improvement in sleep quality, compared with a waitlist control group. However, there was no reduction in PTSD specific sleep difficulties, or in dysfunctional beliefs and attitudes about sleep. Conclusions: A combined CBT/IRT group intervention is successful in reducing insomnia and improving sleep quality in Veterans with PTSD and comorbid insomnia. However, there is no evidence to suggest that it reduces PTSD specific sleep	A: Moderate B: Weak C: Moderate D: Moderate E: Strong F: Moderate Global: Moderate
		PSQI	Significant condition x time (pretreatment, posttreatment) interaction, *F* (1, 32) = 12.54, *p* = 0.001	ηp^2 = 0.282		
		PSQI-A	Non-significant condition x time (pretreatment,	ηp^2 = 0.000		

			posttreatment) interaction, F (1, 31) = .002, p = .965		difficulties or dysfunctional beliefs and attitudes about sleep.	
		DBAS-16	Non-significant condition x time (pretreatment, posttreatment) interaction, F (1, 32) = 2.85, p = .101 (Intent to treat analysis).	η_p^2 = 0.082		
10	Ustinov (2013)	ISI	Non-significant condition x time (baseline, 1 week posttreatment) interaction F (1,63) = 0.03, p = .858	η_p^2 = .001	Veterans with PTSD or subthreshold PTSD, who received a CBT-I group treatment did not show a reduction in insomnia or dysfunctional beliefs and attitudes about sleep, compared with a waitlist control group. Conclusions: There is no evidence to suggest that a CBT-I group treatment is effective in reducing insomnia symptoms or reducing dysfunctional beliefs and attitudes about sleep.	A: Weak B: Strong C: Strong D: Moderate E: Strong F: Strong Global: Moderate
		DBAS-16	Non-significant condition x time (baseline, 1 week posttreatment) interaction F(1,63) = 0.09, p = .766	η_p^2 = .001		
11	Nakamura et al., (2011)	MOS-SS	Significant condition x time (week 1) interaction [MBB (21.0, ES = 1.3) vs. SH (12.8, ES =.73); p = .047] Significant condition x time (posttreatment) interaction [MBB (28.0, ES = 1.89) vs. SH (14.8, ES = .71); p = .012].		Veterans with PTSD and insomnia had reduced patient-reported sleep disturbance and PTSD symptoms after MBB than those in the standard-of-care SH intervention. Conclusions: MBB is successful in reducing sleep disturbance and PTSD symptoms after two sessions, compared to a sleep hygiene intervention.	A: Weak B: Strong C: Strong D: Weak E: Strong F: Strong Global: Weak

Notes: d =Cohen's d effect size (d = 0.2, small; d = 0.5, medium; d = 0.8, large); DBAS-16 = Dysfunctional Beliefs and Attitudes about Sleep Scale; ESS = Epworth Sleepiness Scale; ISI = Insomnia Severity Index; η_p^2 = Partial Eta squared (0.01 = small; 0.09 = moderate; 0.25 = large); NDQ = Nightmare Distress Questionnaire; NES = Nightmare Effects Survey; NM = Nightmares; PSQI = Pittsburgh Sleep Quality Index; PSQI-A = Pittsburgh Sleep Quality Index-Addendum; TRNS = Trauma Related Nightmare Survey.

Discussion

The aims of the current review were to present a recent systematic review of the effectiveness of psychological therapies to treat sleep disturbances (such as insomnia and nightmares) in PTSD sufferers and to investigate whether differences exist between the effectiveness of different psychological therapies, including within specific therapy modalities such as different CBT approaches i.e., CBT-I and IRT. Eleven studies were included in the review, all of which were randomised controlled trial designs and all used psychological interventions to treat sleep difficulties in PTSD sufferers.

There was a large range of diversity in the studies included, as although all of the interventions (apart from one that used a non-CBT approach of MBB i.e., study 11) used a CBT approach, the specific interventions varied and included pure CBT-I (2, 10), three combined CBT-I and IRT (1, 3, 9) one used only IRT (4) and one used MBB (11). Two used exposure, relaxation and rescripting therapy (EERT) (6, 7), one used a behavioural sleep intervention (BSI) (6) and another used a brief behavioural treatment of insomnia – military version (BBTI-MV) (8). This meant that the second aim of the study was not achieved i.e., to investigate whether differences exist between the effectiveness of different psychological therapies, especially as the non-CBT study (11) only measured insomnia and did not measure sleep quality, PTSD specific sleep difficulties or nightmares. Despite findings from the non-CBT study showing a significant improvement in sleep and achieving a large effect size (comparative to four of the CBT studies that also achieved a large effect size (1, 2, 3, 9)), firm conclusions cannot be drawn by comparing a predominantly CBT body of research to one non-CBT based study, especially as the MBB study only used two

intervention sessions and additionally, research supporting MBB is in its infancy and therefore limited (e.g., Nakamura, et al., 2010).

There was also diversity in the participant samples of included studies, and they included Armed Forces veterans or civilians, and exposure to very different traumatic experiences (such as war or sexual assault). The studies were conducted in a variety of settings including clinical settings such as hospitals and non-clinical settings. Participants were recruited in different ways via advertising and flyers or through attendance at a mental health clinic such as US Veterans Affairs treatment centres.

The studies included in the current review varied in effectiveness and some of the findings contradicted each other. For example, one study found that CBT/IRT improved PTSD specific sleep difficulties, whereas an additional two studies that used CBT/IRT did not find the same improvements. Studies that targeted nightmares and included a nightmare outcome measure found an improvement in nightmare severity and frequency and reduced distress of nightmares following the intervention, but not in number of nightmares per week. However, this was a small number of studies and therefore this finding needs to be interpreted with caution.

Symptom expression in PTSD sufferers with comorbid sleep difficulties is heterogeneous (Wallace, Iyengar, Bramoweth, Frank, & Germain, 2015) and in the studies included in the current review, sleep difficulties were operationalised in four ways, namely ‘insomnia’, ‘sleep quality’, ‘PTSD specific sleep difficulties’ and ‘nightmares’.

The effectiveness of the interventions varied in their effectiveness in reducing all four variants of sleep difficulties. All of the interventions apart from one, demonstrated a reduction in insomnia following the intervention, although the studies

that targeted nightmares did not measure insomnia. However, these studies did measure sleep quality, and generally this improved following intervention, apart from one study that used EERT where sleep quality was not improved. Sleep quality improved following intervention in almost all of the other studies, suggesting that the interventions were effective in targeting different aspect of sleep difficulties in PTSD sufferers. However, the varying results of the included studies might mean that there are conceptual differences in PTSD symptom expression and therefore specific approaches may be more effective than others in treating different sleep difficulties.

As aforementioned, the second aim of the review was not possible to evaluate. There were only a small number of studies for each type of CBT treatment, which meant that firm conclusions cannot be drawn regarding the effectiveness of these interventions. For example, some studies indicate that insomnia and sleep quality is improved by behavioural approaches including CBT-I, which incorporates stimulus control, sleep restriction, sleep hygiene and cognitive restructuring (Morin, 1993). In contrast, some studies indicate that PTSD specific sleep difficulties and nightmares might benefit from approaches that target these symptoms (such as EERT or IRT), which utilise exposure and rewriting of nightmare content (Davis & Wright, 2006). However, due to the small number of studies and as most studies used inactive control groups, it is not possible to say with confidence that any effects are due to treatment modality rather than simply receiving therapeutic input (e.g., Karlsson & Bergmark, 2014).

Dose-response effects have been investigated previously in CBT-I for insomnia, and the results suggested that four individual biweekly sessions were the optimal dose (Edinger, Wohlgemuth, Radtke, Coffman & Carney, 2007). However, in the current review although the intervention frequency varied across studies, this did

not seem to determine whether the intervention was effective or not, as some studies used as few as two weekly sessions, whereas others used eight weekly sessions and both successfully reduced insomnia and improved sleep quality.

Using CBT-I for PTSD specific sleep difficulties may be effective, but more intensive intervention might be needed, as Talbot et al., (2014) found that an 8-week group CBT-I intervention successfully reduced PTSD specific sleep difficulties whereas a 4-week group CBT-I intervention did not (Ustinov, et al., 2013). There is also evidence that combining the two approaches and targeting both sleep difficulties and nightmares has benefit for both insomnia and nightmares (Margolies et al., 2013). However, the evidence suggests that the intervention format should be delivered on an individual basis and over a longer duration (e.g., Margolies et al., 2013) rather than delivered in a group format and over a shorter period of time (e.g., Mack, 2013) in order to successfully reduce nightmares and PTSD specific sleep difficulties.

The difference in treatment effectiveness identified in the current study, may signify conceptual differences in symptom expression of PTSD specific sleep difficulties (such as episodes of terror during sleep). For example, Ulmer et al., (2011) found that insomnia and sleep quality reduced following psychological intervention whereas nightmares did not. Differences in symptom expression might indicate differences in PTSD severity, which may differentiate between symptom profiles, with more severe PTSD exhibiting the most difficulties with disruptive nocturnal behaviours and poor sleep quality (Wallace et al., 2015).

Strengths and Limitations

A strength of the current review is that it offers an updated systematic evaluation of the available evidence for psychological interventions to treat sleep

difficulties in PTSD sufferers. Past reviews that have investigated the evidence are outdated as a systematic review has not been conducted for two years which only included studies published before 2014 (Ho et al., 2016). It was notable that despite two years elapsing since the last review (Ho, et al., 2016) and the differences in search terms and methodology between the two reviews, only one further study was identified which is of an acceptable design and quality to use in a systematic review (i.e., Germain, et al, 2014) i.e., using RCT design (Cochrane Guidance, 2017). The fact that only eleven studies of adequate nature were identified in the current review, is testament to the small evidence base and lack of rigorous studies conducted in this population of PTSD sufferers with comorbid sleep difficulties, which highlights the need for further research in this area.

As aforementioned, sleep difficulties are heterogeneous in their presentation in PTSD sufferers, which has made it difficult to determine which approaches are beneficial for different sleep difficulties. Past reviews have encompassed all PTSD sleep difficulties under 'insomnia' and 'nightmares' or have neglected to report outcomes on nightmares and PTSD specific sleep difficulties, but in the current review, it was felt that this was an overly simplistic account and does not appreciate the diversity in symptom expression in PTSD sufferers (e.g., Wallace et al., 2015). Idiosyncrasies regarding treatment effectiveness seem to exist for different PTSD presentations, and therefore the results of the current review were described for each of these presentations.

Given that mostly CBT interventions were identified for the current review, it was not possible to make comparisons regarding the effectiveness of different psychological therapies e.g., CBT vs non-CBT psychological therapies. Other non-CBT interventions were not selected for the current review as firstly there was a

parsimony of studies and secondly, when studies were identified they did not meet the inclusion criteria i.e., they did not use a RCT design. Within the studies identified for the current review, firm conclusions cannot be drawn about comparisons regarding the effectiveness of different CBT approaches, such as CBT-I or IRT for the four different elements of sleep disturbance in PTSD sufferers. This is in part due to the large range of diversity in the study characteristics such as participant characteristics, study setting, duration and frequency of intervention, and also there were only a small number of studies for each intervention which therefore limits the generalisability of results in the current review.

Additionally, there were methodological concerns regarding some of the study designs included in the review, as although generally the quality of studies was good, across almost all of the studies there were issues with allocation concealment due to the nature of the RCT waitlist control condition. Additionally, some of the outcome measures, including the TRNS, have questionable validity which could explain why some of the results, especially regarding nightmares, seemed to contradict each other. Other nightmare measures that have satisfactory reliability and validity could have been used such as the newly developed Nightmare Distress and Impact Questionnaire which has demonstrated adequate reliability (Chronbach's *a* = .75) (NDIQ; Kunze, Lancee, Morina, Kindt & Amtz, 2016).

Further Research

Individual differences inherent in this population of PTSD sufferers (Wallace, et al., 2015) should be considered in future research such as gender differences, as men tend to report more frequent nightmares than women (King, Street, Gradus, Vogt, & Resick, 2013). Some studies suggest that vocation may even be a stronger moderating factor in PTSD development such as being in the military (Brewin,

Andrews & Valentine, 2000) and also is a stronger predictor of PTSD symptom expression (King et al., 2013), so it would be worthwhile conducting further research into which treatments are most effective for different symptoms profiles (Wallace et al., 2015) and if further dose-specific effects are observed (Edinger et al., 2007).

Studies have identified that disturbed sleep prior to trauma exposure and immediately after trauma exposure increases PTSD vulnerability (e.g., Gehrman et al., 2013), therefore future research could investigate the effectiveness of psychological therapies in treating insomnia immediately after a trauma and the impact this has on the development of PTSD. Additionally, if insomnia following a trauma is exacerbated by adverse conditions such as soldiers on deployment in a war zone or blue light services working long shifts, it could be important for organisations to consider this in mental health prevention strategies, as improving insomnia symptoms reduces PTSD symptoms (Ho, et al., 2016) and treating insomnia soon after exposure to a trauma could prevent the development of PTSD and/or accelerate recovery (Germain, 2013).

Further studies should also investigate the effectiveness of different approaches such as CBT-I or IRT for the different elements of sleep disturbances in PTSD sufferers.

Conclusion

The current systematic review has provided a recent review of the effectiveness of psychological interventions for treating sleep difficulties in PTSD sufferers. Focusing on and treating sleep difficulties in PTSD sufferers is important as disturbed sleep impacts the severity of PTSD symptoms (Belleville et al., 2009) and can increase vulnerability to development of PTSD (e.g., Gehrman et al., 2013; Mellman, et al., 2002). Improving sleep difficulties in PTSD sufferers improves quality

of life (Margolies, 2011) and can also reduce PTSD symptoms without targeting PTSD symptoms specifically (Ho et al., 2016).

The current review has demonstrated that sleep difficulties are reduced by psychological therapies, which offer an alternative to pharmacology which has limited efficacy (Edinger et al., 2009; Lipinska, Baldwin, & Thomas, 2016). Different CBT interventions such as CBT-I or EERT and IRT may be better suited to treat insomnia and nightmares respectively and further research should be conducted into which of these approaches are beneficial for different PTSD specific sleep difficulties.

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Appendices

This section includes information supplementing the main manuscript.

Appendix A – PRISMA Statement

Appendix B – Search Terms

Appendix C – Quality Assessment Tool

Appendix D. Journal of Behavior Therapy – Instructions for Authors

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Appendix A

PRISMA Statement (Moher et al., 2009)

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	

DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**.

Appendix B

Search Terms

Population: PTSD or post-trauma* or trauma or disaster

Insomnia* or sleep*

Intervention: Psycho* therapy* or CBT or Cognitive behavio* therapy or psychological therapy or treatment* or therap* or behavio* or cognitive or program* or intervent*

Study type: Random* or controlled trial or RCT or Randomi*ed control* trial or *trial or quasi-experimental or experimental or random allocation

RANDOMISED CONTROLLED TRIALS
The search filter used by SIGN to retrieve randomised controlled trials has been adapted from the first two sections of strategy designed by the Cochrane Collaboration identifying RCTs for systematic review.
Medline
1 Randomized Controlled Trials as Topic/
2 randomized controlled trial/
3 Random Allocation/
4 Double Blind Method/
5 Single Blind Method/
6 clinical trial/
7 clinical trial, phase i.pt
8 clinical trial, phase ii.pt
9 clinical trial, phase iii.pt
10 clinical trial, phase iv.pt
11 controlled clinical trial.pt
12 randomized controlled trial.pt
13 multicenter study.pt
14 clinical trial.pt
15 exp Clinical Trials as topic/
16 or/1-15
17 (clinical adj trial$).tw
18 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw
19 PLACEBOS/
20 placebo$.tw
21 randomly allocated.tw
22 (allocated adj2 random$).tw
23 or/17-22
24 16 or 23
25 case report.tw
26 letter/
27 historical article/
28 or/25-27
29 24 not 28
Embase
1 Clinical Trial/ (505836)
2 Randomized Controlled Trial/ (430740)
3 controlled clinical trial/ (91696)
4 multicenter study/ (211094)
5 Phase 3 clinical trial/ (0)
6 Phase 4 clinical trial/ (0)
7 exp RANDOMIZATION/ (88833)

8 Single Blind Procedure/ (0)
9 Double Blind Procedure/ (0)
10 Crossover Procedure/ (0)
11 PLACEBO/ (0)
12 randomi?ed controlled trial$.tw. (118033)
13 rct.tw. (13355)
14 (random$ adj2 allocat$).tw. (26671)
15 single blind$.tw. (14081)
16 double blind$.tw. (131298)
17 ((treble or triple) adj blind$).tw. (496)
18 placebo$.tw. (184669)
19 Prospective Study/ (431057)
20 or/1-19 (1362945)
21 Case Study/ (1825273)
22 case report.tw. (246534)
23 abstract report/ or letter/ (941014)
24 Conference proceeding.pt. (0)
25 Conference abstract.pt. (0)
26 Editorial.pt. (418735)
27 Letter.pt. (941014)
28 Note.pt. (0)
29 or/21-28 (3053616)
30 20 not 29 (1330027)

CINAHL for EBSCO (created by Mark Clowes)

Query
S12 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11
S11 TX allocat* random*
S10 (MH "Quantitative Studies")
S9 (MH "Placebos")
S8 TX placebo*
S7 TX random* allocat*
S6 (MH "Random Assignment")
S5 TX randomi* control* trial*
S4 TX ((singl* n1 blind*) or (singl* n1 mask*))
or TX ((doubl* n1 blind*) or (doubl* n1 mask*))
or TX ((tripl* n1 blind*) or (tripl* n1 mask*))
or TX ((trebl* n1 blind*) or (trebl* n1 mask*))
S3 TX clinic* n1 trial*
S2 PT Clinical trial
S1 (MH "Clinical Trials+")

Appendix C

Quality Assessment Tool (QAT) for Quantitative Studies from the Effective Public Health Project (Armijo-Olivo, Stiles, Hagen, Biondo, & Cummings, 2012)

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

EPHPP
Effective Public Health Practice Project

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

1 Very likely
2 Somewhat likely
3 Not likely
4 Can't tell

(Q2) What percentage of selected individuals agreed to participate?

1 80 - 100% agreement
2 60 – 79% agreement
3 less than 60% agreement
4 Not applicable
5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

1 Randomized controlled trial
2 Controlled clinical trial
3 Cohort analytic (two group pre + post)
4 Case-control
5 Cohort (one group pre + post (before and after))
6 Interrupted time series
7 Other specify _____
8 Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

1 Yes
2 No
3 Can't tell

The following are examples of confounders:

1 Race
2 Sex
3 Marital status/family
4 Age
5 SES (income or class)
6 Education
7 Health status
8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

1 80 – 100% (most)
2 60 – 79% (some)
3 Less than 60% (few or none)
4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

1 Yes
2 No
3 Can't tell

(Q2) Were the study participants aware of the research question?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

1 Yes
2 No
3 Can't tell

(Q2) Were data collection tools shown to be reliable?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

1 Yes
2 No
3 Can't tell
4 Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell
5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell

(Q2) Was the consistency of the intervention measured?

1 Yes
2 No
3 Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

4 Yes
5 No
6 Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

(Q3) Are the statistical methods appropriate for the study design?

1 Yes
2 No
3 Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

1 Yes
2 No
3 Can't tell

GLOBAL RATING

COMPONENT RATINGS
Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

A	**SELECTION BIAS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
B	**STUDY DESIGN**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
C	**CONFOUNDERS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
D	**BLINDING**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
E	**DATA COLLECTION METHOD**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
F	**WITHDRAWALS AND DROPOUTS**	**STRONG**	**MODERATE**	**WEAK**	
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1 STRONG
2 MODERATE
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Appendix D

Journal of Behavior Therapy – Instructions for Authors

BEHAVIOR THERAPY

AUTHOR INFORMATION PACK

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DESCRIPTION

Behavior Therapy, published six times a year, is an international journal devoted to the application of the **behavioral** and **cognitive sciences** to the conceptualization, assessment, and treatment of psychopathology and related clinical problems. It is intended for mental health professionals and students from all related disciplines who wish to remain current in these areas and provides a vehicle for scientist-practitioners and clinical scientists to report the results of their original empirical research. Although the major emphasis is placed upon empirical research, methodological and theoretical papers as well as evaluative reviews of the literature will also be published. Controlled single-case designs and clinical replication series are welcome.

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GUIDE FOR AUTHORS

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Behavior Therapy, published six times a year, is an international journal devoted to the application of the behavioral and cognitive sciences to the conceptualization, assessment, and treatment of psychopathology and related clinical problems. It is intended for mental health professionals and students from all related disciplines who wish to remain current in these areas and provides a vehicle for scientist-practitioners and clinical scientists to report the results of their original empirical research. Although the major emphasis is placed upon empirical research, methodological and theoretical papers as well as evaluative reviews of the literature will also be published. Controlled single-case designs and clinical replication series are welcome.

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Denise M. Sloan, Ph.D.
Associate Director, Behavioral Science Division, National Center for PTSD
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SCHOOL OF PSYCHOLOGY

DOCTORATE IN CLINICAL PSYCHOLOGY

EMPIRICAL PAPER

Can Self-compassion Be Elicited in Armed Forces Veterans?

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CONTENTS

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Abstract

Initial studies demonstrate that self-compassion reduces symptoms of PTSD in Armed Forces Veterans (AFV), however the use of self-compassion approaches in AFV is under-researched. The current study utilised self-report and psychophysiological measures to investigate whether a single self-compassion experimental induction reduced hyperarousal symptoms (PTSD Cluster E symptoms) and increased feelings of social connectedness in AFV. The study hypothesised that there would be a decrease in hyperarousal symptoms and an increase in social connectedness, which would be associated with PTSD severity. Fifty-three AFV who had been deployed to a combat zone took part in the study, of which *n* = 15 (28.3%) currently met criteria for PTSD and *n* = 4 (7.5%) met criteria for Subsyndromal PTSD[4] on the PCL-5. Participants listened to a recording of a Loving Kindness Meditation for self-compassion (LKM-S) and psychophysiological recordings were taken throughout. Participants completed state measures of hyperarousal and social connectedness before and after the LKM-S. Findings partially demonstrated that self-compassion can be elicited in an AFV population. However, changes on the self-report measures were largely not supported by psychophysiological measures, apart from skin conductance levels (SCL). The longevity of the effects observed in the study were not measured and should be investigated in future studies. Although this study has demonstrated that self-compassion can be elicited within the AFV population, further research is needed including to test a longer self-compassion intervention.

Keywords: PTSD, self-compassion, loving kindness, Armed Forces Veterans.

[4] Subsyndromal PTSD is categorised as endorsing one Cluster B symptom (intrusion symptoms), and one of either cluster C (avoidance), D (negative alterations in cognitions), or E (hyperarousal).

Introduction

The impact of war-related trauma on soldiers is well recognised and leads to the development of posttraumatic stress disorder (PTSD) (Fontana & Rosenheck, 1993). Being in the Armed Forces can include exposure to traumatic events and people risk developing PTSD as a result of carrying out their occupational duties (Dunn, Brooks, Rubin, & Greenberg, 2015). The multitude of threats experienced by soldiers whilst on deployment to a combat zone, along with long periods of separation from family and friends, are a common experience to soldiers and are significant predictors of PTSD (King, King, Gudanowski, & Vreven, 1995). PTSD is characterised by symptoms including intrusive memories, avoidance of associations with the traumatic event, negative alterations in cognitions and mood and marked alterations in arousal and reactivity (see Appendix A, APA; American Psychiatric Association, 2013).

Reports of PTSD prevalence rates in the Armed Forces population vary (Kok, Herell, Thomas, & Hoge, 2012) and some have estimated rates in currently serving Armed Forces personnel at 4% (Hotopf et al., 2003; Fear et al., 2010) and for personnel prior to deployment or those who are not exposed to stressors in combat such as firefights at 3.3-6.1% (Hoge et al., 2004). However, studies that focus on only soldiers that held combat roles reveal high rates of PTSD (Kok, et al., 2012) and rates of PTSD rise exponentially when soldiers are exposed to combat during deployments (11.9% - 22.5%) (Kang, Natelson, Mahan, Lee & Murphy, 2003). PTSD rates increase with greater exposure to enemy contact and firefights e.g., 4.5% developed PTSD who engaged in no firefights, up to 19.3% who engaged in more than five firefights (Hoge et al., 2004). Humanitarian and peacekeeping missions also pose risk for developing PTSD and prevalence rates are similar to those who

have experienced combat i.e., 16.8% of veterans who were deployed to Cambodia, Rwanda or Somalia developed PTSD (Forbes et al., 2016).

The hypervigilance symptomology of combat PTSD is different to other types of trauma including those found in civilian populations (Kimble, Fleming & Bennion, 2013), as individuals report enhanced physiological reactivity, an overactive startle response and emotional numbness compared with those who experience civilian events (Prescott, 2012). Elevated hypervigilance and being in a threatened state might maintain PTSD in combat veterans as it can prevent changes to the nature and appraisal of trauma memories (see Figure 1) (Ehlers & Clark, 2000). Additionally, hypervigilance could be self-reinforcing as coping strategies and avoidance symptoms such as constantly being on high alert and on the lookout for danger (Conoscenti, Vine, Papa, & Litz, 2009) lead individuals to feel safe and protected. This might make it more difficult to engage in psychological therapies where exposure to traumatic memories may increase feelings of threat and therefore increase hypervigilant behaviours.

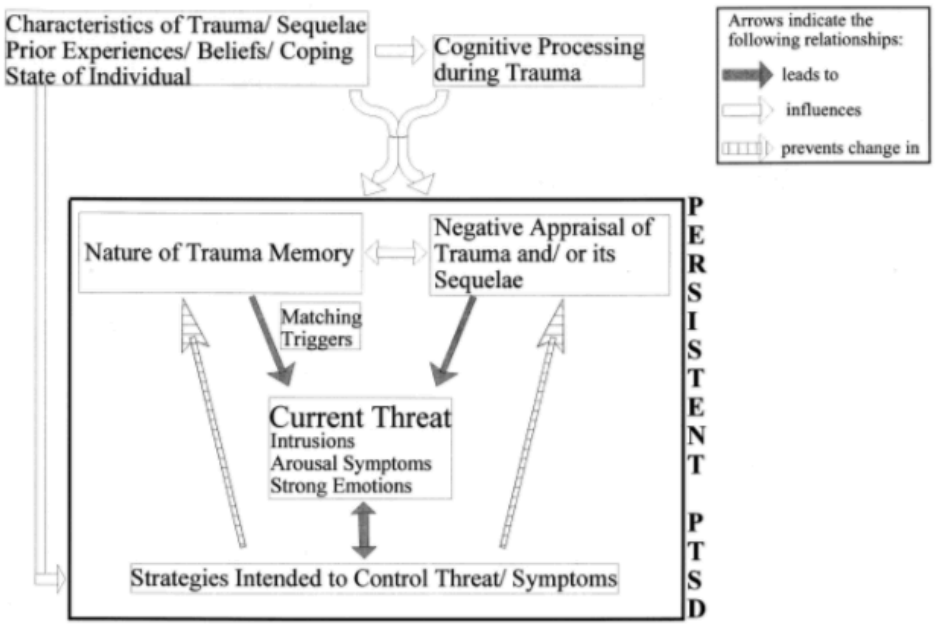

Figure 1. Ehlers and Clark (2000) Cognitive Model of PTSD.

Hyperarousal/Hypervigilance and PTSD

Hypervigilance is highly adaptive for soldiers in war zones however it can be maladaptive when taken out of context, as the individual is on constant 'high alert' even when threat is low (Kimble et al., 2013). In soldiers, hypervigilant behaviour in war zones includes constant sensory scanning and searching e.g., listening for footsteps and weapon sounds or looking for rising dust and shadows (Army Field Manual, AFM 21-75) which is endured for long periods of time due to the constant threat to life or of serious physical injury (Kimble, et al., 2013). Hypervigilance is reinforced whilst on deployment and it can become habitual to the extent where it is triggered easily and difficult to eradicate once back in civilian life where it can be problematic as it can include over-alertness, reacting quickly if threat is perceived, restlessness, irritability (Conoscenti, et al., 2009), aggression (Taft et al., 2007) and sleep problems (Germain, & Neilsen, 2003).

Hypervigilance and other PTSD symptoms can also leave people feeling detached and estranged from others and have a difficulty experiencing positive feelings (APA, 2013). This can be distressing and often people report a feeling of difference, or 'having changed' since the traumatic event (Demers, 2011). This can lead to difficulties in maintaining relationships (King, Taft, King, Hammond & Stone, 2006) resulting in a lack of social support which can contribute to a deterioration in mental health (Freedman, Gilad, Ankri, Roziner, & Shalev, 2015).

Social Connectedness and PTSD

Social support and social connectedness are both important factors to consider in the prevention and alleviation of PTSD. Social support is negatively related to PTSD both in combat veterans (e.g., Pietrzak, Johnson, Goldstein, Malley, & Southwick, 2009) and civilian populations (e.g., Schumm, Briggs-Phillips, &

Hobfoll, 2006). The role of social support and secure attachment in recovery from trauma has been well established and diminished social support can contribute to PTSD development and severity (e.g., Freedman et al., 2015; Pearlman & Curtois, 2005). Social connectedness has been shown to be negatively associated with PTSD and other psychological pathology and a persistent and pervasive lack of belongingness and social connection is psychologically distressing and is associated with psychological problems (Baumeister & Leary, 1995). Conceptually, social support and social connectedness are distinct constructs, though they likely interact with each other. Social support is defined as 'perceived or actual instrumental and/or expressive provisions supplied by the community, social networks, and confiding partners' (Lin, 1986, p.18) whereas 'social connectedness' is a person's opinion of the self in relation to other people, including the emotional distance or connectedness between themselves and others (Lee & Robbins, 1995). Social connectedness is associated with a *sense* of one's own ability to connect to others, a type of relational schema (Lee & Robbins, 1998) rather than being defined by group membership (Baumeister & Leary, 1995), and perception of social connection is more important than actual social connection (Heinrich & Gullone 2006).

Serving in the Armed Forces can provide a sense of social connectedness, which arguably is needed in order for people to engage in war (Wessely, 2006). The Armed Forces community can provide a strong sense of group cohesion and social connectedness (Tick, 2005), which has been shown to increase both psychological and physical wellbeing (De Vries, Glasper, & Detillion, 2003). However, the masculinised culture of the Armed Forces (Reit, 2009) can prevent people from sharing emotional distress, and this may be further compounded during civilian life whereby veterans may feel alone in their experiences (Demers, 2011). Transitioning

from the Armed Forces to civilian life is a major life event and involves changing social experiences, resources and networks (Hatch et al., 2013). A loss of social embeddedness and group cohesion provided by the military membership, can impede successful transition to civilian life (Hatch et al., 2003) where the sense of social support and community might be less available (Hachey, Sudom, Sweet, MacLean & VanTil, 2016).

Generally, high rates of PTSD are reported in the UK Armed Forces Veteran[5] (AFV) population compared to currently serving personnel, with estimates between 15% (Palmer, 2012) to 70% (van Hoorn et al., 2013). This could be explained by the stigma of help seeking whilst serving in the Armed Forces which would lead to underreporting during active service (Sharp et al., 2015), or the onset of PTSD could be delayed or might develop, or simply become more of a problem, once individuals leave the Armed Forces, due to reduced social support and adapting to civilian life (Hachey, et al., 2016).

Lack of social support, difficulties in social relationships, or threats to social connection contribute to PTSD severity (Freedman, et al., 2015) and activate the same stress response system as physical threats to survival i.e. the flight/flight response, including the sympathetic nervous system (SNS) and the Hypothalamus-pituitary-adrenal (HPA) axis (Eisenberger, & Cole, 2012). The link between an elevated flight/flight response and mental health problems is well established (Southwick, Vythilingam & Charney, 2005) and an elevated HPA response has been identified in people with PTSD. This elevated flight/flight state (i.e., hyperarousal) and constant activation of threat mode (i.e., hypervigilance), combined with a lack of

[5] The definition of an Armed Forces Veteran (AFV) is those who have served for at least one day in the HM Armed Forces, whether as a Regular or Reservist (Armed Forces Covenant, MOD).

social support may maintain PTSD in combat veterans, as individuals might be stuck in 'current threat' mode (Ehlers & Clark, 2000). Therefore, therapeutic approaches that emphasise reducing hyperarousal and the stress response as well as building social connectedness might reduce PTSD symptoms. By increasing positive social connections, recovery from PTSD is enhanced (e.g., Freedman et al., 2015) and also, by reducing hyperarousal, this may firstly facilitate social connections but also reduce symptoms of PTSD and enable the processing of trauma memories (e.g., Cloitre et al., 2012).

Self-compassion

Compassion based therapies use strategies that reduce the 'threat' emotional system and facilitate activation of the 'soothing' emotional system, which facilitates social connection (Figure 2) (Gilbert 2009a). Self-compassion can be described as "an intimate awareness of the suffering by oneself and others with the wish to alleviate it" (Germer & Neff, 2013) and has been conceptualised as: self-kindness versus self-judgement, common humanity versus isolation and mindfulness versus over-identification (Germer & Neff, 2013). Reviews demonstrate that self-compassion is negatively related to psychopathology (Barnard & Curry, 2011; MacBeth & Gumley, 2012) and self-compassion in therapeutic settings is gaining popularity to treat a number of mental health difficulties (e.g., Germer & Neff, 2013; 2015) including PTSD and shame based flashbacks (Lee, 2009) as well as other shame-based difficulties (Leaviss & Uttley, 2015).

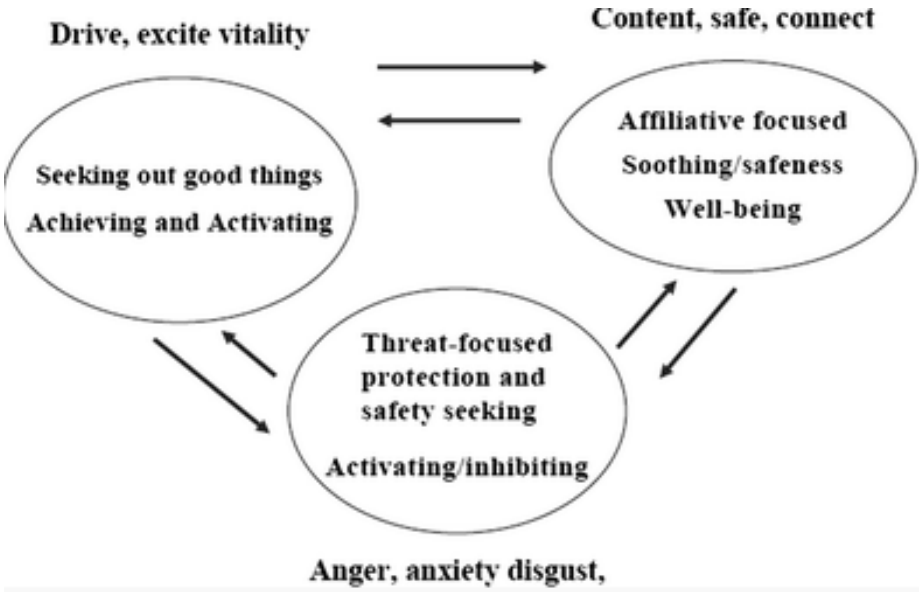

Figure 2. Gilbert (2009a). Three types of affect regulation system.

Self-compassion and PTSD. Self-compassion might be beneficial for the treatment of PTSD for two reasons: Firstly, aetiological models of PTSD and supporting empirical research indicate that negative self-appraisals prevent adaptive processing and integration of the traumatic experience into the individual's autobiographical memory leading to symptom maintenance (Ehlers & Clark, 2000). The individual is stuck in the 'threat' mode of emotion regulation (see Figure 2, Gilbert, 2009a), which detects threat and uses survival mechanisms such as the fight/flight response and activates the sympathetic part of the autonomic nervous system (as indicated by increased heart rate (HR) and skin conductance level (SCL), e.g. Pole et al., 2007), to protect against danger (MacBeth & Gumley, 2012). In contrast, facilitating self-compassion activates the soothing and contentment system (Gilbert, 2009a) characterised by a calm and content positive state and increased parasympathetic activation (as indicated by increased heart rate variability; HRV, Kirschner et al., 2016). This allows the individual to activate self-soothing and kindness and to feel safe and socially connected which reduces the fight/flight state

(Gilbert, 2010; Kirschner et al., 2016). This effect has been demonstrated by Kirschner (2016) who found that the one-off short-term Loving Kindness Meditation for self-compassion (LKM-S) used in the current study, in a sample of healthy individuals, reduced physiological arousal symptoms; (i.e. reduced HR, SCL) and increased parasympathetic activation (i.e., increased HRV). Storr (2015) also found that civilian trauma survivors with and without PTSD who followed the same LKM-S had a reduction in self-reported negative self and physiological arousal and in the non-symptomatic group there was an increase in positive self. Similarly, Kirschner (2016) found for individuals with a history of recurrent depression, the LKM-S reduced negative perceptions of the self and increased positive self-perception. Additionally, a physiological pattern of calm and content positive affect (reduced HR and SCL and increased HRV) was detected in those patients with recurrent depression who had completed an 8-week MBCT course (Kirschner, 2016). These past studies demonstrate that the LKM-S is effective in firstly eliciting self-compassion in individuals, but also to reduce arousal and increase parasympathetic activation, in clinical and non-clinical samples.

In other treatments for PTSD such as Eye-Movement Desensitisation and Reprocessing (EMDR), reduced psychophysiological responses (HR and SCL) and increased parasympathetic tone (HRV) has also been found for individuals with PTSD following treatment (Sack, 2007; Sack, 2008). Patients who continued to meet PTSD diagnostic criteria following EMDR treatment, compared to those who remitted, held elevated levels of psychophysiological response and may have benefitted from further intervention in order to see reduced psychophysiological arousal and increased parasympathetic tone (Hogberg, et al., 2008). As PTSD causes a chronic overreaction of the threat mode (e.g., Ehlers and Clark, 2000)

people with enduring/more severe PTSD might find it more difficult to benefit from psychological therapies. Therefore, in the current study, the one-off self-compassion experimental induction (i.e., the LKM-S), which activates the soothing and contentment system will be more challenging to those who have higher levels of PTSD which might result in a dose-response effect of that ability i.e., higher levels of PTSD will need more effort and a longer intervention to reduce HR, SCL and increase HRV compared with lower levels of PTSD.

Being in a 'safe' state, enables more adaptive coping with stressful and adverse events and leads to a reduction in perceived distress and biological stress response (Gilbert, 2010). This increased ability to tolerate negative emotions and adverse events helps with effective processing of the traumatic event, as for example targeted in exposure-based trauma focused CBT (Cloitre et al., 2012). This first possible mechanism of self-compassion facilitation can be described as reduction of chronic stress by improved emotion regulation and coping, which is on a biological level of reducing the physical stress response and enables effective processing of the event.

Secondly, self-compassion could reduce PTSD symptomology by increasing feelings of social connectedness (e.g., Freedman et al., 2015; Pearlman & Curtois, 2005) and studies have shown that social support is negatively related to PTSD in combat veterans (e.g., Pietrzak, et al., 2009). Serving personnel may feel a sense of safety and security which could help them to regulate emotions more effectively but upon leaving the Armed Forces, the sense of belongingness and social cohesion might be less available (Hachey, et al., 2016). Studies have found that additional personal stress of civilian life can contribute to risk factors of PTSD (Polusny et al., 2011). Facilitating self-compassion in a one-off meditation, has been shown to

increase perceived interpersonal connectedness (Hutcherson, Seppala, & Gross, 2008) and state secure attachment (Kirschner, Karl, & Kuyken, 2013). Therefore, a second mechanism of self-compassion facilitation relevant for AFV is the effect on one of the most consistent risk factors i.e., lack of perceived social support and isolation.

Self-compassion and the Armed Forces. The use of self-compassion with AFV with PTSD is in its infancy, however initial studies have found that self-compassion is negatively associated with PTSD (Dahm et al., 2015). Self-compassion levels are predictive of PTSD symptom severity (Hiraoka et al., 2015), and it is negatively related to maladaptive coping strategies such as impulsivity in military recruits (Mantzios, 2014). A study that investigated the effects of a 12-week course of loving kindness meditation (LKM) in veterans with PTSD found that self-compassion increased while symptoms of PTSD decreased (Kearney et al., 2013).

More extensive inquiry has been conducted into moral injury and in particular the relationship between PTSD symptoms and shame in civilian and the AFV population (Saraiya & Lopex-Castro, 2016; Linz et al., 2009). Shame forms an integral part of moral injury and is linked to mental health difficulties in AFV (Linz, et al 2009), which is consistent with the self-compassion literature (Gilbert, 2009a). Shame is significantly associated with hyperarousal symptoms in PTSD (Feiring, & Taska, 2005) and leads to social withdrawal and lack of social connectedness (Litz et al., 2009). Additionally, shame and self-criticism act as a barrier to care and therefore treatments that reduce levels of shame could be beneficial for sufferers of PTSD (Gaudet, Sowers, Nugent, & Boriskin, 2016). Self-compassion has demonstrated effectiveness for shame-based difficulties including PTSD (Lee, 2009) and it may be that self-compassion interventions use mechanisms that are

potentially distinct from other traditional treatments for PTSD (Talkovsky, & Lang, 2017) as it tackles shame specifically (Lee, 2009).

Loving Kindness Meditation

The LKM-S used in the current study is a one-off self-compassion experimental manipulation, used in order to determine how self-compassion generates beneficial effects in an AF population. As aforementioned, this is proposed to work through the reduction of chronic stress by reduced arousal and improved emotion regulation and also through increasing social connectedness.

It is proposed that the LKM-S will reduce levels of chronic stress by reducing threat in the affect regulation system as described in Gilbert (2009a) and the sense of 'current threat' in Ehlers & Clark (2000) both on an internal (e.g., self-criticism) and external level (e.g., hypervigilance) (Gilbert, 2009a; Ehlers & Clark, 2000). Also, by activating the soothing and contentment system (Gilbert, 2009a), this enables better emotion regulation and coping of stressful events (Gilbert, 2009a). The reduction in arousal symptoms in turn could reduce the perception of 'current threat' (Ehlers and Clark, 2000) which may therefore have an effect on reducing the maintenance system of PTSD. Further, the sense of internal threat i.e., perceptions of the self, may play an important role in maintaining PTSD, especially when people find it difficult to generate self-kindness, have a lack of self-compassion and are self-critical which can contribute to the maintenance of PTSD symptoms (Harman & Lee, 2010). Previous studies using the LKM-S have demonstrated that there is a reduction in self-reported negative self and also increased positive self-perception (Storr, 2015; Kirschner, 2016) which can lead to a 'broadening mindset' leading to further positive self-perceptions and building resilience (Kirschner et al., 2013) thus reducing threat systems in Gilbert's model (2009a) and Ehlers & Clark (2000).

Secondly, facilitating self-compassion through the LKM-S is proposed to increase social connectedness, and previous studies show that a one-off meditation increased perceived interpersonal connectedness (Hutcherson, Seppala, & Gross, 2008). Kirschner et al. (in press) also demonstrated that the LKM-S leads to increased HRV and social connectedness. By activating self-soothing and kindness (i.e., the soothing/contentment system, Gilbert, 2009a) this enables people to feel safe and socially connected, which also in turn reduces the 'threat' state (Gilbert, 2010; Kirschner et al., 2016). This mechanism is likely underpinned by reducing feelings of shame, especially in terms of how one exists both in the minds of the self and of others, which may facilitate people to feel connected to others (Gilbert & Procter, 2011).

Current Study, Aims and Rationale

Little is known about the effects of self-compassion and the AFV population, especially in those with PTSD. Studies suggest that a LKM can reduce symptoms of PTSD in AFV (e.g., Kearney et al., 2013) although to our knowledge there have been no further empirical studies to support this.

The aim of the current study is to investigate the effects of a short-term one-off self-compassion LKM-S[6] in AFV who have been exposed to danger whilst on deployment to a combat zone.

The study will explore pre-post changes on self-report hyperarousal symptoms (DSM-5, PTSD Cluster E) and feelings of social connectedness. As well, exploring physiological reactions before, during and after the meditation will measure the effects of the self-compassion meditation on the fight/flight response.

[6] The LKM-S focuses first on compassion for a loved one and then for several minutes on the self. This is different from typical LKM where the focus is firstly on the self, then a loved one, then a neutral one and then a difficult person.

Research Questions (RQ) and Hypotheses (H)

RQ1. Does a single self-compassion induction reduce hyperarousal symptoms in AFV, as indicated by a reduction in self-reported hyperarousal symptoms and reduced sympathetic arousal?

H1. It was hypothesised that there would be a decrease in self-reported hyperarousal symptoms following the LKM-S and a reduction in HR and SCL.

RQ2. Does a single self-compassion induction increase feelings of social connectedness in AFV, as indicated by an increase in self-report feelings of social connectedness and parasympathetic activation?

H2. It was hypothesised that there would be an increase in self-reported social connectedness and there would be an increase in HRV.

RQ3. Are PTSD symptoms associated with the extent of change in questions 1 & 2, following the LKM-S?

H3. It was hypothesised that PTSD severity will be associated with the extent of change in questions 1 & 2, given that more severe PTSD presentations can take longer to respond to psychological interventions (Hogberg et al., 2008).

It was also anticipated that self-compassion would be cultivated in AFV, in both those who did and did not have PTSD as indicated by an increase on the self-compassion questions.

Method

Participants Characteristics

Participants were recruited between November 2017 and April 2018 through local veteran charities, NHS services and online via social media platforms (see Appendix B for recruitment strategy). Fifty-three UK AFV (49 men, 4 women) were recruited for the current study. Eligibility criteria included being an AFV and having

deployed to a combat zone during their career which included exposure to danger. Participants were excluded if they had a severe mental health problem such as Schizophrenia or were actively suicidal. Risk was assessed and if participants scored positively on question 9 of the PHQ-9[7] then a full risk assessment was completed. If participants were deemed to be high risk, they were excluded from the study, provided with contact details of Samaritans and advised to contact their mental health service. The researchers gained permission from participants to call their GP to inform them of risk if necessary. Participants were also excluded if they were not able to attend a testing session at the University of Exeter (see Appendix C for full eligibility criteria).

Ages ranged from 30 to 75 and the mean age was M = 52.04 (SD = 13.21). The prevalence of PTSD was *n* = 19 in the current sample (those who had received a previous diagnosis from a psychiatrist). Based on scores on the PCL-5, *n* = 15 (28.3%) currently met criteria for PTSD, *n* = 4 (7.5%) met criteria for Subsyndromal PTSD[8] on the PCL-5 and *n* = 34 (64.2%) did not have PTSD. All apart from one of the participants had PTSD symptoms as a result of their deployment experiences to a war zone, *n* = 18 (34%). One participant had PTSD as a result of an accident on a training operation during a non-combat deployment.

All participants had been deployed to a combat zone which included conflicts such as the Falkland Islands, Northern Ireland, Kosovo, Iraq, and Afghanistan. Deployment length ranged from approximately two months to three years (including leave periods). There was an average of M = 4.06 (SD = 2.61) (Median and Mode = 3) deployments to combat zones per participant. There were *n* = 24 (45.3%)

[7] PHQ-9 Question 9: *thoughts that you would be better off dead or hurting yourself in some way.*
[8] Subsyndromal PTSD is categorised as endorsing one Cluster B symptom (intrusion symptoms), and one of either cluster C (avoidance), D (negative alterations in cognitions), or E (hyperarousal).

participants who had sustained a physical injury whilst on deployment. Forty-two participants (79.2%) had experienced at least one Traumatic Brain Injury (TBI) (see Table 2).

Sampling Procedures

Participants were self-selected and were recruited from a range of veteran organisations and charities in the South West of England, NHS services in Devon and online social media adverts (see Appendix B). Nighty-two people expressed an interest in the study and eighty-one people completed the telephone screening. Sixty-seven participants were eligible and signed up to take part in the study, fourteen participants dropped out at this stage due to reasons such as work commitments and illness. A total of fifty-three participants completed the study (see Figure 3.

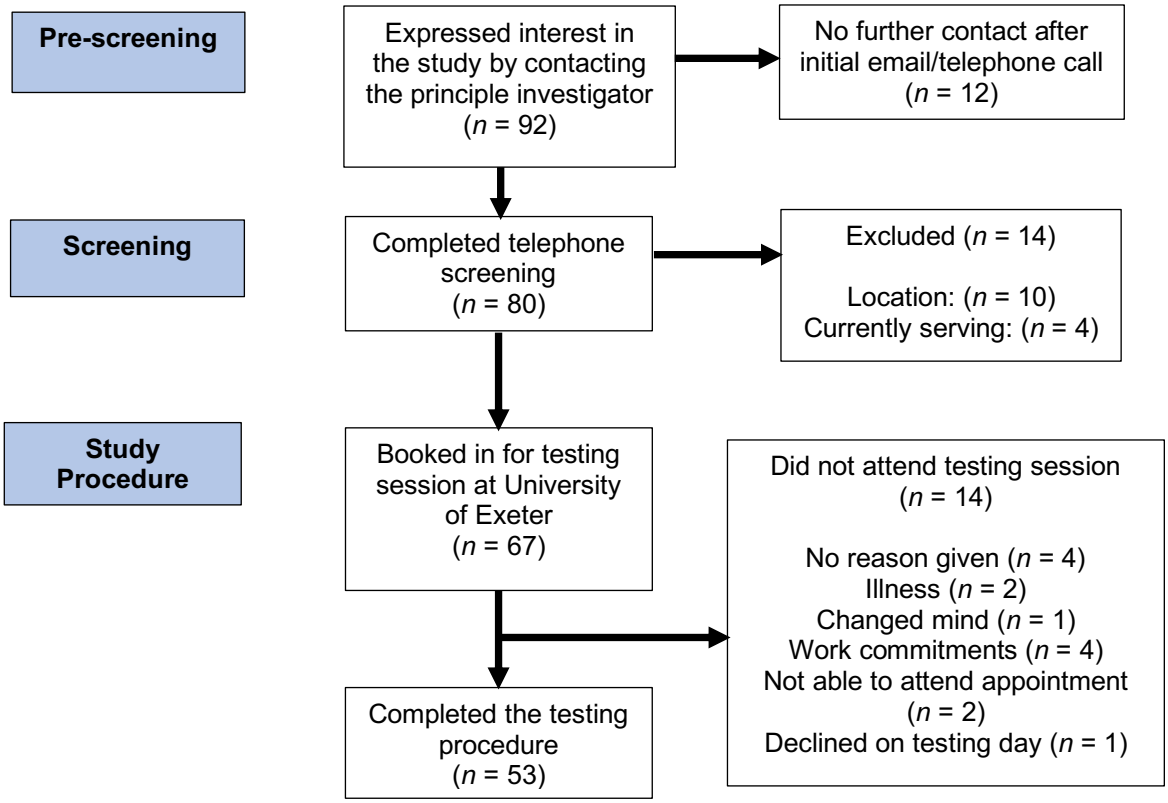

Figure 3. Flow of Participants through the Study.

Study Procedure

Eligible participants were booked in for a testing session at the University of Exeter following a telephone screening call. The study procedure included collecting demographic information, completing psychometric measures, and listening to the LKM-S (see Figure 4). All participants were paid a small sum of £10 for taking part.

Ethical approval and safety monitoring. Ethical approval was gained by NHS Health Research Authority (17/SW/0158) (see Appendix D) in order to recruit participants from local NHS services. Ethical approval was also gained from the School of Psychology ethics committee at University of Exeter (see Appendix D). Safety monitoring procedures for risk were in place throughout the study, a full risk assessment was completed if risk was identified and a letter was sent to the participant's General Practitioner (see Appendix E).

Sample Size

Sample size for the current study was determined using G*Power (Faul, Erdfelder, Bucher & Lang, 2009) to calculate a-priori the required sample size. Based on a medium effect size, it was calculated that 55 participants were needed for a statistical power of .8 and alpha = .05 (see Appendix F for details).

Measures

Demographic information. Demographic information (see Appendix G) was collected (see Table 1) including age, gender, and current employment and information about their Armed Forces career such as deployments, time served and reason for discharge.

TBI assessment. Due to associations between brain injury and combat related PTSD (e.g., Belanger, Kretzmer, Vanderploeg & French, 2009), participants

were assessed for TBI and it was classified as per the work of Williams, Cordan, Mewse Tonks & Burgess (2010) (see Appendix H) (see Table 2).

Posttraumatic stress disorder. PTSD was measured by the PTSD Checklist for DSM-5 (PCL-5; Weathers, et al., 2013) (see Appendix I). Validation studies for the PCL-5 show strong internal consistency (a = .94), test-retest reliability (r =.82), and convergent (rs = .74 to .85) and discriminant validity (rs = .31 to .60) (Blevins, Weathers, Davis, Witte & Domino, 2015).

Patient Health Questionnaire for Depression. The Patient Health Questionnaire for depression **(**PHQ-9; Kroenke, Spitzer & Williams, 2001) (see Appendix I) was used to establish levels of depression as well as to screen for suicidal risk, as per the exclusion criteria. The PHQ-9 has excellent reliability, internal = .89 and test re-test = .84 and validity for detecting depression = .95 (Solomon et al., 2000).

Emotional Regulation Questionnaire. The Emotional Regulation Questionnaire (ERQ, Gross & John, 2003) (see Appendix I) was used to determine participants' ability to regulate their emotions in terms of cognitive reappraisal[9] and expressive suppression[10]. Differences in these traits may affect the course of trauma, therefore this is important to measure at baseline. Prior research has shown that the ERQ has high internal reliability, and convergent and discriminant validity (Gross & John, 2003).

Trait self-compassion. To measure differences in participants' trait level of self-compassion prior to the LKM-S, a short form of the Self-Compassion Scale (SCS; Neff, 2011) was used (SCS-SF; Raes, Pommier, Neff & Van Gucht, 2011)

[9] Cognitive Reappraisal is cognitive change which can alter how we interpret a situation and therefore changes the emotional response (Lazarus & Alfert, 1964).
[10] Expressive Suppression is the ability to inhibit the emotive-expressive behaviour triggered by an emotional response (Gross, 1998).

(Appendix I). The short form is near perfectly correlated with the long form *r* = .98 (Raes, et al., 2011) and the scale has demonstrated validity and reliability (Neff, 2003).

Loving kindness meditation (LKM-S). A self-compassion LKM-S (see Appendix J) was used to induce self-compassion in the current study. The LKM-S has been developed by the ACCEPT clinic, at the University of Exeter Mood Disorder Centre. The LKM-S audio clip was recorded by an experienced mindfulness practitioner, and the LKM-S has been used in prior research (e.g., Kirschner, 2013). Participants are asked to direct loving/friendly feelings towards themselves and others and the audio is 11.5 minutes in length.

Experimental Measures

Visual analogue scales. Visual Analogue scales (VAS, ranging from 0-100) (see Appendix K) were used to establish state levels of self-compassion, hyperarousal and social connectedness before and after the LKM-S. This measure is adapted from Kirschner, et al., (2013) and questions are taken from the Self-Compassion Scale (SCS; Neff, 2003a), social connectedness questions are based on the state adult attachment measure (SAAM; Gillath, Noftle, & Stockdale, 2009) and four adapted items from the PCL-5 have been added to measure state hyperarousal. The VAS has been used in previous studies (Kirschner et al., 2016) which found Cronbach's α = .66 for state affiliative affect, state self-compassion (Cronbach's α = .73 in this sample) and state self-criticism (Cronbach's alpha in this sample was .73 for the inadequate self, .76 for the hated self, and .77 for the reassure self).

Physiological measurement. All physiological parameters were recorded continuously using a BIOPAC MP150 system using the AcqKnowledge 4.2 (BIOPAC Systems; Goleta, CA) software.

Heart rate (HR) and heart rate variability (HRV). HR and HRV was determined from the electrocardiogram (ECG) using standard procedures (Berntson et al., 1997, 1998). ECG was recorded from below the participant's right collar bone and the participant's left lower ribcage using a BIOPAC ECG100C amplifier at a sampling rate of 1 kHz with a low pass filter of .5 Hz and a high pass filter of 35 Hz.

Skin conductance levels (SCL). SCL was recorded using a BIOPAC SCL100C amplifier and a skin resistant transducer (TSD203) from the middle phalanx of the first and second fingers of the participant's non-dominant hand at a sampling rate of 500 Hz with a low pass filter of 1.0 Hz. SCL was pre-processed using recommended procedures (Lykken et al., 1966).

Data Collection

Data was collected by the principle investigator as part of the Doctorate in Clinical Psychology programme and third year BSc Psychology students from the University of Exeter.

Research Design

The study used a repeated measures design to test the hypotheses, using outcome score at Time 1 (pre-LKM-S) and Time 2 (post-LKM-S) as dependent variables. The variables are hyperarousal, social connectedness, self-compassion, HR, HRV and SCL. To test hypothesis 3, residualised gains scores (RGS) were calculated for hyperarousal and social connectedness, which were used as outcome variables, with PCL scores, SCL, social connectedness and hyperarousal as

predictors. State self-compassion was used as a manipulation check to determine whether the LKM-S induced self-compassion in participants.

Experimental Procedure

The experimental procedure (see Figure 4) included answering demographic questions, completing psychometric measures and listening to the LKM-S, all of which lasted approximately 1-1.5 hours. Standardised instructions were given for the VAS questions and LKM-S audio.

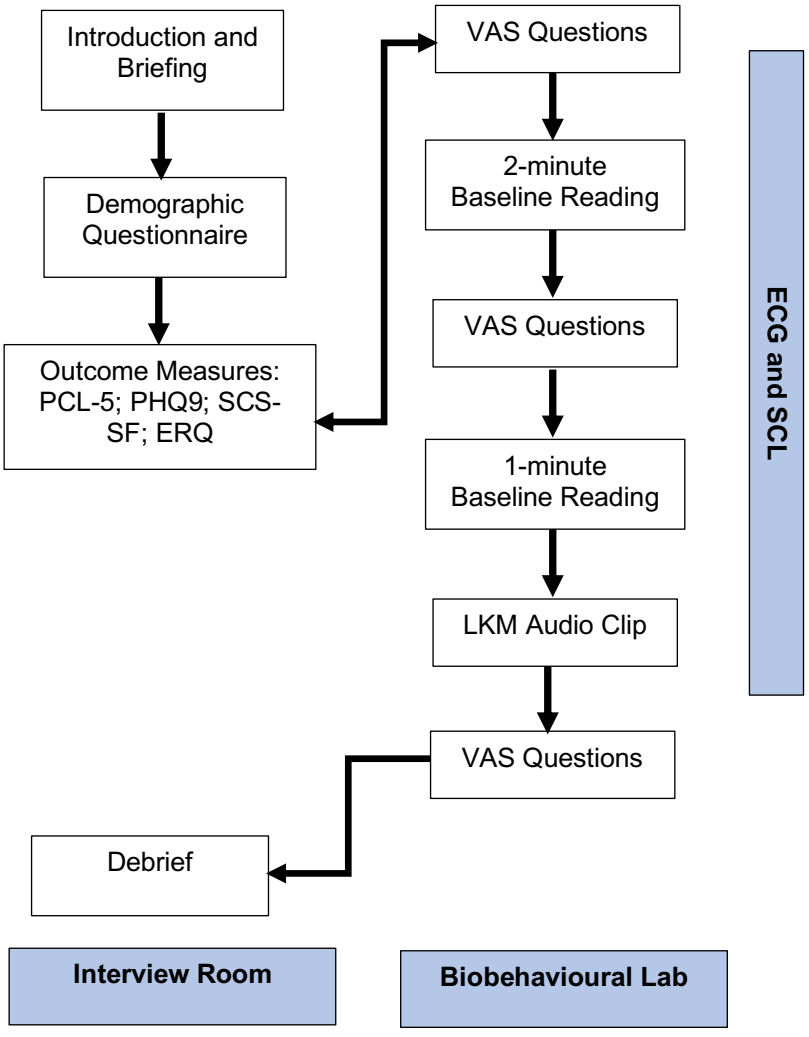

Figure 4. Experimental Procedure.

Statistical Methods

There was missing psychophysiological data for one participant therefore the analysis for psychophysiological data is based on 52 participants. No other missing data was detected in the data set.

Assumption testing. Outliers were detected after examining boxplots: inspection of their values did not reveal them to be extreme, so they were kept in the analysis. These data points were changed to the next closest value that was under the cut off which is a technique for dealing with outliers, whilst maintaining the shape of the sample distribution, but the outliers do not distort the data (Tabachnick & Fidell, 2007). Assumptions of normality were not violated. For the regression analysis, assumptions of independence of observations, linearity, homoscedacitiy, normality and multicollinearity were all fulfilled (see Appendix L) for a detailed description of assumption testing).

Physiological Data Processing

Data pre-processing and further statistical analyses of the psychophysiological data followed established procedures; i.e., determining the size of the response in relation to a pre-induction baseline as per previous studies (Kirschner et al., 2013, 2016; Storr et al., 2015) (see Appendix M, for detailed description).

Manipulation Checks and Hypothesis Testing

To test the hypotheses, paired sample t-tests were used to examine pre and post scores and one sample t-tests were used for the psychophysiological data to determine whether scores differed from zero (i.e., HR, HRV; as index of parasympathetic activation and SCL as measure of sympathetic arousal). For self-report measures of hyperarousal, social connectedness and self-compassion on the

VAS, the data was collected at two time points (pre and post the LKM-S). Correlations and regression analysis were used to examine the influence of PTSD severity on scores on the outcome variables.

Results

Sample Characteristics and Analyses

Demographic information for participants is displayed in Table 1, results from the TBI screening are displayed in Table 2 (see Appendix N), and continuous data for each of the primary outcome measures is displayed in Table 3. Zero-order correlations for all variables are included in Table 4 (see Appendix O)

Table 1.

Demographic Information.

Characteristic	N = 53
Gender, no. %	
Female	4 (7.55)
Male	49 (92.5)
Age, mean (SD), years	52.0 (13.2)
Marital Status, no. %	
Married	36 (67.9)
Single	5 (9.43)
Divorced/separated	5 (9.43)
Cohabiting	4 (7.55)
Engaged	3 (5.66)
Religion, no. %	
No religion	20 (37.7)
Church of England	23 (43.4)
Catholic	3 (5.66)
Buddist	2 (3.77)
Methodist	1 (1.89)
Other	2 (3.77)
Not stated	2 (3.77)

Characteristic	N = 53
Occupation, no. %	
Employed Full-Time	24 (45.3)
Employed Part-Time	13 (24.5)
Retired	15 (28.3)
Unemployed	1 (1.89)
Nationality, no. %	
British	51 (96.2)
Dual British Nationality	2 (3.77)
Armed Forces Branch, no. %	13 (24.5)
British Army	5 (9.43)
Royal Navy	27 (50.9)
Royal Marines	5 (9.43)
Royal Air Force	1 (1.89)
Army Reserves	1 (1.89)
Royal Marines Reserves	1 (1.89)
Special Forces	
Rank at Discharge, no. %	
Colonel	1 (1.89)
Lieutenant-Colonel	4 (7.55)
Major/ Lieutenant Commander	5 (9.43)
Captain/ Flight Lieutenant	7 (13.2)
Sub-Lieutenant	1 (1.89)
Sergeant Major	1 (1.89)
Warrant Officer 1st Class	3 (5.66)
Warrant Officer 2nd Class	1 (1.89)
Sergeant	9 (17.0)
Corporal/ Leading Hand	9 (17.0)
Lance Corporal/ Junior technician	5 (9.43)
Private/Marine/Senior Aircraftman	6 (11.3)
Physical Injury on Deployment, no. %	
Yes	24 (45.3)
No	29 (54.7)
PTSD from Combat Experiences, no. %	
Yes	18 (34)
No	35 (66)

Table 3.

Primary Outcome Measures.

	Pre		Post	
Variable	N = 53	Mean (SD)	N = 53	Mean (SD)
Self-compassion manipulation	53	55.21 (25.70)	53	65.78 (22.84)
VAS Hyperarousal	53	35.56 (20.78)	53	27.33 (13.08)
VAS Social Connectedness	53	61.52 (20.13)	53	63.66 (16.79)
PCL Total	53	22.13 (20.94)	-	-
SCS-SF	53	36.62 (8.00)	-	-
PHQ9	53	6.60 (7.33)	-	-
ERQ Cognitive Appraisal	53	4.48 (1.36)	-	-
ERQ Expression Suppression	53	3.94 (1.55)	-	-

Self-compassion Manipulation Checks

Paired-samples t-tests were used as a manipulation check for self-compassion levels pre and post the LKM-S comprising questions 3[11] and 4[12] on the VAS. There was a significant increase in the score for self-compassion from pre-LKM-S (M= 55.21, SD= 25.70) to post-LKM-S (M= 65.78, SD = 22.84) conditions; t (52) = -3.68, p = 0.001, Cohen's d = - .51. This indicates that the self-compassion exercise was successful in cultivating self-compassion and created a medium effect size was observed.

Q1. Does a single self-compassion induction reduce hyperarousal symptoms in AFV, as indicated by a reduction in self-reported hyperarousal symptoms and reduced physiological arousal?

[11] *'I do/do not feel like being kind and understanding towards myself'.*
[12] *'I am/am not tolerant of my flaws and inadequacies'.*

Self-reported hyperarousal. A paired-samples t-test was conducted to compare hyperarousal pre and post the LKM-S. There was a significant reduction in scores from pre-LKM (M= 35.56, SD= 20.78) to post-LKM-S (M = 27.33, SD = 13.08) conditions, t (52) = 4.14, p = .000, Cohen's d = 0.66. This indicates that the LKM-S reduced self-reported hyperarousal symptoms and a medium effect size was observed.

Physiological arousal.

Skin conductance (SCL) response. A one-sample t-test revealed that mean SCL response (M = -0.04, SD = 0.06) was significantly lower than zero, t (51) = -4.45, p < .001, Cohen's d = - .62. This indicates that a one-off LKM-S did significantly reduce physiological arousal as indicated by SCL and a medium effect size was observed.

Heart rate (HR) response. A one-sample t-test revealed that mean HR response (M = 0.68, SD = 2.56) did not significantly differ from zero, t (51) = 1.92, p = .06, Cohen's d = .27 This indicates that a one-off LKM-S did not significantly reduce physiological arousal as indicated by HR.

Overall, hypothesis 1 was partially confirmed by significant pre-post changes in self-reported hyperarousal and reduced physiological arousal as indicated by the SCL. However, results from HR did not support hypothesis 1 as HR was not significantly reduced as a result of the LKM-S.

Q2. Does a single self-compassion induction increase feelings of social connectedness in AFV, as indicated by an increase in self-report feelings of social connectedness and parasympathetic activation?

Self-reported social connectedness change. A paired-samples t-test was conducted to compare social connectedness pre and post the LKM-S. There was not

a significant difference in the score for pre-LKM (M= 61.52, SD= 20.13) and post-LKM-S (M= 63.66, SD = 16.79) conditions; t (52) = -1.46, p = .15, Cohen's d = - .21. This indicated that the LKM-S did not significantly increase social connectedness.

Parasympathetic activation.

Heart rate variability (HRV) response. A one-sample t-test revealed that mean HRV response (M = -0.09, *SD* = 1.0) did not significantly differ from zero, t (51) = - .63, p = 0.53, Cohen's d = - .09. This indicates that a one-off LKM-S did not significantly increase parasympathetic activation as indicated by HRV.

Overall hypothesis 2 was not confirmed as there were not significant pre-post changes in self-reported social connectedness following the LKM-S or increased parasympathetic activation as indicated by HRV.

Q3. Are PTSD symptoms associated with the extent of change in state hyperarousal and social connectedness and SCL, HR and HRV response following the LKM-S?

Self-report VAS

Hyperarousal change. Table 4 shows that hyperarousal change was significantly positively correlated with PCL Intrusions, PCL Avoidance and negatively correlated with social connectedness. However, hyperarousal change was not significantly correlated with PCL total score.

A multiple regression was run to test if change in social connectedness, PCL intrusions and PCL avoidance significantly predicted change in hyperarousal following the LKM-S. The overall model was significant with R^2 = 0.16, F (3,49) = 3.07, p = 0.04 and explained 16% of variance. Only social connectedness change was a significant predictor (β = - .27, p = 0.05) but PCL Intrusions (β = 0.24, p =

0.41) and PCL Avoidance (β = - .002, p = .99) did not significantly explain change in hyperarousal.

This indicates that higher increases in social connectedness were associated with greater reductions in state hyperarousal to LKM-S but PTSD symptoms intrusions and avoidance did not contribute to explain state hyperarousal change.

Social connectedness change. Table 4 shows that social connectedness change was significantly negatively correlated with change in hyperarousal, and Mean SCL response, and significantly positively correlated with self-compassion score. However, social connectedness was not significantly correlated with PCL total score.

A multiple regression was run to test if change in hyperarousal, self-compassion score and Mean SCL response significantly predicted change in social connectedness following the LKM-S. The overall model was significant with R^2 = 0.26, F (3,48) = 5.58, p = 0.02, and explained 26% of variance. SCL Mean response was the only significant predictor (β = - .33, p = 0.01) for change in state social connectedness. Self-compassion was not a significant predictor (β = .25, p = 0.054) and change in hyperarousal did not make a significant contribution (β = - .22, p = 0.10). This indicates that greater reductions in SCL were associated with greater increases in state social connectedness whereas neither change in state hyperarousal to LKM-S, self-compassion score, nor PTSD symptoms explained significant variance.

Physiological arousal.

Mean SCL response. Mean SCL response was significantly positively correlated with PCL avoidance and social connectedness, but it was not significantly correlated with the PCL total score.

A multiple regression was run with Mean SCL response as the outcome, and change in social connectedness and PCL avoidance as predictors. The overall model was significant with R^2 = .18, F (2,49) = 5.24, p = 0.009, and explained 18% of variance. Only change in social connectedness significantly predicted Mean SCL response (Beta = -.30, p = 0.03) whereas PCL avoidance (β = .23, p = .10) did not significant explain variance. As described above, greater reductions in SCL were associated with higher increases in social connectedness whereas PTSD symptoms did not explain LKM-S related SCL changes.

Mean HR response. Table 4 indicates that Mean HR was not significantly correlated with total PCL score or with PCL subscales nor was it associated with any other self-report measure (see Table 4). Therefore, no regression analyses was performed.

Parasympathetic activation.

Mean HRV. Table 4 indicates that Mean HRV was not significantly correlated with total PCL score or with PCL subscales nor was it associated with any other self-report measure (see Table 4). Therefore, no regression analysis was performed.

Overall, hypothesis 3 was only partially confirmed as hyperarousal change was associated with PTSD intrusions and avoidance symptoms and social connectedness change however, in the regression only social connectedness change came out a significant predictor.

Social connectedness change was significantly negatively correlated with change in hyperarousal, and SCL response, and significantly positively correlated with self-compassion score however, in the regression SCL response was the only significant predictor.

Mean SCL response was the only psychophysiological measures associated with PCL avoidance and social connectedness, but in the regression, only social connectedness was the significant predictor.

Exploratory Findings

ERQ (Expression and suppression). ERQ (emotional suppression) was positively correlated with PCL total and all PCL subscales, and negatively with self-compassion (Table 4, see Appendix O).

Discussion

The current study investigated self-report and psychophysiological effects of a one-off self-compassion meditation (LKM-S) in AFV who had been exposed to combat with varying levels of PTSD symptom severity. In line with previous research conducted in both healthy and clinical samples with recurrent depression (Kirschner, 2016) and in trauma survivors with and without PTSD (Storr, 2015), this study found that self-reported state self-compassion was significantly increased following a one-off self-compassion meditation. Extending previous research (e.g., Kirschner, 2016), the LKM-S was not only accompanied by a reduction in skin conductance but also self-reported hyperarousal symptoms.

Contrary to previous research (Hutcherson, et al., 2008; Kirschner, 2016) the study failed to reveal a significant reduction in HR and a significant increase in state social connectedness and parasympathetic activation as indicated by HRV following the self-compassion meditation. In addition, contrary to the hypotheses, LKM-S induced self-report and physiological changes were largely not associated with PTSD severity, apart from PCL avoidance which was positively associated with SCL mean response, and reduction of hyperarousal was associated with lower PCL intrusion and avoidance symptoms. Although zero order correlations indicated that

the reduction of hyperarousal following the LKM-S is associated with lower PTSD symptoms (intrusions and avoidance), and PCL avoidance score is associated with reduced sympathetic activation i.e., Mean SCL score, in the regression these variables did not come out as significant predictors.

Associations between PTSD severity and key variables were largely not found following the LKM-S. This may be explained by the type of trauma experienced by participants in the current study as combat related PTSD can present with elevated hyperarousal symptoms compared with civilian traumas (Kimble et al., 2013; Prescott, 2012) and arguably leads to more severe PTSD compared with non-interpersonal trauma (Yoo, et al., 2018). In the current study, participants with and without PTSD had all experienced deployment to a combat zone where interpersonal trauma and a need to remain hypervigilant is commonplace (Conoscenti, et al., 2009). Additionally, bearing witness to 'human-caused' traumatic events can lead to a breakdown in a sense of safety and social norms and compromise trust in others (Charuvastra & Cloitre, 2009) therefore this might have made it difficult to cultivate feelings of safety and social connectedness in the LKM-S.

The associations between PCL avoidance and SCL mean response might mean that those with higher sympathetic arousal levels utilise avoidance strategies (e.g., avoiding memories related to the trauma) more so than those with lower sympathetic responses. Additionally, the PCL total score was correlated with ERQ emotion suppression score (e.g., 'I control my emotions by not expressing them'). This might suggest that avoiding reminders of the traumatic event, as well as suppressing emotions, leads to an elevated threat state (Gilbert, 2009a) and forms part of the maintenance cycle in PTSD (e.g., Ehlers & Clark, 2000).

Self-compassion was also negatively related to emotion suppression and also PCL total score which might suggest that people with higher levels of PTSD and those who tend to suppress their emotions, might find self-compassion difficult to engage with. Previous studies have demonstrated that some have a fearful response to self-compassion particularly if people have experienced childhood adversity (Gilbert, 2010a). Additionally, PTSD cluster D symptoms[13] which could indicate an increased sense of threat from the self and others was negatively associated with trait self-compassion score.

This is in line with previous research (e.g., Gilbert, 2009a), whereby some people find affiliative emotions threatening rather than pleasant (Gilbert, 2010) and self-compassion inductions can lower HRV especially in self-critical people (Glover, 2008). Therefore, in the current study high levels of self-criticism may have prevented an increase in parasympathetic activation as indicated by HRV and self-report social connectedness. However, associations were not found between the key variables and PTSD cluster D symptoms which was expected given that PTSD has been related to negative posttraumatic cognitions about the world and others (Ehlers & Clark, 2000).

Although significant changes were not found in social connectedness pre-post the LKM-S, the change in social connectedness was associated with both a change in hyperarousal and also mean SCL. Despite it not being supported by an increase in parasympathetic activation (i.e., HR and HRV), there was a relationship between social connectedness change and reduction in sympathetic response and self-reported hyperarousal. These changes in part, support our predictions of where the

[13] i.e., *Persistent and exaggerated negative beliefs or expectations about oneself, others, or the world* (APA, 2013)

LKM-S would work in already established models (Gilbert, 2009a; Ehlers & Clark, 2000), whereby the LKM-S elicited a reduction in arousal and the 'threat' systems in the affect regulation model (Gilbert, 2009a) and cognitive model of PTSD (Ehlers & Clark, 2000). However, as significant changes were not found for social connectedness, this might mean that a longer intervention might be needed in order to increase feelings of social connectedness and also have an increase in HRV, in AFV whereby the 'soothing/contentment system' is activated as per the affect regulation model (Gilbert, 2009a).

The discrepancy between the self-report measures and physiological measures means that results should be interpreted with caution and has been noted in previous studies, where changes were not observed on all physiological measures of parasympathetic activation following the LKM-S (e.g, Kirschner, 2016; Storr, 2015). However, studies show that after an 8-week Mindfulness Based Cognitive Therapy (Kirschner, 2016), participants demonstrated concordant results of self-report measures and psychophysiological response, therefore, further investigation is warranted into the conditions in which the LKM-S facilitates concordant changes in self-report and psychophysiological measures in AFV, which may include an intervention of longer duration as per previous studies (e.g., Kok, et al., 2013; Kearney et al., 2013). Also, as PTSD is associated with lower levels of baseline/resting HRV and poor autonomic functioning (Dennis et al., 2014), a longer intervention may be needed in order to elicit parasympathetic activation in AFV. By activating self-compassion i.e., the soothing and parasympathetic nervous system (Kirschner, 2016), this may enable people to engage with difficult emotions without judgement which can lead to healthier psychological functioning (Schanche, Stiles, McCollough, Swartberg, & Nielsen, 2011) and may be important in alleviating PTSD

symptoms in AFV. In addition, social connectedness and experiencing safety among others, may have the capacity to inhibit circuits implicated in the fight/flight response (Williamson et al., 2015).

Overall, the results from the current study demonstrate that a one-off, LKM-S can temporarily reduce self-reported symptoms of hyperarousal and sympathetic arousal as indicated by skin conductance, which may be useful in treatment of PTSD. In future settings, it may be beneficial for self-compassion interventions to be utilised as a stand-alone PTSD treatment (e.g., Lee, 2009) or if hyperarousal symptoms remain after PTSD specific therapy (Zayfert, & DeViva, 2004).

Strengths, Limitations and Future Research

This is the first study to investigate the effects of a one-off self-compassion meditation in an AFV population, using measures of psychophysiology, self-compassion and self-report state measures. A large sample was recruited in a short time-frame (5 months) and participants travelled from outside of the UK to participate, which shows promise for recruitment in future AFV studies.

In the current study, changes in state self-compassion, state-hyperarousal and state social-connectedness were assessed, which is different from previous research (e.g., Storr, 2015) that used trait and dispositional measures which are not susceptible to change. In addition, self-report measures were complemented with psychophysiolological measures which provides an objective measure of sympathetic and parasympathetic activation. In addition, the correlational approach used in the current study provides an understanding of the relationships between self-report state measures, PTSD and psychophysiological results.

Limitations of the current study include that the recruitment target was not achieved (by two participants), therefore the results should be interpreted with

caution and need to be replicated in a larger sample. Our sample was predominantly male (92.5%) which did not enable us to test for gender differences as discussed in Crum-Cianflone & Jacobson (2014).

Additionally, the correlational approach taken and absence of a control group without combat exposure, or comparison of a control group with a PTSD group, means that conclusions about the impact of self-compassion on a PTSD group versus a control sample cannot be established.

The study only measured changes in self-compassion immediately after the session and did not include a follow-up session at a later date. Therefore, there is the possibility that the shift in self-compassion is only temporary and the gains are not maintained. In more intensive interventions with longer duration shown to elicit self-compassion, changes in self-compassion is long lasting and it is maintained at 6-month and 1-year follow-up (e.g., Germer & Neff, 2013).

Participant trauma history was restricted to time in the Armed Forces however studies investigating childhood adversity in AFV have established that early trauma experiences can contribute to the development PTSD (Iverson et al., 2007). Assessing childhood trauma was outside the remit of ethical approval in the current study, however, in future it would be important to measure to establish whether this affects individuals' ability to elicit self-compassion (e.g., Gilbert, 2010). This may be important for establishing dose-response effects or treatment adaptations.

Conclusion

The study has partially demonstrated that self-compassion can be elicited in AFV who have experienced combat, after just a short LKM-S. Our findings support other studies that have investigated self-compassion (e.g., Kirschner, 2016) and self-compassion in AFV (e.g., Kearney et al., 2013). However, the evidence base for self-

compassion in the AFV population is small and further studies are needed in order to establish whether self-compassion interventions are a suitable treatment option for PTSD.

To our knowledge, this is the first study of its kind, and it is hoped that this will, along with other studies (e.g., Kearney et al., 2013) enable further investigation into self-compassion approaches to treat PTSD. Psychological therapies are less effective for combat trauma compared with other types of trauma (Bradley, Greene, Russ, Dutra, & Westen, 2005) and therefore further research needs to be conducted in order to establish effective treatments for PTSD in the AFV population.

The study has highlighted that although self-compassion can be elicited in AFV, new interventions need to be implemented with caution, as differences exist such as the severity of hypervigilance symptoms (Prescott, 2012).

Moving forward, future research should investigate the effects of longer-term self-compassion interventions in the AFV population as per the work of Neff and colleagues (e.g., Germer & Neff, 2015).

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Appendices

This section includes information supplementing the main manuscript.

Appendix A

Posttraumatic Stress Disorder Diagnostic Criteria (Diagnostic and statistical manual

Criterion	Description
A	Exposure to actual or threatened death, serious injury, or sexual violence in one (or more) of the following ways: 1. Directly experiencing the traumatic event (s). 2. Witnessing, in person, the event(s) as it occurred to others. 3. Learning that the traumatic events(s) occurred to a close family member or close friend. In cases of actual or threatened death of a family member or death, the event(s) must have been violent or accidental. 4. Experiencing repeated or extreme exposure to aversive details of the traumatic events(s) (e.g., first responders collecting human remains; police officers repeatedly exposed to details of child abuse).
B	Presence of one (or more) of the following intrusion symptoms associated with the traumatic event(s), beginning after the traumatic event(s) occurred: 1. Recurrent, involuntary, and intrusive distressing memories of the traumatic event(s). **Note:** In children older than 6 years, repetitive play may occur in which themes or aspects of the traumatic event(s) are expressed. 2. Recurrent distressing dreams in which the content and/or affect of the dream are related to the traumatic event(s). **Note:** In children, there may be frightening dreams without recognizable content. 3. Dissociateive reactions (e.g., flashbacks) in which the individual feels or acts as if the traumatic event(s) were recurring. (Such reactions may occur on a continuum, with the most extreme expression being a complete loss of awareness of present surroundings.) **Note:** In children, trauma-specific re-enactment may occur in play. 4. Intense or prolonged psychological distress at exposure to internal or external cues that symbolize or resemble an aspect of the traumatic event(s). 5. Marked physiological reactions to internal or external cues that symbolize or resemble an aspect of the traumatic event(s).
C	Persistent avoidance of stimuli associated with the traumatic event(s), beginning after the traumatic event(s) occurred, as evidenced by one or both of the following: 1. Avoidance of or efforts to avoid external reminders (people, places, conversations, activities, objects, situations) that arouse distressing memories, thoughts, or feelings about or closely associated with the traumatic event(s). 2. Avoidance of or efforts to avoid external reminders (people, places, conversations, activities, objects, situations) that arouse distressing memories, thoughts, or feelings about or closely associated with the traumatic event(s).
D	Negative alterations in cognitions and mood associated with the traumatic event(s), beginning or worsening after the traumatic event(s) occurred, as evidence by two (or more) of the following: 1. Inability to remember an important aspect of the traumatic event(s) (typically due to dissociative amnesia and not to other factors such as head injury, alcohol, or drugs). 2. Persistent and exaggerated negative beliefs or expectations about oneself, others, or the world (e.g., “I am bad,” “No one can be trusted,” “The world is completely dangerous,” “My who nervous system is permanently ruined”). 3. Persistent, distorted cognitions about the cause or consequences of the traumatic event(s) that lead the individual to blame himself/herself or others. 4. Persistent negative emotional state (e.g., fear, horror, anger, guilt, or shame). 5. Markedly diminished interest or participation in significant activities. 6. Feelings of detachment or estrangements from others. 7. Persistent inability to experience positive emotions (e.g., inability to experience happiness, satisfaction, or loving feelings).
E	Marked alterations in arousal and reactivity associated with the traumatic event(s), beginning or worsening after the traumatic event(s) occurred, as evidence by two (or more) of the following: 1. Irritable behaviour and angry outbursts (with little or no provocation) typically expressed as verbal or physical aggression toward people or objects. 2. Recless or self-destructive behaviour. 3. Hypervigilance. 4. Exaggerated startle response. 5. Problems with concentration. 6. Sleep disturbance (e.g., difficulty falling or staying asleep or restless sleep).
F	Duration of the disturbance (Criteria B, C, D, and E) is more than 1 month.
G	The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
H	The disturbance is not attributable to the physiological effects of a substance (e.g., medication, alcohol) or another medical condition.

of mental disorders (5th ed.); APA, 2013

Appendix B

Recruitment Strategy

Poster Distribution	
Black Horse	Phoenix Sound
Bowling Green	Waterstones
Henry's	Steve's Gym
Co-Op on Penny C road	Newton Abbot Library
Boston Tea Party	Newton Abbot Train Station
Sainsburys in the Guildhall	Knotts deli & Bakery
The Plant Café	Nature's Bounty health shop
Guildhall leaflet stand	Newton Barbers
Devon Coffee notice board	Coffee Couture
Cathedral staff notice board	Argos- staff board
Oxfam notice board x 2	British Heart Foundation-staff board
RSPCA	Spar- staff board
Hair a No.5	St David's Community Centre
London Town Barbers	Queens building
Waterstones notice board	Camper Coffee
City Barbers	The Kit Shop
Trail Outdoors	

Online Advertising	
CTC Lympstone family support group.	UK Wags
Royal Marine Partners support group.	Post on personal facebook, shared 3 times.
Stonehouse 30 Commando Support Group	

Other Advertising	
The Warrior Programme –Hannah's House Newton Abbott	Correspondence with the Royal Marine Association
Devon Partnership Trust (DPT): Meeting with clinicians at Veterans Service, poster displayed in Psychological Therapies Service (waiting room), email to all clinicians at Psychology Department, meeting with Devon Anxiety and Depression Service (poster/leaflets disseminated to service leads), dissemination at Audit Research and Implementation meeting (service leads across DPT), dissemination at Psychology Governance meeting (service leads across DPT).	Correspondence with Exeter Association of WRENS. Combat Stress – sent posters to display. Correspondence with Dr Sarah Bulmer (Military Afterlives Project, University of Exeter). Post on personal Facebook. Post on Linkedin account. Post on Twitter account. Advert displayed on Mood Disorders Centre webpage Advert sent out in university news bulletin email

Advert sent out to DPT staff through news bulletin (HUB bites) and advertised on HUB page. Breaking Ground – correspondence and sent posters/flyers to advertise. The White Ensign Club – correspondence and posters sent. Correspondence with NIHR Clinical Research Network South West Peninsula: GP practices – sent posters to 8 x practices.	Advert placed in Pathfinder magazine and promoted through their social media pages. Meeting with DPT Research and Development and Comms Dept to promote on internal website (Daisy), in internal news bulletin, on external DPT website as news item and on DPT Research project page. DPT promoted through twitter and Facebook pages.

Appendix C

Inclusion and Exclusion Criteria

Fifty-five Armed Forces Veterans, who served in the Army, Royal Navy, Royal Air Force including Reserves, and have been deployed to a combat zone such as Northern Ireland, Iraq or Afghanistan, will be recruited for the study.

Risk will be assessed and if participants score positively on question 9 of the PHQ-9 (PHQ-9 Question 9: *thoughts that you would be better off dead or hurting yourself in some way*) then a full risk assessment will be completed. If participants are deemed to be high risk (i.e., actively suicidal), they will be excluded from the study and provided with contact details of Samaritans and asked to contact their mental health service and the researchers will contact their GP. Participants will be asked if they have acquired a traumatic brain injury (TBI) and the frequency and severity will be classified as per the work of Williams, Cordan, Mewse Tonks & Burgess (2010). If participants have a severe TBI of which they continue to experience symptoms, then they will be excluded from the study. Further inclusion and exclusion criteria is presented below.

Inclusion/Exclusion Criteria

Criteria	
Inclusion	The position held whilst on deployment must have involved exposure to foot patrols indicating having experienced danger during deployment, such as being under enemy fire.
Exclusion	Participants will be excluded if they have been exposed to traumatic experiences other than whilst on deployment to combat-zones, or if their role did not involve exposure to threat or danger to their safety.
Exclusion	Participants will be excluded if they are a currently serving member of the Armed Forces, including being a Reservist.
Exclusion	Participants will be excluded if upon screening they show severe symptoms of depression, as measured by scoring ≥20 on the PHQ-9.
Exclusion	Participants will be excluded if they have received a diagnosis for a severe mental health problem such as Schizophrenia.

Appendix D

Ethical Approval Documents

UoE School of Psychology - Ethical Approval

From: ethics@exeter.ac.uk <ethics@exeter.ac.uk>
Sent: 01 November 2017 10:29
To: Gerdes, Samantha
Cc: Karl, Anke
Subject: Samantha Gerdes e-Ethics Application outcome decided (eCLESPsy000142 v4.1)

Dear Samantha Gerdes,

Application ID:	**eCLESPsy000142 v4.1**
Title:	**Can Self-Compassion Be Cultivated in Individuals who have been exposed to life-threatening or prolonged stressors such as Armed Forces Veterans?**

Your e-Ethics application has been reviewed by the CLES Psychology Ethics Committee.

The outcome of the decision is: **Favourable**

Potential Outcomes

Favourable:	The application has been granted ethical approval by the Committee. The application will be flagged as Closed in the system. To view it again, please select the tick box: View completed
Favourable, with conditions:	The application has been granted ethical approval by the Committee under the provision of certain conditions. These conditions are detailed below.
Provisional:	You have **not** been granted ethical approval. The application needs to be amended in light of the Committee's comments and re-submitted for Ethical review.
Unfavourable:	You have **not** been granted ethical approval. The application has been **rejected** by the Committee. The application needs to be amended in light of the Committee's comments and resubmitted / or you need to complete a new application.

Please view your application here and respond to comments as required. You can download your outcome letter by clicking on the 'PDF' button on your eEthics Dashboard.

If you have any queries please contact the CLES Psychology Ethics Chair:
Lisa Leaver L.A.Leaver@exeter.ac.uk

Kind regards,
CLES Psychology Ethics Committee

Health Research Authority Approval

Miss Samantha Gerdes
Trainee Clinical Psychologist
Taunton and Somerset NHS Foundation Trust
College of Life and Environmental Sciences (CLES),
Psychology
University of Exeter Washington Singer Laboratories
Perry Road, Exeter
EX4 4QG

Email: hra.approval@nhs.net

06 October 2017

Dear

Letter of HRA Approval

Study title:	**Can Self-Compassion Be Cultivated in Individuals who have been exposed to life-threatening or prolonged stressors such as Armed Forces Veterans?**
IRAS project ID:	**220845**
Protocol number:	**1617/18**
REC reference:	**17/SW/0158**
Sponsor	**University of Exeter**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

IRAS project ID	220845

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

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IRAS project ID	220845

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **220845**. Please quote this on all correspondence.

Yours sincerely

Nabeela Iqbal
Assessor

Email: hra.approval@nhs.net

Copy to: *Ms G M Seymour, University of Exeter, Sponsor contact*
Sarah Laidler, Devon Partnership Trust - Research and Development- Lead NHS R&D contact

IRAS project ID	220845

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Copies of advertisement materials for research participants [220845_Advert_Version 1_15062017]	1	15 June 2017
Copies of advertisement materials for research participants [220845_Advert]	2	17 August 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [220845_GERDES_Sponsor letter to CI-non-CTIMP]	1	15 June 2017
GP/consultant information sheets or letters [220845_GP_Risk_Letter_Version 1_15062017]	1	15 June 2017
HRA Schedule of Events [SOE validated]	1.0	06 October 2017
HRA Statement of Activities [SOA validated]	1.0	06 October 2017
IRAS Application Form [IRAS_Form_05072017]		05 July 2017
Letter from sponsor [220845_Sponsorship confirmation letter_non-CTIMP]	1	15 June 2017
Non-validated questionnaire [220845_Visual_Analogue_Scale_Version 1_15062017]	Version 1	15 June 2017
Other [220845_UoE - Public Liabilityto31Oct17]	1	15 June 2017
Other [220845_UoE - Professional Indemnityto31Oct17]	1	15 June 2017
Other [220845_MDC Risk_Assessment_Version 1_15062017]	Version 1	15 June 2017
Other [220845_Participant_Debrief_Sheet]	2	17 August 2017
Participant consent form [220845_Participant_Consent_Form_Version 1_15062017]	1	15 June 2017
Participant information sheet (PIS) [220845_Participant_Information_Sheet_Version 1_15062017]	1	15 June 2017
Research protocol or project proposal [220845_Study_Protocol_Version 1_15062017]	1	15 June 2017
Summary CV for Chief Investigator (CI) [220845_CV_Gerdes_Version 1_15062017]	Version 1	15 June 2017
Summary CV for student [220845_CV_Phillips_Version 1_15062017]	1	15 June 2017
Summary CV for supervisor (student research) [220845_CV_Karl_Version 1_15062017]	1	15 June 2017
Summary CV for supervisor (student research) [220845_CV_ Williams_Version 1_15062017]	1	15 June 2017
Validated questionnaire [220845_SCS_Version 1_15062017]	1	15 June 2017
Validated questionnaire [220845_PHQ-9_Version 1_15062017]	1	15 June 2017
Validated questionnaire [220845_PCL-5_Version 1_15062017]	1	15 June 2017
Validated questionnaire [220845_ERQ_Version 1_15062017]	1	15 June 2017
Validated questionnaire [220845_CES_Version 1_15062017]	1	15 June 2017

IRAS project ID	220845

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations*, *capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Ms G M Seymour
Tel: 01392726621
Email: g.m.seymour@exeter.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The SOA will act as an agreement with sites.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this

IRAS project ID	220845

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			research study
4.3	Financial arrangements assessed	Yes	This is a PhD study and no funding will be available to sites, as detailed in Schedule 1 of the SOA.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC FO issued on the 4th September 2017.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

IRAS project ID	220845

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

This is a single site type study where it is limited to PIC activity. The PIC activity involves identification and dissemination of PIS at assessment or review appointments by the direct clinical care team.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If Chief Investigators, sponsors or Principal Investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the Chief Investigator, sponsor or Principal Investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England **will be expected to formally confirm their capacity and capability** to host this research.

- The sponsor should ensure that participating NHS organisations are provided with a copy of this letter and all relevant study documentation, and work jointly with NHS organisations to arrange capacity and capability whilst the HRA assessment is ongoing.
- Further detail on how capacity and capability will be confirmed by participating NHS organisations, following issue of the Letter of HRA Approval, is provided in the *Participating NHS Organisations* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections of this appendix.
- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

IRAS project ID	220845

Principal Investigator Suitability

This confirms whether the sponsor's position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England, and the minimum expectations for education, training and experience that PIs should meet (where applicable).
There will be no requirement for LC or PI since activity is limited to staff disseminating PIS. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken.
As a study undertaken by local staff, it is unlikely that letters of access or honorary research contracts will be applicable, except where local network staff employed by another Trust (or University) are involved (and then it is likely that arrangements are already in place).

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England in study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Devon Partnership Trust - Confirmation of Capacity and Capability

Devon Partnership NHS
NHS Trust

Research and Development
Directorate
Wonford House
Dryden Road
EXETER
EX2 5AF

Tel: 01392 675 689
Email: sarahlaidler@nhs.net

11 October 2017

Samantha Gerdes
Trainee Clinical Psychologist
Taunton and Somerset NHS Foundation Trust
College of Life and Environmental Sciences, Psychology
University of Exeter Washington Singer Laboratories
Perry Road
Exeter EX4 4QG

Dear Samantha

IRAS Project ID: 220845
DPT reference: DPT0345
Study Title: Can Self-Compassion be cultivated in Armed Forces Veterans?

This letter confirms that Devon Partnership NHS Trust (DPT) has the capacity and capability to support the above referenced study, which has received approval from the appropriate regulatory bodies.

Devon Partnership Trust will be a Patient Identification Centre for the above named study.

The documents approved for use in this study are those approved by the Health Research Authority and Research Ethics Committee.

As named Investigator for the research that is being undertaken at this Trust, it is your responsibility to manage and conduct this study in accordance with;

- The requirements of the **Research Governance Framework for Health and Social Care (2005)** and **Medicines for Human Use (Clinical Trials) Regulations 2004** (if applicable).
- **ICH-GCP** (Good Clinical Practice) – It is mandatory for those staff who will be consenting participants into this study to have undertaken GCP and to ensure it is updated every 2 years.
- The **Human Tissue Act 2004** and the **EU Tissue and Cells Directive (2006)** for research involving human tissue.
- The **Data Protection Act 1998** which details the eight principles of 'good information handling'.
- **R&D Standard Operating Procedures** (SOPs) and **Trust policies** which are available on the Trust intranet site

As Lead Investigator for this research, you are required to ensure study specific duties are appropriately delegated and clearly documented on the study Delegation Log. This guarantees clarity

Devon Partnership NHS
NHS Trust

of roles and must be signed and dated by each individual on the study and yourself as Lead Investigator.

Safety Reporting
Guidance on the classification of Adverse Events/Reactions (AEs/ARs) / Serious Adverse Events/Reactions (SAEs/SARs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) and the requirements for reporting to the sponsor can be found in the study protocol. For Devon Partnership NHS Trust sponsored studies this is also detailed in the sponsorship letter. All safety events that involve DPT patients, that require reporting to the Sponsor, must also be reported by fax marked for the attention of Sarah Laidler and sent to the R&D Office within 24 hours of becoming aware of the event (01392 6744929) alternatively via email to sarahlaidler@nhs.net.

Progress Reporting
You are required to submit regular recruitment updates to the R&D Office, as well as annual progress reports to Ethics, MHRA (where applicable) and R&D. Please note that new government and Trust targets require you to have recruited your **first patient within 30 days of the date of Trust Approval** and to have recruited your target number of participants within the time frame stipulated on your SSI form (Time to Target).

Monitoring and Audit
Your study may be monitored by the Sponsor and selected for audit by the R&D Office (where DPT is not the Sponsor) and Regulatory Authorities at any time. The team involved in conducting this research must ensure full co-operation with any requests from any of these bodies. Action may be taken to suspend research if it is found to not be conducted in accordance with the protocol and all applicable regulations.

Archiving
Upon completion of this Research an **End of Study Report** must be submitted to the Regulatory Authorities (this will be done by the CI) and a copy submitted to the R&D Office. All studies must be archived appropriately and in accordance with the applicable Law. Where DPT is the Sponsor or where the Sponsor has delegated archiving to the Investigator team, it is your responsibility to contact the R&D Office to discuss appropriate archiving arrangements.

Any publications arising from the Research conducted at this site must be sent to the R&D Office as part of the on-going Research Governance Process.

You should be aware that the Trust accepts no responsibility for the provision of any study drug outside of Clinical Trials and specifically would not fund the continuing prescription of any therapy once the trial has concluded unless there is a written agreement.

Trust Agreement to host the study is for the duration of the study. Research must **commence** within **6 months** of Trust Agreement. If you have received an Honorary Contract or Letter of Access in order to conduct the above research at this Trust, it is important that you check the termination date on these documents and if applicable contact the R&D Office to extend the document end date.

Devon Partnership NHS
NHS Trust

We wish you every success with your study.

Yours sincerely

Tobit Emmens

Managing Partner, Research & Development, Devon Partnership NHS Trust

Appendix E

Example Letter to GP

Private & Confidential

University of Exeter
College of Life and Environmental Sciences
Department of Psychology
Washington Singer Laboratories
Perry Road
Exeter
EX4 4QG

Telephone: 07757 245163
Email: Samantha.gerdes@exeter.ac.uk

Date: 2018

Re. xxxx xxxx DOB: xx/xx/xxxx

Dear GP,

I am writing to inform you that **xxxx xxxx** took part in a research study at the University of Exeter on Friday 9th March 2018. **xxxx** has agreed for me to write to you to inform you of his involvement in the study. The study is investigating the effects of a short meditation on mood in Armed Forces Veterans and as part of the process we use psychometric tools to assess levels of Post Traumatic Stress Disorder (PTSD) and depression. Whilst these are not diagnostic tools, as part of the study protocol we are informing GPs of the results, so that they are able to follow up as appropriate. Please note that the clinical management of this patient remains your responsibility, but it is part of our protocol to inform you of any risks disclosed to ourselves so that you can take account of them in your care plan.

As part of the study, **xxxx** completed the PTSD Checklist (PCL5) questionnaire and Patient Health Questionnaire (PHQ9) for which he scored 18 and 4 respectively. As you are probably aware, scoring 18 on the PCL5 does not meet the threshold that would indicate a presence of PTSD (cut point = 33) and scoring 4 on the PHQ9 does not indicate the presence of depression. **xxxx** said that he has received psychological therapy through the MOD which he found helpful and his PTSD symptoms have drastically reduced as a result. xxxx felt that he was managing well currently, but he is willing to consider psychological therapy in the future if needed. I would recommend that If xxxxx feels that he needs further support, that he makes an appointment with you to discuss further so that you can refer to a psychological therapy service as appropriate.

Please get in touch with me if you would like to discuss further.

Yours Sincerely,

Samantha Gerdes, Trainee Clinical Psychologist, University of Exeter
Cc: (participant address).

Appendix F

Power Calculation

Sample size for the current study was determined using G*Power (Faul, Erdfelder, Bucher & Lang, 2009) to calculate a-priori the required sample size. Due to the absence of prior research to address the research questions in the current study, power calculations and sample size considerations were based on a medium effect size. A power calculation for hypothesis 1, using a paired sample t-test with state hypervigilance at Time 1 and Time 2 as the dependent variables, assuming a medium effect size of Cohen's d = .5 for a statistical power of .8 and alpha = .05, revealed that 34 participants will be needed. A power calculation for hypothesis 2 revealed that, using a paired sample t-test with social connectedness at Time 1 and Time 2 as the dependent variables assuming a medium effect size of Cohen's d = .5 for a statistical power of .8 and alpha = .05, 34 participants will be needed. A power calculation for hypothesis 3 revealed that, for a regression with PCL-5 score as the predictor variable, assuming a medium effect size of f^2 = .15 for a statistical power of .8 and alpha = .05, 55 participants would be needed.

Appendix G

Demographic Questionnaire

Participant number:

Name:

General questions:

Age:

Gender:

Nationality:

Religion:

Marital Status: Single, Married, Cohabiting, Divorced, Seperated, Widowed

Highest qualification: GCSE, A-Levels, Diploma, Foundation Degree, Undergraduate Degree, Masters Degree, Doctorate.

Current employment (full time, part time etc):

Forces experience:

Armed Forces Branch:

Army, Army reserves, Royal Navy, Royal Navy Reserves, Royal Marines, Royal Marine Reserves, Royal Air Force.

Date joined, date left (length of service):

Rank at discharge: Junior non-commissioned officer, Senior non-commissioned officer, Junior officer, Senior officer.

Number of times deployed throughout career:

Where deployed to (Afgan, NI, Bosnia etc.):

When deployed:

Average length of tour:

Role on deployment:

Mode of discharge: Medical, At own request (PVR), Administrative, End of Engagement, Redundancy, Compulsory Discharge

Reason for medical discharge: physical injury, mental health problem, mental health problem and physical injury, other.

Sustain any physical injuries whilst on deployment?

Do you have any health problems? Cardiac disease? Medication for this?

Mental health:

Diagnosis (and when diagnosed):

PTSD diagnosis? As a result of combat experience?

Current and previous MH treatment (type, duration):

(Department of Community Mental Health, Private counselling, Combat Stress, NHS Primary Care, NHS Secondary Care, Help for Heroes, Specialist Services.)

Medication?

Do you drink alcohol? How much alcohol do you consume over a given week? Units? Have you ever been a heavy drinker?

Alcohol or drugs in the past 48 hours?

Do you have previous experience of meditation? Yes, what?

Would you like you GP to be informed that you are taking part in the study? Would you like the results of your questionnaires to be included?

Would you like to be contacted for future research opportunities with this project and others?

Would you like to be informed about the results of the study (Autumn 2018). How? By email/post.

Appendix H

Traumatic Brain Injury Assessment

(Williams, Cordan, Mewse Tonks & Burgess, 2010)

Participants were asked “have you ever sustained a head injury or been knocked unconscious?” If participants answered yes, they were then asked how many times they had sustained such injuries and the duration of each period of loss of consciousness (LOC). Severity was assessed using the length of LOC of the worst injury such as: 0 = no history; 1 = feeling dazed and confused but no LOC, minor concussion; 2 = LOC <10 minutes, mild TBI; 3 = LOC 10 to 30 minutes, complicated mild TBI; 4 = LOC 30 to 60 minutes, moderate/severe TBI; 5=LOC>60 minutes, very severe TBI (Williams et al., 2010).

Appendix I

Outcome Measures

PTSD Checklist (PCL-5)

Instructions: Below is a list of problems that people sometimes have in response to a very stressful experience. Please read each problem carefully and then circle one of the numbers to the right to indicate how much you have been bothered by that problem in the past month.

In the past month, how much were you bothered by:	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Repeated, disturbing, and unwanted memories of the stressful experience?	0	1	2	3	4
2. Repeated, disturbing dreams of the stressful experience?	0	1	2	3	4
3. Suddenly feeling or acting as if the stressful experience were actually happening again (as if you were actually back there reliving it)?	0	1	2	3	4
4. Feeling very upset when something reminded you of the stressful experience?	0	1	2	3	4
5. Having strong physical reactions when something reminded you of the stressful experience (for example, heart pounding, trouble breathing, sweating)?	0	1	2	3	4
6. Avoiding memories, thoughts, or feelings related to the stressful experience?	0	1	2	3	4
7. Avoiding external reminders of the stressful experience (for example, people, places, conversations, activities, objects, or situations)?	0	1	2	3	4
8. Trouble remembering important parts of the stressful experience?	0	1	2	3	4
9. Having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?	0	1	2	3	4
10. Blaming yourself or someone else for the stressful experience or what happened after it?	0	1	2	3	4
11. Having strong negative feelings such as fear, horror, anger, guilt, or shame?	0	1	2	3	4
12. Loss of interest in activities that you used to enjoy?	0	1	2	3	4
13. Feeling distant or cut off from other people?	0	1	2	3	4
14. Trouble experiencing positive feelings (for example, being unable to feel happiness or have loving feelings for people close to you)?	0	1	2	3	4
15. Irritable behavior, angry outbursts, or acting aggressively?	0	1	2	3	4
16. Taking too many risks or doing things that could cause you harm?	0	1	2	3	4
17. Being "superalert" or watchful or on guard?	0	1	2	3	4
18. Feeling jumpy or easily startled?	0	1	2	3	4
19. Having difficulty concentrating?	0	1	2	3	4
20. Trouble falling or staying asleep?	0	1	2	3	4

Patient Health Questionnaire (PHQ-9)

Patient Name _____ Date of Visit _____

Over the past 2 weeks, how often have you been bothered by any of the following problems?	**Not At all**	**Several Days**	**More Than Half the Days**	**Nearly Every Day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3
3. Trouble falling asleep, staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you're a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or, the opposite - being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

Column Totals _____ + _____ + _____

Add Totals Together _____

Emotional Regulation Questionnaire (ERQ; Gross & John, 2003)

Instructions and Items:
We would like to ask you some questions about your emotional life, in particular, how you control (that is, regulate and manage) your emotions. The questions below involve two distinct aspects of your emotional life. One is your emotional experience, or what you feel like inside. The other is your emotional expression, or how you show your emotions in the way you talk, gesture, or behave. Although some of the following questions may seem similar to one another, they differ in important ways. For each item, please answer using the following scale:

Strongly Disagree			Neutral			Strongly Agree
1	2	3	4	5	6	7

1. ____ When I want to feel more positive emotion (such as joy or amusement), I change
what I'm thinking about.
2. ____ I keep my emotions to myself.
3. ____ When I want to feel less negative emotion (such as sadness or anger), I change
what I'm thinking about.
4. ____When I am feeling positive emotions, I am careful not to express them.
5. ____When I'm faced with a stressful situation, I make myself think about it in a way
that helps me stay calm.
6. ____ I control my emotions by not expressing them.
7. ____When I want to feel more positive emotion, I change the way I'm thinking about
the situation.
8. ____ I control my emotions by changing the way I think about the situation I'm in.
9. ____When I am feeling negative emotions, I make sure not to express them.
10. ____When I want to feel less negative emotion, I change the way I'm thinking about
the situation.

Scoring:
Items 1, 3, 5, 7, 8, 10 make up the Cognitive Reappraisal facet.
Items 2, 4, 6, 9 make up the Expressive Suppression facet.

Self-Compassion Scale – Short Form (SCS-SF)

HOW I TYPICALLY ACT TOWARDS MYSELF IN DIFFICULT TIMES

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

Almost never				Almost always
1	2	3	4	5

_____1. When I fail at something important to me I become consumed by feelings of inadequacy.

_____2. I try to be understanding and patient towards those aspects of my personality I don't like.

_____3. When something painful happens I try to take a balanced view of the situation.

_____4. When I'm feeling down, I tend to feel like most other people are probably happier than I am.

_____5. I try to see my failings as part of the human condition.

_____6. When I'm going through a very hard time, I give myself the caring and tenderness I need.

_____7. When something upsets me I try to keep my emotions in balance.

_____8. When I fail at something that's important to me, I tend to feel alone in my failure

_____9. When I'm feeling down I tend to obsess and fixate on everything that's wrong.

_____10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.

_____11. I'm disapproving and judgmental about my own flaws and inadequacies.

_____12. I'm intolerant and impatient towards those aspects of my personality I don't like.

Appendix J

Loving Kindness Meditation (LKM-S) Script

Script for Loving Kindness Meditation clip (In the style of Loving-Kindness for Beginners, Neff)

Sit in a comfortable position, reasonably upright and relaxed. (Pause) Close your eyes fully or partly. (Pause) You will now be guided through a few minutes exercise.

Bring to mind a person with whom you have a positive relationship, someone who you feel naturally warmly towards. This could be a child, a grandparent, a former teacher or mentor your cat or dog - whoever naturally brings happiness to your heart. Allowing yourself to feel what it's like to be in that being's presence (pause for 2 sec).
(Pause)
Holding this person in mind now extending best wishes towards them. Repeat softly with this person in mind:
May you be safe.
May you be peaceful.
May you be healthy.
May you live with ease.
(Pause)
May you be safe.
May you be peaceful.
May you be healthy.
May you live with ease.
(Pause)
When you notice that your mind has wandered, return to the words and the image of the loved one you have in mind. Savour any warm feelings that may arise. Go slow.
(Pause)
Now add yourself to your circle of good will. Put your hand over your heart and feel the warmth and gentle pressure of your hand (for just a moment or for the rest of the exercise), saying:
May I be safe.
May I be peaceful.
May I be healthy.
May I live with ease.
(Pause)
May I be safe.
May I be peaceful.
May I be healthy.
May I live with ease.
(Pause)
Holding your body in awareness, notice any stress or uneasiness that may be lingering within you, and offer kindness to yourself.
May I be safe.
May I be peaceful.
May I be healthy.
May I live with ease.

Repeat the phrases inwardly with enough space between them so that they are pleasing you. As best you can, gather all your attention behind one phrase at a time. (Pause)
If you find your attention wandering, don't worry, that's what minds do. You can simply let go of distractions and begin from here you are.
May I be safe.
May I be peaceful.
May I be healthy.
May I live with ease. (Pause)
Feelings, thoughts, or memories may come and go; allow them to arise and pass away. Let the anchor be the repetition of these phrases:
May I be safe.
May I be peaceful.
May I be healthy.
May I live with ease. (Pause)
Just rest and sit quietly in your own body, savouring the good will and compassion that flows naturally from your own heart. Know that you can return to the phrases anytime you wish.
(Pause for 15 sec)

(Pause, then end) Now, in your own time, slowly open eyes. The exercise is over.

Appendix K

Visual Analogue Scales (VAS)

Right now I feel:

0----------100

I don't feel distressed at all	———	**I feel very distressed**
I am feeling like not criticising myself at all	———	**I am feeling like criticising myself very**
I do not feel like being kind and understanding towards myself at all	———	**I am feeling like being very kind and understanding towards myself**
I am not tolerant of my flaws and inadequacies	———	**I am very tolerant of my flaws and inadequacies**
I feel jumpy or like I could be easily startled	———	**I do not feel jumpy or like I might be easily startled**
I feel super-alert	———	**I do not feel super-alert**
I feel irritable and I feel like acting aggressively	———	**I do not feel irritable and I do not feel like acting aggressively**
I am finding it difficult to concentrate	———	**I have no difficulty concentrating**
I feel isolated and apart from others	———	**I feel connected to others**
I don't feel loved and safe at all	———	**I feel very loved and safe**
I don't need to feel loved at all	———	**I really need to feel loved**
The idea of being emotionally close to someone doesn't make me nervous	———	**The idea of being emotionally close to someone makes me very nervous**

Appendix L

Assumption Testing

Prior to hypothesis testing, the assumptions were checked for violations of normality and homogeneity of variance. In the paired sample t-tests, data was checked for outliers and normality. Outliers were detected after examining boxplots: one outlier was found in the self-compassion manipulation check (participant 46) and five participants in the VAS hyperarousal (participants 20, 28, 37, 46 & 47). Inspection of their values did not reveal them to be extreme so they were kept in the analysis. These data points were changed to the next closest value that was under the cut off which is a technique for dealing with outliers, whilst maintaining the shape of the sample distribution, but the outliers do not distort the data (Tabachnick & Fidell, 2007). Results are presented after these data points were changed, however, it must be noted that this did not alter statistical significance of any of the tests. Normality was assessed by Shapiro-Wilk's test and normality was not violated for the self-compassion manipulation check (p = .0.7) or VAS social connectedness (p = 0.42). However, Shapiro-Wilk's test for VAS hyperarousal indicated a violation of normality (p = 0.002). Visual inspection of the normal Q-Q plot however appeared approximately normally distributed for sample size >50, in addition, paired sample t-tests are also robust to violations of normality therefore the data was analysed using parametric tests (Laerd Statistics, 2015).

For the correlations, two outliers were identified and underwent the Winsorising process (participants 25 & 50). Assumptions of normality were not violated as assessed by Shapiro-Wilks test for RGS Hyperarousal (p = .49) and RGS Social Connectedness (p = .17)

For the regression analysis, assumptions of independence of observations, linearity, homoscedacitiy, normality and multicollinearity were all fulfilled. Linearity was assessed by partial regression plots and a plot of studentized residuals against the predicted values. There was independence of residuals, as assessed by a Durbin-Watson statistic for Heart Rate Variability of .341, Skin Conducatance Levels of 2.27, Heart Rate of 2.64, Hyperarousal Residualised Gains Score (RGS) of 2.02, Social Connectedness RGS of 1.16. There was homoscedasticity as assessed by visual inspection of a plot of studentized residuals versus unstandardized predicted values. There was no evidence of multicollinearity of independent variables, as assessed by tolerance values greater than 0.1. The assumption of normality was met, as assessed by a Q-Q Plot.

Examination of studentized deleted residuals revealed six outliers (participants 16, 25 30, 40, 54, 57) and therefore their score were changed to the next highest value that was not an outlier (Tabachnick & Fidell, 2007). There were five cases with leverage values greater than 0.2 ranging from 0.23 to 0.30. However these cases were left unchanged as no influential points were identified, as there were no values for Cook’s distance above 1.

Appendix M

Physiological Data Processing

Heart Rate (HR). The raw ECG data was filtered by applying a FIR bandpass filter between .5 and 35 Hz and 8000 coefficients. AcqKnowledge (Version 4.1., BIOPAC Systems Inc.) software was used to determine HR in beats per minute and was based on a semi-automatic R-wave detection algorithm. Any artefacts such as noisy or missing beats were identified and then deleted using a template correlation and interpolation from the adjacent R-peaks (Solem at al., 2006; Berntson, Quigley, Jang, & Boysen, 1990; Berntson & Stowell, 1998). The interpolation procedure was applied for less than 5% of the ECG data.

Heart rate variability (HF-HRV; as index of parasympathetic activation). HRV was determined from the artifact-free ECG (see above) by calculating a time series of the R-peaks and submitting it to a fast Fourier transformation that calculates the power spectrum of the R-R interval variation in a given time window (Berntson et al., 1997; Malik et al., 1996). Of particular interest was the frequency range between .15 Hz and .4 Hz (high frequency, HF). This high frequency band of HRV is generally considered a marker of parasympathetic input. Mean HF-HRV were then extracted for each data section using the same process as used with the HR.

Skin conductance level (SCL) (as measure of sympathetic arousal). Mean SCL, maximum SCL values and minimum SCL values were extracted for the same time windows and a range correction as recommended was applied to each data section for each participant to give a mean SCL corrected for individual differences (Lykken, et al.,, 1996). The formula for this was: Corrected SCL = (SCL mean - SCL min) / (SCL max - SCL min).

The mean scores (i.e., HR, HRV) per minute was calculated by using the R-waves for each data section, in particular 2 minutes of resting/ baseline and for the meditation. Mean values for HR, HRV and SCL were determined for the duration of the 11 minute meditation in one minute segments. The one minute prior to the meditation start was used as a baseline. To determine the responses to the meditation, the baseline was subtracted from each minute of the meditation value and change from the baseline was then determined for each minute.

Appendix N

TBI Results

Table 2.

Traumatic Brain Injury

Classification	N = 53 (%)
0 = No history	12 (22.6)
1 = Feeling dazed and confused but no LOC, minor concussion	1 (1.89)
2 = LOC < 10 minutes, mild TBI	24 (45.3)
2a = LOC but no concussion symptoms	14 (26.4)
3 = LOC 10 to 30 minutes, complicated mild TBI	1 (1.89)
4 = LOC 30 to 60 minutes, moderate/severe TBI	1 (1.89)
5 = LOC > 60 minutes, very severe TBI	0

Note. LOC = Loss of consciousness. TBI was assessed over the participant's lifetime rather than restricted to just their Armed Forces career.

Appendix O

Table 4. *Intercorrelations, Means and Standard Deviations for Variables.*

Variable	1	2	3	4	5	6	7	8	9	10	11	12	13	14	*15*	*M*	*SD*
1. RGS Hyperarousal	-															.01	.96
2. RGS Social Connectedne	-.326*	-														-.03	.87
3. PCL Total	.160	-.204	-													22.13	20.95
4. PCL Intrusions	.297*	-.231	.938**	-												4.85	5.12
5. PCL Avoidance	.274*	-.243	.863**	.889**	-											2.32	2.49
6. PCL Cognitive	.079	-.174	.939**	.816**	.761**	-										7.53	7.77
7. PCL Physiological	.074	-.158	.932**	.832**	.712**	.811**	-									7.43	7.19
8. Self-compassion	-.237	.284*	-.609**	-.544**	-.509**	-.662**	-.495**	-								36.62	8.00
9. ERQ (Cognitive	-.056	-.214	.145	.112	.191	.169	.093	-.088	-							4.48	1.36
10. ERQ (Expression &	.037	-.244	.434**	.372**	.344*	.460**	.383**	-.471**	.168	-						3.94	1.55
11. HRV Mean Response	.017	.004	.011	.074	.137	-.023	-.042	.146	.027	.063	-					-.09	1.0
12. SCL Mean Response	.173	-.358**	.151	.204	.302*	.089	.097	.035	.059	.039	.172	-				-.04	.06
13. HR Mean Response	-.002	-.057	-.050	-.051	.004	-.073	-.034	.057	.035	.243	-.121	.206	-			.68	2.56

14. PHQ9 Total	.181	-.223	.889**	.796**	.707**	.897**	.807**	-.702**	.147	.430**	.012	.070	-.047	-		6.60	7.33
15. TBI Severity	-.244	.005	.161	.063	.034	.144	.255	-.050	.089	.077.	.045	.105	.009	.161-	-	-	-

Note. N = 52 – 53. *p <.05. **p <.01

Appendix P

Dissemination Statement

The findings of this study will be disseminated in the following ways:

1. A research presentation to trainee clinical psychologists and staff at the University of Exeter (June 2018).

2. A summary of the findings will be sent to participants and organisations who helped with recruitment, who opted to be informed of the study results (August, 2018).

3. The study will be submitted to a peer reviewed journal article i.e. Journal of Consulting and Clinical Psychology (November, 2018).

Appendix Q

Journal of Clinical and Consulting Psychology – Copy of Instructions for Authors

Overview

The following instructions pertain to all journals published by APA and the Educational Publishing Foundation.

Please also visit the web page for the journal to which you plan to submit your article for submission addresses, journal-specific instructions, and exceptions.

- **Manuscript Preparation**
- **Submitting Supplemental Materials**
- **Abstract and Keywords**
- **References**
- **Figures**
- **Permissions**
- **Publication Policies**
- **Ethical Principles**
- **Other Information**

Manuscript Preparation

Prepare manuscripts according to the *Publication Manual of the American Psychological Association* (6th edition). Manuscripts may be copyedited for bias-free language (see Chapter 3 of the *Publication Manual*). Additional guidance on APA Style is available on the APA Style website.

Double-space all copy. Other formatting instructions, as well as instructions on preparing tables, figures, references, metrics, and abstracts, appear in the *Manual*.

Below are additional instructions regarding the preparation of display equations, computer code, and tables.

Display Equations

We strongly encourage you to use MathType (third-party software) or Equation Editor 3.0 (built into pre-2007 versions of Word) to construct your equations, rather than the equation support that is built into Word 2007 and Word 2010. Equations composed with the built-in Word 2007/Word 2010 equation support are converted to low-resolution graphics when they enter the production process and must be rekeyed by the typesetter, which may introduce errors.

To construct your equations with MathType or Equation Editor 3.0:

- Go to the Text section of the Insert tab and select Object.
- Select MathType or Equation Editor 3.0 in the drop-down menu.

If you have an equation that has already been produced using Microsoft Word 2007 or 2010 and you have access to the full version of MathType 6.5 or later, you can convert this equation to MathType by clicking on MathType Insert Equation. Copy the equation from Microsoft Word and paste it into the MathType box. Verify that your equation is correct, click File, and then click Update. Your equation has now been inserted into your Word file as a MathType Equation.

Use Equation Editor 3.0 or MathType only for equations or for formulas that cannot be produced as Word text using the Times or Symbol font.

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If you would like to include code in the text of your published manuscript, please submit a separate file with your code exactly as you want it to appear, using Courier New font with a type size of 8 points. We will make an image of each segment of code in your article that exceeds 40 characters in length. (Shorter snippets of code that appear in text will be typeset in Courier New and run in with the rest of the text.) If an appendix contains a mix of code and explanatory text, please submit a file that contains the entire appendix, with the code keyed in 8-point Courier New.

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Use Word's Insert Table function when you create tables. Using spaces or tabs in your table will create problems when the table is typeset and may result in errors.

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▼ **Abstract and Keywords**

All manuscripts must include an abstract containing a maximum of 250 words typed on a separate page. After the abstract, please supply up to five keywords or brief phrases.

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List references in alphabetical order. Each listed reference should be cited in text, and each text citation should be listed in the References section.

Examples of basic reference formats:

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  Hughes, G., Desantis, A., & Waszak, F. (2013). Mechanisms of intentional binding and sensory attenuation: The role of temporal prediction, temporal control, identity prediction, and motor prediction. *Psychological Bulletin, 139,* 133–151. http://dx.doi.org/10.1037/a0028566
- **Authored Book:**
  Rogers, T. T., & McClelland, J. L. (2004). *Semantic cognition: A parallel distributed processing approach.* Cambridge, MA: MIT Press.
- **Chapter in an Edited Book:**
  Gill, M. J., & Sypher, B. D. (2009). Workplace incivility and organizational trust. In P. Lutgen-Sandvik & B. D. Sypher (Eds.), *Destructive organizational communication: Processes, consequences, and constructive ways of organizing* (pp. 53–73). New York, NY: Taylor & Francis.

Figures

Graphics files are welcome if supplied as Tiff or EPS files. Multipanel figures (i.e., figures with parts labeled a, b, c, d, etc.) should be assembled into one file.

The minimum line weight for line art is 0.5 point for optimal printing.

For more information about acceptable resolutions, fonts, sizing, and other figure issues, please see the general guidelines.

When possible, please place symbol legends below the figure instead of to the side.

APA offers authors the option to publish their figures online in color without the costs associated with print publication of color figures.

The same caption will appear on both the online (color) and print (black and white) versions. To ensure that the figure can be understood in both formats, authors should add alternative wording (e.g., "the red (dark gray) bars represent") as needed.

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