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Rapid Exposure Supporting Trauma Recovery

Final Report for the RESTORE Trial



Final Report

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Glossary

ADF	Australian Defence Force
ADFCMH	ADF Centre for Mental Health
ADHREC	Australian Defence Human Research Ethics Committee
ANCOVAs	Analyses of covariance
AQoL-6D	Assessment of Quality of Life Scale – 6
CAPS	Clinician-Administered PTSD Scale for DSM-5
CI	Confidence interval
CO	Commissioned officer
DAR-5	Dimensions of Anger Reactions-5
Defence	Department of Defence
DSM	Diagnostic and Statistical Manual of Mental Disorders
DVA	Department of Veterans' Affairs
DVA HREC	Department of Veterans' Affairs Human Research Ethics Committee
DDVA HREC	Departments of Defence and Veterans' Affairs Human Research Ethics Committee
HADS	Hospital Anxiety and Depression Scale
MHP	Mental Health Professional
MO	Medical Officer
MPE	Massed prolonged exposure
NCO	Non-commissioned officer
NHMRC	National Health and Medical Research Council
Open Arms	Open Arms – Veterans & Families Counselling
PCL-5	PTSD Checklist-5
PE	Prolonged exposure
PTSD	Posttraumatic stress disorder
RCT	Randomised controlled trial
RESTORE	Rapid Exposure Supporting Trauma Recovery
SD	Standard deviation
SE	Standard error
SPE	Standard prolonged exposure
SPSS	Statistical Package for the Social Sciences
T1	Pre-treatment baseline assessment
T2	4 weeks post-treatment commencement assessment
T3	12 weeks post-treatment commencement assessment
T4	12 months post-treatment commencement assessment
UNSW	University of New South Wales
US	United States
WHODAS	World Health Organization Disability Assessment Schedule 2.0

Executive summary

Posttraumatic stress disorder (PTSD) in current and ex-serving Australian Defence Force (ADF) members has prevalence estimates of 8.0% and 20.0%, respectively. Given that PTSD is associated with long-term disability, impaired functioning, lost productivity, high service use and high healthcare costs, it is imperative that current-serving and ex-serving personnel have timely access to treatment. There are several evidence-based treatments for PTSD, one of which is prolonged exposure (PE) therapy, a manualised trauma-focused cognitive behavioural therapy, which is a first-line treatment according to international guidelines for PTSD.

While PE therapy has previously demonstrated success for military-related trauma, the length of time required for treatment (currently 10 weeks) is a barrier to implementation, particularly for current-serving military personnel. Further, studies of United States (US) veterans have shown considerable dropout rates from 10 weeks of PE therapy. A course of PE shorter in duration could decrease barriers to therapy implementation and potentially reduce the dropout rate from therapy in addition to ameliorating symptoms of PTSD. Recent international evidence showed that a massed form of PE (MPE), delivered within 2 weeks instead of 10, effectively reduces PTSD symptom severity for military-related trauma.

In partnership with the Australian Government Department of Defence and Department of Veterans' Affairs, and with funding from a National Health and Medical Research Council partnership grant, Phoenix Australia – Centre for Posttraumatic Mental Health conducted the Rapid Exposure Supporting Trauma Recovery (RESTORE) trial, the first randomised controlled trial of MPE in Australia.

The primary aim of the RESTORE trial was to evaluate the efficacy of 2 weeks of MPE relative to the standard 10 weeks of PE (SPE) in reducing the severity of PTSD in military personnel and veterans who have experienced a traumatic event while serving. It was expected that MPE would work equally as well as SPE, thereby generating an evidence base to allow both forms to be offered with confidence to current and ex-serving military personnel in the future.

There were 138 participants randomised to therapy. Two-thirds of the sample were ex-serving ADF members, while 35.8% were current-serving ADF. Of the 138 participants, 88.1% were male. **MPE was found to be as effective as SPE in reducing PTSD symptoms** by 12 weeks post-commencement of therapy (T3). By T3, 54.1% of SPE participants and 53.8% of MPE participants **lost their PTSD diagnosis**. Treatment dropout was significantly different across the treatment groups: participants in SPE ($n = 12$, 16.9%) were nearly four times more likely to drop out from treatment than in the MPE group ($n = 3$, 4.8%). Notably, comorbid mental health issues, including depression, anxiety, and anger, also significantly improved in both groups following treatment. **The reduction of PTSD symptoms was maintained by the 12-month follow-up in both MPE and SPE groups.**

The finding that MPE and SPE were equally effective in significantly reducing symptoms of PTSD is in line with previous international research. These findings are also critically important in informing future decisions about how we can improve access to effective therapy for PTSD for current and ex-serving military members.

Introduction

Background

Posttraumatic stress disorder (PTSD) is a common and often severe problem, affecting current and ex-serving military personnel at higher rates than the general community. The prevalence of PTSD across the Australian Defence Force (ADF) has been reported to be 8.0% (McFarlane et al., 2011), while lifetime and past-year estimates of PTSD prevalence in the general community in Australia are approximately 7.2% and 4.4%, respectively (McEvoy et al., 2011). Evidence also suggests that the risk of developing PTSD increases with the number of traumatic events experienced (Dobson et al., 2012). PTSD also affects a substantial proportion of veterans; the Australian Transition and Wellbeing Research Programme found that 18.0% of veterans who had transitioned out of the ADF in the previous 5 years met the criteria for PTSD (Van Hooff et al., 2019). PTSD is associated with long-term disability, impaired functioning, lost productivity, high service use and high healthcare costs (Rodriguez et al., 2012; Sareen et al., 2007; Schnurr et al., 2009; von der Warth et al., 2020). Therefore, it is imperative that serving and ex-serving personnel have timely access to effective treatments for PTSD.

The recent Australian Guidelines for Posttraumatic Stress Disorder (Phoenix Australia, 2020), alongside multiple international treatment guidelines (American Psychological Association, 2017; National Institute for Health and Care Excellence, 2018), systematically identified the most effective psychological treatments for PTSD. Prolonged exposure (PE) therapy (Foa et al., 2007) has been shown to be a first-line 'gold-standard' treatment for PTSD. PE is underpinned by emotion and information-processing theories that emphasise the role of a traumatic memory network in the development and maintenance of PTSD symptoms. PE encourages the client to safely engage in the activation and subsequent processing of the trauma network through repeatedly addressing traumatic memories (known as *imaginal exposure*) and confronting related triggers (known as *in vivo exposure*). Findings from meta-analyses indicate PE is effective in treating PTSD (Lewis et al., 2020), including in veterans (Haagen et al., 2015). In addition, PE has been successfully disseminated across veteran and military clinical settings in the United States (US) (Borah et al., 2013; Eftekhari et al., 2013).

Despite the availability of evidence-based treatments, such as PE, many individuals with PTSD, including current and ex-serving military personnel, do not access therapy. Only approximately half of those who need mental health services receive care (Fikretoglu et al., 2008; Forbes et al., 2018; Ramchand et al., 2015; Sharp et al., 2015). Low utilisation of evidence-based PTSD treatments may be due to a range of factors and access barriers. Regarding standard PE (SPE), the 10-week duration of treatment can be a practical barrier for current-serving personnel who have posting cycles, frequent and extended off-base training exercises, and deployments (Hall-Clark et al., 2019). Further, many treatment-seeking individuals who do access therapy fail to achieve clinically significant improvements in symptoms (Koek et al., 2016). This may be due to dropping out of treatment before receiving the intended dose of therapy, or receiving the intended dose (i.e., completing treatment) but not responding to treatment. Treatment dropout from trauma-focused interventions, such as PE, and treatment non-response are significant issues in military populations (Gerger et al., 2014; Steenkamp et al., 2015; Varker et al., 2021). For example, a recent meta-analysis of predominantly US-based studies of military trauma populations reported significantly higher dropout rates for trauma-focused treatments (34.4%) compared to non-trauma-focused treatments (18.7%) (Varker et al.,

2021). Commonly reported dropout reasons in PTSD treatment trials included loss of contact, competing demands, and dislike of the allocated intervention (Varker et al., 2021).

In order to overcome barriers to treatment-seeking, treatment dropout, and non-response to treatment, recent research examined adapting available evidence-based treatments to better meet the needs of treatment-seeking individuals, particularly serving and ex-serving personnel with PTSD. Session frequency is a potential mechanism to improve accessibility and acceptability (Sciarrino et al., 2020). This includes delivering the full standard treatment protocol content over a significantly shorter timeframe (e.g., 2 weeks), which has previously been referred to as 'intensive' and, more recently, 'massed' treatment. For over 30 years, this massed approach to exposure therapy has been incorporated into treatments for a range of anxiety disorders, including obsessive-compulsive disorder, specific phobias, and panic disorder (Telch et al., 2014). More recently, the concept of a massed intervention has been extended to the treatment of PTSD with promising results (Foa et al., 2018; Sciarrino et al., 2020). To date, the study of MPE methods in military populations is limited to studies originating from the US. This includes one published case study (N = 1) (Blount et al., 2014), one open trial program evaluation of MPE with no comparison arm (N = 49) (Yasinski et al., 2017), one retrospective effectiveness study (N = 77) (Rauch et al., 2021), and one randomised controlled trial (RCT) comparing MPE with SPE, present-centred therapy, and a control condition, and focussing on active duty personnel (Foa et al., 2018). Results of the RCT demonstrated non-inferiority of MPE to SPE (i.e., they were found to be equally effective), which was maintained after 6 months of follow-up (Foa et al., 2018). However, it is worth noting that over 350 participants underwent therapy with just one of three clinicians. Although highly controlled for the purpose of an RCT, the design of this study had implications for the generalisability and feasibility of MPE in a 'real-world' setting (multi-site, multi-therapist), underscoring the importance of not only independent replication, but at a broader scale.

MPE has several advantages, most importantly, the potential to minimise the practical barriers posed by the 3-month period of active therapy required in standard treatment approaches. Foa et al. (2018) found that MPE was easier to schedule than SPE in current-serving military personnel due to their demanding work schedules, including military training, changes of station, and short-notice deployments (Peterson et al., 2018). For veterans (and civilians), barriers include the potential for crises or other significant vocational or domestic demands to impede the person's capacity to attend treatment for the required 3 months consistently. MPE may also assist individuals in returning to work sooner.

In addition, daily therapy sessions may overcome barriers to treatment engagement posed by PTSD. For example, the frequency of sessions may be helpful for avoidant patients (Sherrill et al., 2020). It may also assist in consolidating information for those with concentration and memory difficulties (Ehlers et al., 2014). Other perceived benefits of MPE identified in treatment-completing veterans include limiting distractions between sessions (e.g., work and family obligations) and demotivation (i.e., experiencing quick therapeutic gains which enhanced motivation and engagement in treatment) (Sherrill et al., 2020). Fewer dropouts in MPE compared to SPE have also been reported (13.6% and 24.5%, respectively) (Foa et al., 2018), meaning individuals in the MPE condition receive a higher dose of therapy and so may experience greater therapeutic benefit.

The RESTORE trial

The Rapid Exposure Supporting Trauma Recovery (RESTORE) trial is a randomised, multi-site, non-inferiority trial. Through a partnership between Phoenix Australia – Centre for Posttraumatic Mental Health (Phoenix Australia), the Department of Defence (Defence) and the Department of Veterans' Affairs (DVA) via Open Arms - Veterans & Families Counselling (Open Arms), this project explores whether a modified form of PE delivering treatment over 10 days in 2 weeks (massed PE: MPE) can obtain equivalent outcomes to standard PE (SPE). Should MPE prove equally as effective as SPE, this may significantly reduce the barriers that current and ex-serving military personnel can experience when attempting to access gold-standard treatment for PTSD.

This trial is funded by a Partnership Projects grant from the National Health and Medical Research Council (NHMRC). The partner organisations working with Phoenix Australia (Defence, DVA and Open Arms) also provided funding and in-kind support.



The primary organisation responsible for managing the project was Phoenix Australia. The Principal Investigator of the project was Professor David Forbes, with Dr Lisa Dell responsible for the leadership of the trial and Dr Alyssa Sbisa responsible for the day-to-day running of the trial. The RESTORE trial was carried out by a team of researchers, including the principal investigator, other project investigators, statisticians, a project manager, research assistants, study assessors, and therapists. See Figure 1 for the timeline of the RESTORE trial.

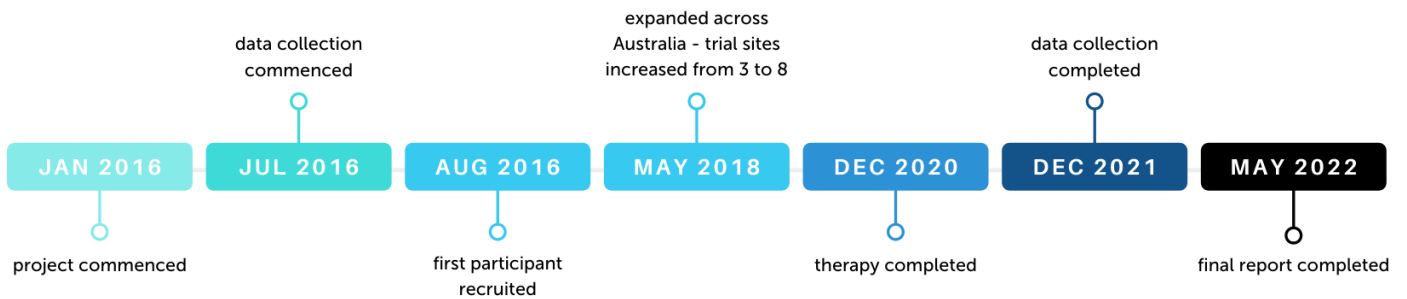


Figure 1. Timeline of the RESTORE trial

Aims

The primary aim of the RESTORE trial was to evaluate the efficacy of MPE relative to SPE in reducing the severity of PTSD in military personnel and veterans. It was not expected that MPE would be superior to SPE but rather that MPE would work equally as well as SPE.

The secondary aim of the RESTORE trial was to evaluate the efficacy of MPE relative to SPE in reducing the severity of common comorbid issues, including depression, anxiety, anger, disability, and quality of life.

The trial had four hypotheses:

1. MPE and SPE would reduce the severity of PTSD at 12 weeks post-treatment commencement

2. MPE would be non-inferior to SPE in reducing the severity of PTSD at 12 weeks post-treatment commencement

3. MPE and SPE would maintain a reduction in PTSD severity at the 12-month follow-up

4. MPE would be non-inferior to SPE in reducing the severity of depression, anxiety, anger, and disability and in improving quality of life

Methods

Trial design and procedure

Ethics approval

A submission was made to the Australian Defence Human Research Ethics Committee (ADHREC) and Department of Veterans' Affairs Human Research Ethics Committee (DVA HREC) to obtain ethics approval for the trial. Approval was granted to 'The Intensive Prolonged Exposure trial' on 7 September 2016 from ADHREC (protocol number 818-16) and 20 May 2016 from DVA HREC (protocol number E016/009).

Twenty-eight amendments were submitted to the combined Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) during the remaining course of the trial. Amendments included changing the trial name to 'Rapid Exposure Supporting Trauma Recovery (RESTORE)', national site expansion, additional measures, a telehealth protocol, and additional therapists, assessors, and research team members.

Therapist training

Over the course of the trial, four rounds of therapist training were offered to Open Arms, Defence and private practitioners (see the Appendix). Training was facilitated by Professor Peter Tuerk, an international expert in PE therapy who has served as a national trainer for the U.S.

Department of Veterans Affairs and U.S. Department of Defense. Each round of training took place over 4 days at The University of Melbourne. A total of 64 therapists were trained; however, not all served as therapists on the trial, due to personal reasons or inaccessibility to one of the eight existing trial sites. Thirty-eight therapists completed at least one session with a participant.

- Training 1 (April 2016) – trained 15 therapists from Brisbane, Melbourne, and Sydney. One therapist was from Open Arms, two from Defence, three were from private practice and nine were from Phoenix Australia.
- Training 2 (April 2017) – trained six therapists from Brisbane, Melbourne, and Sydney. One therapist was from Open Arms, four were from private practice and one was from Phoenix Australia.
- Training 3 (March 2018) – trained 22 therapists from Adelaide, Canberra, Darwin, Hobart, Perth, Rockingham and Townsville. Twelve therapists were from Open Arms, four were from Defence, five were from private practice and one was from Phoenix Australia.
- Training 4 (December 2019) – trained 21 therapists from Adelaide, Brisbane, Cairns, Canberra, Darwin, Davenport, Melbourne, Rockingham, Sydney, and Townsville. Sixteen therapists were from Open Arms, three were from Defence and two were from Phoenix Australia.

**64 therapists
across Australia
were trained in
delivering
prolonged
exposure
therapy**

At the onset of the COVID-19 pandemic and due to government restrictions, trial therapists were offered training to facilitate PE therapy via telehealth. This training consisted of a 2-hour session hosted by Professor Peter Tuerk on the Zoom platform in April 2020 and offered to all existing RESTORE therapists who had completed the face-to-face training. Nineteen therapists completed the telehealth training. Twelve therapists were from Open Arms, three were from Defence, two were from private practice and two were from Phoenix Australia. Twenty-one active therapists remained at the conclusion of the trial.

Participants

The RESTORE trial had five key inclusion criteria and three exclusion criteria evaluated during both the intake screen and the baseline (T1) assessment (see Table 1). Potential participants were required to be (a) between 18 and 80 years old, (b) a current or former ADF member and (c) currently experiencing symptoms consistent with a PTSD diagnosis related to a trauma experienced while serving.

Participants involved in other treatments for trauma-related mental health issues were asked to pause their existing treatment while participating in the PE therapy within the trial. The trial therapists communicated with other treating mental health professionals involved in the participants' care. Participants were allowed to continue non-trauma-focused therapy, including relationship counselling and supportive therapy.

Table 1. RESTORE trial inclusion and exclusion criteria

Inclusion criteria
<ul style="list-style-type: none"> • Aged 18–80 (inclusive)
<ul style="list-style-type: none"> • Current or former ADF member, or a veteran
<ul style="list-style-type: none"> • Current symptoms consistent with PTSD diagnosis*, in the past 4 weeks with a minimum duration of at least 3 months
<ul style="list-style-type: none"> • Able to commit to treatment
<ul style="list-style-type: none"> • If on psychotropic medication, on a stable dose for the last 4 weeks, and not intending to change for the duration of the PE phase (12 weeks)
Exclusion criteria
<ul style="list-style-type: none"> • Current psychosis, mania, or active suicidality†
<ul style="list-style-type: none"> • Current severe alcohol or substance use disorder‡
<ul style="list-style-type: none"> • Currently receiving trauma-focused psychological treatment and unable/unwilling to pause during PE

Note. * PTSD symptoms must be associated with trauma experienced while serving. This may be a single incident or multiple incidents. It may be a non-combat trauma experienced while serving, for example, a car accident on base, or sexual assault while in the military. It may also be a trauma experienced off base or within a civilian context.

† Past experience of these conditions did not necessarily exclude participants.

‡ Alcohol or substance use could not interfere with the capacity to engage with therapy. Participants needed to be capable of refraining from excessive use prior to therapy sessions.

As shown in Figure 2, participants were required to live within a 90-minute drive of one of the eight trial sites at a designated Open Arms office, the University of NSW (UNSW) Traumatic Stress Clinic, HMAS Stirling, or the ADF Centre for Mental Health (ADFCMH). At the onset of the COVID-19 pandemic, the RESTORE trial paused for 2 weeks to implement a telehealth treatment modality, which allowed individuals to undergo therapy within the trial from the safety of their own homes, and also opened up the trial to individuals in rural and remote areas across all the states and territories in Australia. Telehealth treatment involved the same format (10 sessions) and duration of therapy (90-minute sessions) but took place using the Zoom (ex-serving participants) or CoviU (current-serving participants) online platforms. Evidence suggests the feasibility and acceptability of evidence-based PTSD treatments delivered via telehealth compared to face-to-face therapy, with comparable reductions in PTSD symptoms and dropout rates (Liu et al., 2020; Morland, Mackintosh et al., 2020; Morland, Wells et al., 2020).



Figure 2. RESTORE trial site locations prior to the implementation of telehealth: Adelaide, Brisbane, Canberra, Darwin, Melbourne, Perth, Sydney, and Townsville

Intake screen

Following self-referral or referral by a health practitioner into the trial, individuals underwent an intake screening via telephone with an experienced clinician ('intake officer'). With the individual's consent, intake officers conducted a semi-structured interview designed to elicit information regarding the inclusion and exclusion criteria (see Table 1) and other information relevant to suitability for the trial. Intake officers contacted the referring or nominated medical or health professional to discuss suitability before confirming a current or ex-serving member could go through to pre-treatment baseline assessment (T1).

If an individual was assessed to be ineligible for the trial, they were provided with alternative mental health treatment options at external services. Contact was made with their referrer informing them of the outcome

of the screening or, if self-referred, their nominated medical or health professional with their consent. An additional telephone call was made to the Medical Officer (MO) or Mental Health Professional (MHP) for current-serving members. If there was no nominated MO, the Senior Medical Officer at the relevant Garrison Health facility was contacted.

Assessment and allocation

Participants consenting to the trial underwent a pre-treatment baseline assessment (T1), during which they were assessed by a clinically trained study assessor who undertook a clinical interview and administered a self-report booklet. Eligible participants were randomly allocated to either (a) SPE treatment or (b) MPE treatment (see Figure 3) using a randomisation list created by an independent statistician. Follow-up assessments occurred at the following intervals:

1. 4 weeks post-treatment commencement (T2)
2. 12 weeks post-treatment commencement (T3)
3. 12 months post-treatment commencement (T4).

Assessments were single blind, meaning that the study assessor was unaware of which treatment groups participants were placed.

RESTORE TRIAL

PARTICIPANT JOURNEY

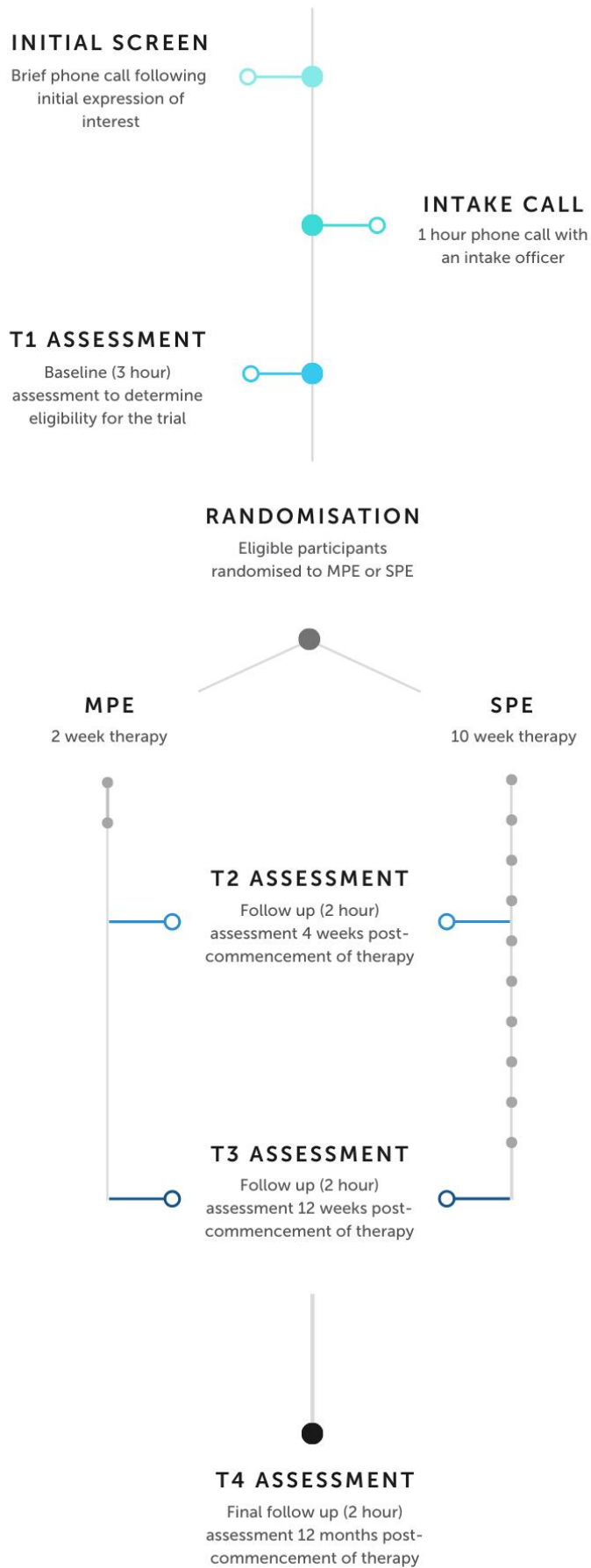


Figure 3. RESTORE trial participant journey

Recruitment

Individuals were referred into the trial by their MO or MHP (current-serving), Open Arms centre-based clinicians and Outreach Program Counsellors, private practitioners, or could self-refer. To assist with recruitment of current and ex-serving ADF, several forms of advertising were undertaken for the RESTORE trial. The following were used regularly throughout the course of recruitment:

- trial information on Open Arms and Defence websites
- advertisements on Phoenix Australia and Open Arms Facebook, Twitter and LinkedIn
- printed flyers and brochures accessible at:
 - Open Arms sites in Adelaide, Brisbane, Canberra, Darwin, Melbourne, Perth, Sydney and Townsville
 - ADFCMH Sydney
 - Mates4Mates Brisbane
 - Soldier On clinics in Brisbane, Canberra, Melbourne, Perth and Sydney.

See Figure 4 for further promotional activities during the 4-year recruitment period (August 2016 – September 2020).

Treatment

Participants randomly allocated to the SPE condition received 10 weekly sessions of 90-minute face-to-face manualised standard PE therapy. Participants randomly allocated to MPE received an intervention identical to SPE, except that it was delivered rapidly over the course of 2 weeks (Tuesday to Tuesday, 90-minute session with a therapist each morning followed by homework tasks [*in vivo* activities] each afternoon). Therapy did not begin on a Monday to allow for at least 2 weekends within the treatment timeframe, providing more time for the participant to undertake *in vivo* exposure. Participants were considered treatment completers if they attended at least seven of the 10 sessions.

For both conditions, therapists made phone contact with the participant 1 week, 3 weeks and 6 weeks following conclusion of therapy. The purpose of these calls was to encourage the participant to continue undertaking *in vivo* activities and to check in on what activities they had done since therapy or the last telephone call. The final telephone call at 6 weeks wrapped up the therapeutic relationship and ensured that the participant was linked into other support services (where appropriate).



Figure 4. A snapshot of the RESTORE trial promotional activities from July 2016 to September 2020

Primary outcome measure

CAPS-5

Posttraumatic stress symptomology was measured using the Clinician-Administered PTSD Scale for Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (CAPS-5) (Blake et al., 1998; Weathers et al., 2018). The structured clinical interview comprises 30 items scored on a 5-point Likert scale (0 = 'absent', 4 = 'extreme/incapacitating'), measuring symptom clusters of avoidance, negative alterations in cognition and mood, arousal and reactivity, and re-experiencing. The CAPS-5 provides an overall severity score ranging from 0–80, with moderate scores ranging from 23–34, severe scores between 35–47, and extreme scores ≥ 48 (Weathers et al., 2018). The CAPS-5 is one of the most widely used tools for diagnosing and measuring PTSD severity and has demonstrated excellent reliability and validity (Weathers et al., 2018).

Secondary outcome measures

Secondary outcome measures were assessed via self-reporting at all assessment timepoints. PTSD symptoms as measured by both the CAPS-5 and the PTSD Checklist-5 (PCL-5) were assessed for the month prior to T1 and T4 and assessed for the 2 weeks prior to T2 and T3.

PCL-5

The PCL-5 is a 20-item self-report rating scale used to assess the DSM-5 symptoms of PTSD (Weathers et al., 2013). Respondents rated each item on a 5-point Likert scale (0 = 'not at all', 4 = 'extremely') to indicate the degree to which the participant had been bothered by that particular symptom. A total symptom severity score (range 0–80) was computed by adding the 20 items, with higher scores indicative of greater severity. A cut-off score of equal to or greater than 33 was considered indicative of a possible diagnosis of PTSD. The PCL-5 has been found to be a psychometrically sound measure of PTSD symptom severity among civilian populations (Blevins et al., 2015) and treatment-seeking military members (Wortmann et al., 2016).

DAR-5

Problematic anger was measured by the Dimensions of Anger Reactions-5 (DAR-5) self-report questionnaire (Forbes, Alkemade, Mitchell et al., 2014) at all time points. The DAR-5 is a 5-item measure of anger frequency, intensity, duration, aggression, and effect on relationships, with individuals responding on a scale of 0 (none or almost none of the time) to 5 (all or almost all of the time) (Forbes, Alkemade, Mitchell et al., 2014). The DAR-5 demonstrates strong internal reliability, convergent concurrent and discriminant validity, and, particularly relevant to this study, has been validated in populations with and without a history of trauma (Forbes, Alkemade, Mitchell et al., 2014) and with combat veterans (Forbes, Alkemade, Hopcraft et al., 2014).

HADS Anxiety and Depression

The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) was used to measure anxiety and depression symptoms at all time points. The HADS is a 14-item self-report measure of depression and anxiety symptoms, asking respondents to indicate from 0 to 3 the frequency or intensity with which they experience each symptom. A score of 8 on either the depression or anxiety subscales indicates pathology (Bjelland et al., 2002). Review of the psychometric properties of the HADS, incorporating over 700 studies, indicated satisfactory sensitivity, specificity, and concurrent validity for both anxiety and depression subscales for those with physical or mental health difficulties and the general population (Bjelland et al., 2002).

WHODAS

Disability was assessed by the 12-item self-report version of the World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) (Üstün et al., 2010). The WHODAS 2.0 asks individuals to indicate their level of difficulty due to health conditions in the areas of understanding and communication, self-care, mobility, interpersonal relationships, work and household activities, and community roles (Marx et al., 2015; Üstün et al., 2010). The WHODAS 2.0 demonstrates good internal consistency, reliability and concurrent validity in a wide range of populations and cultures (Marx et al., 2015; Üstün et al., 2010). Specifically relevant to this study, the interview version of the WHODAS 2.0 has been validated as an assessment of functional impairment among veterans by identifying those with PTSD-related impairment assessed by the CAPS-5 (Marx et al., 2015).

AQoL-6D

Quality of life was assessed at each time point by the Assessment of Quality of Life Scale – 6 dimension version (AQoL-6D) (Maxwell et al., 2016). The AQoL-6D is a 20-item self-report questionnaire reflecting physical and psychosocial domains. Respondents indicate their level of functioning in the areas of independent living, relationships, mental health, coping, pain and senses (Allen et al., 2013). In a large Australian sample, AQoL-6D demonstrated satisfactory levels of construct, concurrent and convergent validity (Allen et al., 2013).

Results

Final sample

The RESTORE trial recorded 667 expressions of interest between July 2016 and September 2020. Some of the reasons for individuals not progressing from expression of interest to an intake call included living in a location not serviced by the trial (prior to the implementation of telehealth), their trauma did not occur while serving (e.g., childhood trauma), or they were not a veteran or current-serving member of the ADF. There were 162 individuals who progressed from the intake call to a baseline assessment to assess their eligibility, and **138 current and ex-serving ADF members with PTSD were randomised to different therapy types in the RESTORE trial** (see Figure 5).

Analyses of baseline data were conducted using Statistical Package for the Social Sciences (SPSS) version 27 (IBM Corp., Armonk, NY, US). Treatment groups were compared across a number of demographic and service characteristics and reservist and ex-serving member characteristics. Treatment dropout rates were compared across groups, and the sessions at which dropout occurred are also presented. Several participants and group proportions are presented for categorical data, with means and standard deviations presented for continuous data. Differences between groups were tested using chi-square tests for categorical data and independent samples t-tests for continuous data. A p value of $<.05$ was considered significant. Hedges' *g* measures the magnitude of clinical effect with .2, .5 and .8 representing small, moderate, and large differences, respectively.

Baseline sample characteristics

Sociodemographic characteristics

Of the 138 participants who were found to be eligible and initially randomised to therapy, four were later found to be ineligible (see Figure 5) and were excluded from the intention-to-treat sample. The final analytic sample comprised 134 participants who were randomised to either the MPE ($n = 63$) or SPE ($n = 71$) groups. Table 2 shows the demographic and service characteristics for the sample by treatment group. This information was collected via participant self-report during the baseline T1 assessment. The sample was predominately male (88.1%), with the majority (81.3%) aged between 28 and 57 years ($M = 45.6$ years). In terms of education, the majority reported a certificate or diploma (44.7%) or a university qualification (24.2%). The sample was primarily comprised of ex-serving members (64.2%). The majority (60.6%) of participants reported service with the Army, and just over half (56.5%) were current or former non-commissioned officers. The mean time served in the ADF was 15.3 years, with over half (59.4%) of the sample serving 10+ years. Most (88.7%) had deployed, with a mean of 4.3 deployments in their career. Chi-square tests and independent samples t-tests (see Table 2) revealed no significant demographic and service differences between the two treatment groups.

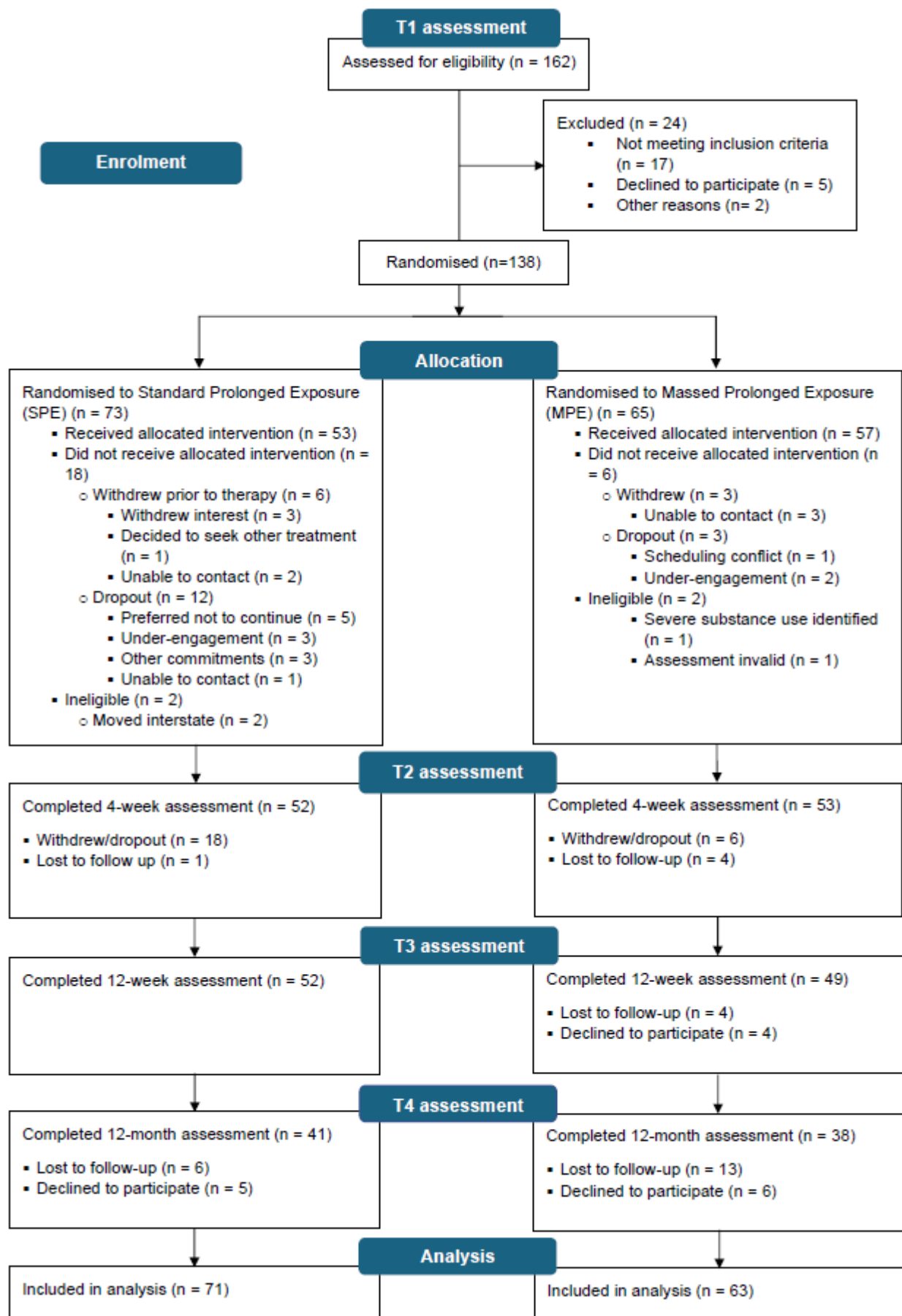


Figure 5. CONSORT diagram describing flow of participants through the study

Notes. CONSORT = Consolidated Standards of Reporting Trials. Withdrew = participants who were randomised to a condition but did not commence treatment. Dropout = participants who were randomised to a condition, commenced treatment but discontinued. Ineligible = ineligible and excluded from analysis. Participants who withdrew or dropped out of therapy were not invited to undergo follow-up assessments.

There were 88 (65.7%) participants that reported being a reservist or ex-serving ADF member. These participants comprised 77.3% ex-serving members, and 10.2% active and 12.5% inactive reservists. The majority were employed in full-time or part-time work (34.1%) or on a sickness allowance or disability pension (33.0%), while 17.0% were retired. The remainder were either unemployed/looking for work (9.1%), conducting unpaid work (5.7%) or studying (1.1%). The most commonly reported reason for not looking for work was the respondents' own ill health (25.36%). Of this subsample, 88.6% reported having a DVA white or gold card. The two treatment groups did not significantly differ on any of these characteristics.

Table 2. Demographic and service characteristics for each treatment group

	MPE (n = 63)		SPE (n = 71)		Total (n = 134)	
	n	%	n	%	n	%
Sex						
Male	56	88.9	62	87.3	118	88.1
Female	7	11.1	9	12.7	16	11.9
Age, years (M, SD)	44.3	10.8	46.7	12.7	45.6	11.9
18–27	3	4.8	3	4.2	6	4.5
28–37	13	20.6	18	25.4	31	23.1
38–47	23	36.5	16	22.5	39	29.1
48–57	17	27.0	22	31.0	39	29.1
58+	7	11.1	12	16.9	19	14.2
Education						
Primary / Secondary school	17	27.4	24	34.3	41	31.1
Certificate / Diploma	32	51.6	27	38.6	59	44.7
University	13	21.0	19	27.1	32	24.2
Serving status (at intake)						
Current ADF member	21	33.3	27	38.0	48	35.8
Ex-serving	42	66.7	44	62.0	86	64.2

	MPE (n = 63)		SPE (n = 71)		Total (n = 134)	
	n	%	n	%	n	%
Service						
Navy	14	23.0	18	25.4	32	24.2
Army	37	60.7	43	60.6	80	60.6
Air Force	9	14.8	9	12.7	18	13.6
Other non-Australian military	1	1.6	1	1.4	2	1.5
Rank						
CO	11	18.0	11	15.7	22	16.8
NCO	36	59.0	38	54.3	74	56.5
Other ranks	14	23.0	21	30.0	35	26.7
Time served (years) (M, SD)	15.4	10.3	15.2	10.7	15.3	10.5
0–4	9	14.8	9	13.4	18	14.1
5–9	15	24.6	19	28.4	34	26.6
10–19	15	24.6	21	31.3	36	28.1
20+	22	36.1	18	26.9	40	31.3
Ever deployed						
No	5	8.1	10	14.1	15	11.3
Yes	57	91.9	61	85.9	118	88.7
Number of deployments (M, SD)	5.0	7.5	3.7	5.5	4.3	6.5

Note. ADF = Australian Defence Force, CO = Commissioned officer, MPE = Massed Prolonged Exposure, NCO = Non-commissioned officer, SPE = Standard Prolonged Exposure.

Baseline mean scores for PTSD and secondary measures by treatment group are presented in Table 3. While the PCL-5 is a self-report of PTSD severity, the CAPS-5 reflects a clinician-rated assessment. Both measures can sum to a total score of 80. A cut-off score of ≥ 33 on the PCL-5 is indicative of probable PTSD, with mean scores of approximately 50 for both groups representing severe levels of PTSD symptomatology among the sample. Consistent with this, the CAPS-5 total score at initial assessment within both groups sits within the severe PTSD score range (35–47). There were no significant differences between the groups on six of the mental health measures. MPE group members reported a significantly higher level of depression than SPE group members.

Table 3. Mean scores on outcome measures at baseline for each treatment group

	MPE (n = 63)		SPE (n = 71)		p
	M	SD	M	SD	
CAPS-5 total score	42.38	9.18	39.44	10.43	ns
PCL-5 total score	50.22	12.62	49.76	12.25	ns
DAR-5 total score	13.03	4.60	12.90	4.48	ns
HADS anxiety total score	12.53	3.58	11.94	3.89	ns
HADS depression total score	11.92	4.01	10.55	3.56	.040
WHODAS total score	18.95	7.39	19.99	8.22	ns
AQoL-6D utility score	0.46	0.17	0.46	0.17	ns

Note. AQoL-6D = Assessment of Quality of Life 6D, CAPS-5 = Clinician-Administered PTSD Scale for DSM-5, DAR-5 = Dimensions of Anger Reactions scale, HADS = Hospital Anxiety and Depression Scale, MPE = Massed Prolonged Exposure, PCL-5 = PTSD Checklist for DSM-5, SPE = Standard Prolonged Exposure, WHODAS = World Health Organization Disability Assessment Schedule 2.0.

Non-inferiority of massed exposure

At T3, non-inferiority between MPE and SPE was tested. CAPS-5 scores reduced (meaning that symptoms decreased) from the baseline [MPE (M = 42.38, SD = 9.18) and SPE (M = 39.44, SD = 10.43)] to 12 weeks post-treatment [MPE (M = 26.90, SD = 17.74) and SPE (M = 25.10, SD = 15.05)] (see Figure 6). The estimate of the difference between the MPE and SPE group means was 0.94, with a 95% confidence interval (CI) of -4.19 to $+6.07$. The upper endpoint of the 95% CI was below the value of $+7$, indicating that the MPE group was non-inferior to the SPE group. Phrased in terms of Cohen's *d*, this result is an effect size of 0.054 with a 95% CI of -0.24 to $+0.34$.

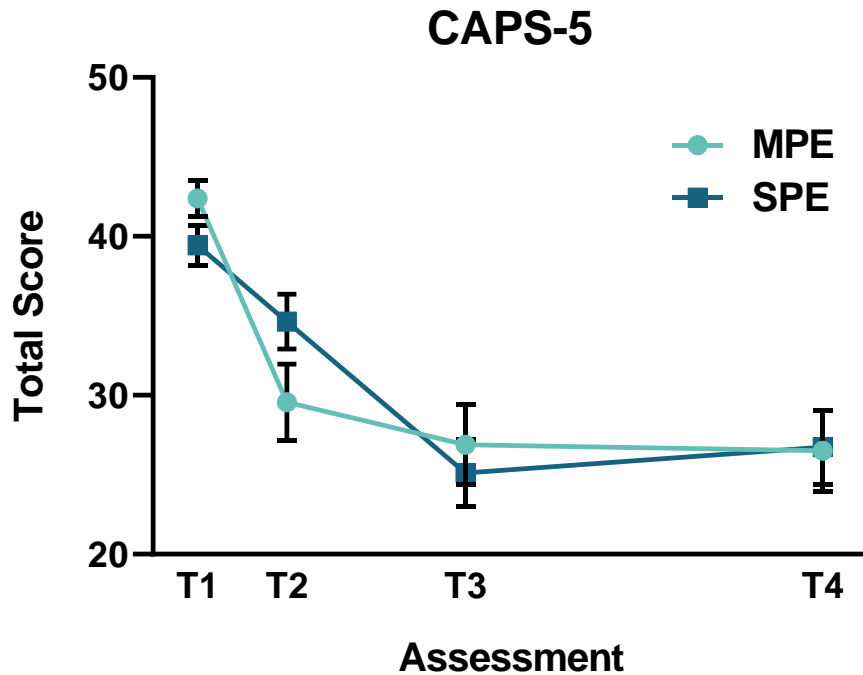


Figure 6. CAPS-5 change from baseline (T1), 4 weeks (T2), 12 weeks (T3) and 12 months (T4) post-commencement of therapy

Non-inferiority was also tested at T4. From the baseline [MPE (M = 42.38, SD = 9.18) and SPE (M = 39.44, SD = 10.43)] to 12 months post-treatment [MPE (M = 26.50, SD = 15.72) and SPE (M = 26.75, SD = 14.79)], treatment gains were maintained in both groups, with a 95% CI of -6.82 to +3.92. The upper endpoint of the 95% CI was below +7, indicating that **the MPE group was non-inferior to the SPE group at 12 months**. Figure 7 shows CAPS-5 scores at each timepoint, including individual data points and severity categories of moderate (scores 23–34), severe (35–47) and extreme (48–80).

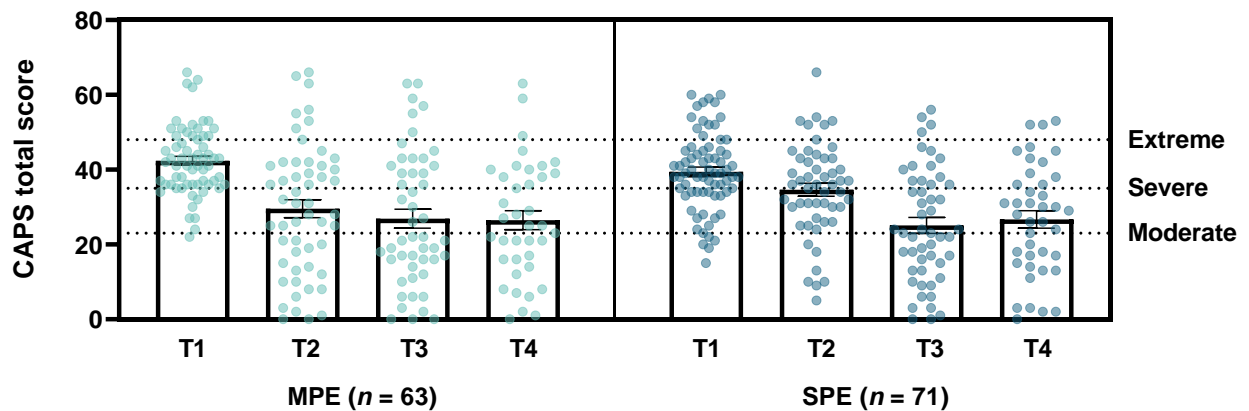


Figure 7. Means and standard errors of CAPS-5 PTSD total score at T1 to T4 by treatment condition, including severity score categories

Comorbid health issues

The baseline (T1), and 4 weeks (T2), 12 weeks (T3) and 12 months (T4) post-commencement of therapy scores for the outcome measures are presented in Figure 8. **Both treatment groups experienced reductions in self-reported symptoms of PTSD, anger, anxiety and depression over time, and improvements in quality of life.**

Linear mixed models were used to examine the patterns of change in outcome scores over time for the two groups separately. Separate analyses were conducted for each outcome measure. Changes in scores on the outcome measures over time for each group are presented in Table 4. Note that the difference in score is an estimation of the change in the outcome measure over the two time points. A negative difference indicates that the score on the second occasion was lower than the score on the first occasion.

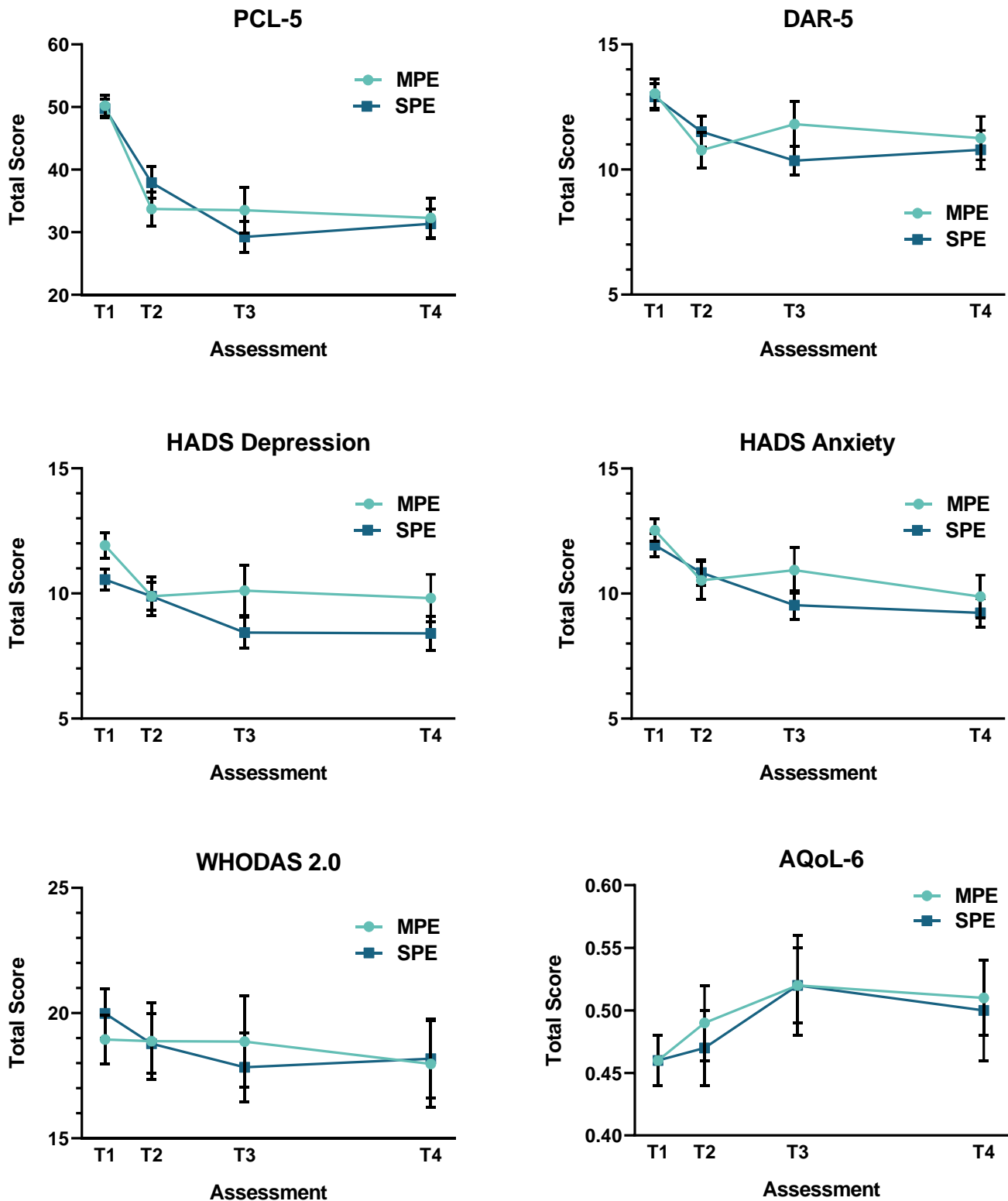


Figure 8. Outcomes for measures at baseline (T1), and 4 weeks (T2), 12 weeks (T3) and 12 months (T4) post-commencement of therapy

For all measures except for the AQoL-6D, a negative score indicates a reduction in symptoms. For the AQoL-6D, which ranges from 1.00 (full health) to 0.00 (death-equivalent health states) to -0.04 (health states worse than death) (Hawthorne & Osborne, 2005), a positive score indicates an improvement in quality of life. Cohen's effect sizes for repeated measures are also presented in Table 4 for the change over time from baseline (T1) to 12 weeks (T3), baseline (T1) to 12 months (T4) and from 12 weeks (T3) to 12 months (T4). Effect size has been calculated as the difference in the sample means over time divided by the sample SD of the differences between scores on the first and second occasions. Small, medium, and large effect sizes correspond to Cohen's *d* of 0.2, 0.5 and 0.8, respectively.

Table 4. Change in scores of outcome measures over time within treatment groups

Measure	T1 vs T3	T3 vs T4	T1 vs T4
	Difference (ES)	Difference (ES)	Difference (ES)
CAPS-5			
MPE	-14.12 (0.98)***	0.45 (0.00)	-13.67 (1.00)***
SPE	-13.75 (1.05)***	1.97 (0.24)	-11.77 (1.01)***
PCL-5			
MPE	-18.29 (0.87)***	0.34 (0.01)	-17.95 (1.05)***
SPE	-20.29 (1.13)***	2.33 (0.25)	-17.96 (0.89)***
DAR-5			
MPE	-1.74 (0.42)*	-0.02 (0.00)	-1.76 (0.37)*
SPE	-2.50 (0.49)***	0.68 (0.22)	-1.82 (0.16)*
HADS Anxiety			
MPE	-2.29 ^b (0.45)**	-0.23 (0.12)	-2.52 (0.61)***
SPE	-2.55 (0.76)***	-0.08 (0.04)	-2.63 (0.67)***
HADS Depression			
MPE	-2.50 (0.51)***	-0.01 (0.05)	-2.51 (0.63)***
SPE	-2.28 (0.58)**	0.02 (0.05)	-2.26 (0.64)**
WHODAS			
MPE	-0.64 (0.18)	-1.09 (0.25)	-1.73 (0.24)
SPE	-2.61 (0.41)*	0.87 (0.16)	-1.74 (0.39)
AQoL-6D			
MPE	0.07 (0.45)*	-0.01 (0.02)	0.05 (0.41)
SPE	0.07 (0.42)**	-0.01 (0.05)	0.06 (0.34)*

Note. T1 = pre-treatment baseline, T2 = 4 weeks post-commencement of therapy, T3 = 12 weeks post-commencement of therapy, T4 = 12 months post-commencement of therapy, ES = Effect size. * $p < .05$; ** $p < .01$ *** $p < .001$.

Except for disability scores for the MPE group, both groups improved significantly over time on all measures on at least one occasion. There were no instances where either group reported a significant deterioration in health.

From baseline (T1) to 12 weeks (T3) and baseline (T1) to 12 months (T4), large effect sizes were observed for both groups on the CAPS-5 and PCL-5. Finally, for both groups, there were no significant changes from 12 weeks (T3) to 12 months (T4) for any of the outcome measures, suggesting maintenance of gains. Correspondingly, effect sizes for changes in the outcome measures over this nine-month period were, at most, rated as small.

Treatment dropout

There were more non-completers in the SPE group ($n = 18/71$, 25.4%) than in the MPE group ($n = 6/63$, 9.5%). However, this number included individuals who were randomised and did not commence session 1 and individuals who dropped out during therapy. Three (4.8%) MPE participants and 12 (16.9%) SPE participants commenced therapy and then dropped out prior to completion, which was significantly different between groups ($\chi^2(1) = 5.35$, $p = 0.021$). Of note, even the more elevated dropout in the SPE group was substantially lower than the 30% reported in many international PE trials (Foa et al., 2018; Ford et al., 2018).

Figure 9 shows the number of participants who dropped out of the study at each session by treatment group.

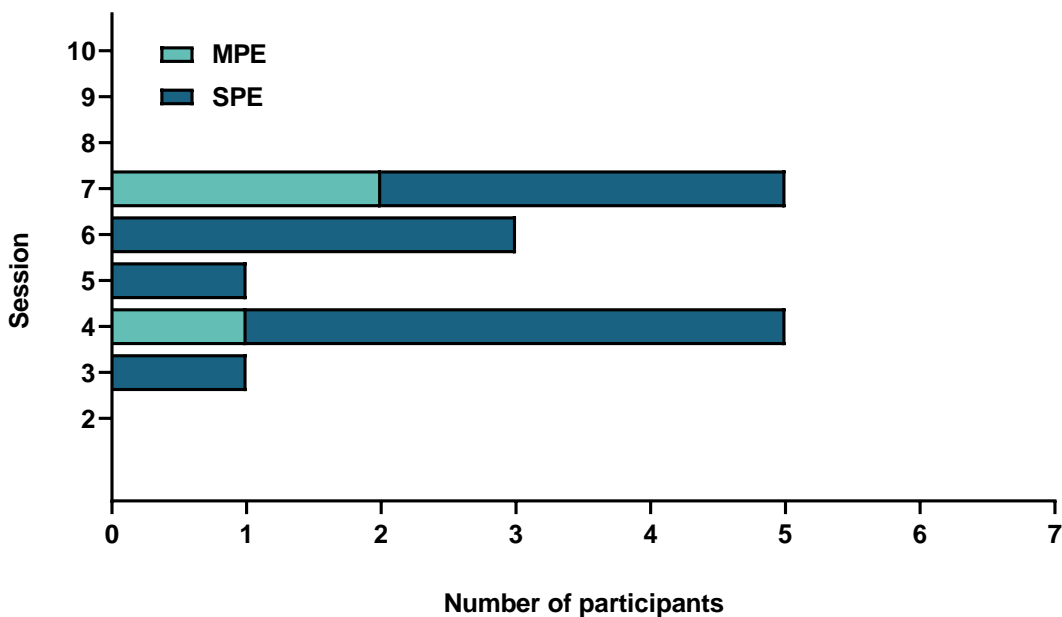


Figure 9. Number of participants who dropped out of the study at each session by treatment group

Loss of diagnosis

PTSD diagnostic status was determined by dichotomising individual symptoms as ‘present’ or ‘absent’, then following the DSM-5 diagnostic algorithm. A symptom was considered present only if the corresponding item severity score was rated 2 = moderate/threshold or higher. In the CAPS-5, items 9 and 11–20 have the additional requirement of a trauma-relatedness rating of definite or probable; otherwise, a symptom was considered absent. The DSM-5 diagnostic rule requires the presence of at least one Criterion B symptom (intrusions), one Criterion C symptom (avoidance), two Criterion D symptoms (negative alterations in cognitions and mood), and two Criterion E symptoms (alterations in arousal and reactivity). In addition, Criteria F and G must be met. Criterion F requires that the disturbance has lasted at least one month. Criterion G requires that the disturbance causes either clinically significant distress or functional impairment, as indicated by a rating of 2 = moderate or higher on items 23–25. This calculation of diagnosis is consistent with Voorendonk et al. (2020). The proportions of participants with a diagnosis of PTSD on the CAPS-5 were compared across time separately for the MPE and SPE groups using McNemar’s test of related samples (Table 5).

Table 5. Chi-square values for McNemar’s test of related samples for loss of PTSD diagnosis

Group	T1 vs T3	T3 vs T4	T1 vs T4
MPE	28.03***	0.12	19.05***
SPE	24.04***	0.44	22.04***

*Note. Degrees of freedom for all tests = 1. *** $p < .001$.*

Consistent with our expectation, **there were statistically significant reductions in the proportions of participants with a PTSD diagnosis in the MPE and SPE groups from baseline (T1) to 12 weeks (T3) and 12 months (T4)**. Neither group changed significantly from T3 to T4. At T3, 46.2% of MPE and 45.9% of SPE members met the criteria for PTSD; $\chi^2 (1, n = 134) = 0.003, p = .959$. At T4, 46.8% of the MPE group and 45.9% of the SPE group had a PTSD diagnosis; $\chi^2 (1, n = 134) = 0.002, p = .963$. These figures suggest that cases reduced quicker in the MPE group initially; however, the SPE group caught up over time and, by T3, there was little change thereafter (see Figure 10).

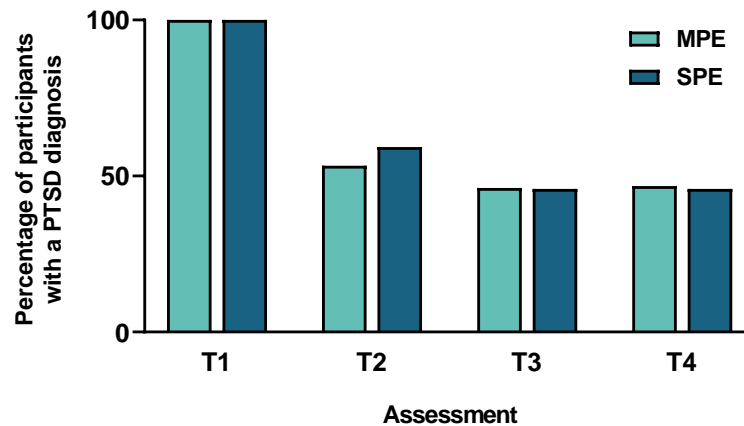


Figure 10. Percentage of participants meeting CAPS-5 PTSD diagnosis at T1 to T4 by treatment condition

Notes. T1 (baseline), T2 (4 weeks post-commencement of therapy), T3 (12 weeks post-commencement of therapy) and T4 (12 months post-commencement of therapy). Percentages were calculated based on the total number of assessments conducted at each time point.

Therapist perceptions

Following the completion of the RESTORE trial therapy, the project team sent a short survey to all therapists who had provided at least one session of therapy to a RESTORE trial participant and sought feedback regarding their experience implementing MPE and/or SPE. The main themes included:

- For both treatment conditions, some therapists reported steady reductions in PTSD symptoms throughout therapy and increased engagement with homework tasks as time in therapy progressed (i.e., *in vivo* exposure). Others noted a slower start to noticeable symptom reduction with some initial exacerbation of pre-existing symptoms, such as nightmares and avoidance behaviours, that then stabilised and reduced. This is not uncommon in any psychological trauma-focused therapy and speaks to the importance of client engagement and therapeutic dose.

‘In MPE, the clients were more focused – less time between sessions for psychosocial issues to occur.’

- Client engagement, session attendance and homework (including *in vivo*) compliance were commonly reported challenges experienced by therapists. Again, these are usual challenges faced by therapists when implementing any form of psychological therapy. The two different treatment conditions in this trial led to some more specific feedback:

- For MPE, therapists noted that due to the short time between sessions, participants had less opportunity to complete homework, including implementing *in vivo* exposures. For some participants, the daily sessions led to fatigue, while for others, it allowed them to be more engaged and focused.
- For SPE, therapists noted that the increased number of days between sessions could lead to avoidance behaviours which hindered treatment engagement.

‘The MPE therapy allowed clients to feel that they were moving rapidly through their treatment ... and meeting their goals of dealing with PTSD.’

- Some therapists noted that it was difficult for them to schedule MPE sessions around other work commitments.
- MPE was reported to be confronting and challenging for the participant, while also associated with rapid reductions in PTSD symptoms.
- Therapists would recommend PE (both MPE and SPE) to other clinicians; however, the clinician needs to have confidence in the therapy and their ability to deliver it.

Overall, being involved in the RESTORE trial was rated as a positive experience for all therapists. Their engagement in fortnightly supervision and with the Phoenix Australia project team was strong throughout the entire trial. The feedback of those involved indicated that they felt more skilled and more confident in delivering PE therapy, with most therapists reporting that they were also using PE with other clients (i.e., those not in the trial). The key message from the therapists, as noted above, was to ensure confidence in implementing PE, which can only occur through well-supported training, supervision and practice.

Discussion

MPE was as effective as SPE in treating PTSD

MPE and SPE were equally effective in significantly reducing self-reported (PCL-5), and clinician-reported (CAPS-5) symptoms of PTSD and gains were maintained at 12 months. Both groups reported very large clinical improvements, although they varied in the rapidity and timing of the change based on the treatment structure: there was stronger early change in MPE and continued change in SPE. This is in line with previous international research, in particular, the only other RCT evaluating the efficacy of 10 sessions of the compressed daily format of PE (MPE) compared to standard weekly PE (Foa et al., 2018). This was a large four-armed RCT of 366 active U.S. Army soldiers, examining MPE, SPE, present-centred therapy (a non-trauma-focused treatment) and a minimal contact condition. Foa et al. (2018) found no significant difference between the MPE and SPE conditions in PTSD symptoms (as measured by PTSD Symptom Scale–Interview) at the post-treatment and 12-week follow-ups. Similar to the findings of this report, the MPE format was non-inferior and showed equivalent efficacy to the SPE format at both the 12-week and 6-month follow-

ups. To our knowledge, this is the first study to show the maintenance of individual MPE therapy gains in military personnel and veterans at 12 months.

Our finding that MPE is equally as effective as SPE is critically important when considering ways in which we can make effective therapy for PTSD more accessible to current and ex-serving members. We now have an evidence base in an Australian population, using multiple Australian therapists across several states and territories, that shows the delivery of PE in a shortened timeframe can provide equivalent change and outcomes as delivering it within the usual timeframe of 10 weeks. This finding greatly increases the potential for flexibility in delivering therapy in a real-world environment and demonstrates that therapy can work around the demanding schedules and work requirements that those in, and out of, the military experience. It is also important to note that this finding can serve to empower clients by giving them more choice and control over their therapeutic experience. For some in the RESTORE trial, there was a clear preference for MPE and a visible commitment to and engagement with this protocol; for others, the slower pace of SPE was more suitable and allowed for a more gradual introduction to the therapy. Empowering individuals in managing their therapy is associated with improved PTSD outcomes (Watts et al., 2015) and improved satisfaction with treatment decisions (Stacey et al., 2017). As such, by providing equally effective options to clients, we can overcome some of the challenges and barriers to engagement with psychological therapy.

PTSD symptom severity reduced over time

At 4 weeks post-commencement of therapy (T2) and 12 weeks post-commencement of therapy (T3), there was a significant reduction in PTSD symptoms compared to T1 for both the MPE and SPE conditions. The significant post-treatment reduction of PTSD symptoms in the SPE condition aligns with a large body of evidence indicating that PE is an efficacious trauma-focused cognitive behavioural treatment for PTSD (Lewis et al., 2020; Steenkamp et al., 2015). This is also consistent with Australian and international treatment guidelines that recommend PE as a first-line treatment for PTSD in adults (Forbes et al., 2020; National Institute for Health and Care Excellence, 2018; Phoenix Australia, 2020).

Notably, a significant reduction of symptom severity was observed at T2 within both conditions, even though participants of SPE were only part-way (4–5 sessions) into their treatment. The reduction in symptom severity at T2 was anticipated for the MPE condition, given this group had concluded their therapy, but it is interesting to note the significant shifts in symptom severity for those in the SPE condition after only a few sessions. Commencing a therapeutic relationship and psychoeducation may have contributed to an early reduction of PTSD symptoms. Only two ‘doses’ of the active components of PE (the *imaginal* and *in vivo* exposure) may be enough to start a substantial trajectory of symptom reduction. Importantly, this finding suggests that those engaged in SPE can make gains early in the course of therapy, which might act as a motivator to continue to remain engaged in the work.

At the point of 12 weeks post-commencement of therapy, the MPE group had concluded therapy 10 weeks prior and the SPE group had concluded therapy 2 weeks prior, but further decreases in symptom severity, most notably for the SPE condition, were found. At this stage, gains made in the MPE condition were beginning to consolidate. Some minor continued reductions in symptom severity were still present 8 to 10 weeks post-treatment and, importantly, were still on a downward trajectory rather than returning to the baseline. By the 12-month assessment, symptom severity as measured by the CAPS-5 was equal between

groups. Importantly, **treatment gains were maintained for both MPE and SPE at the 12-month follow-up**. These findings highlight the ability for treatment outcomes to persist in the long term.

At the T3 assessment, there was a considerable reduction in diagnosis, comparable to previous US research (Foa et al., 2018), with 54.1% of participants in the SPE condition and 53.8% of participants in the MPE condition no longer meeting the criteria for a diagnosis of PTSD. By the T4 assessment, the SPE group had continued to improve. Interestingly, **both groups ended with a similar diagnosis loss, with 53.2% of the MPE group and 54.1% of the SPE group no longer having a diagnosis of PTSD**. These results collectively speak to the therapy's effect and demonstrate that, within both treatment conditions, meaningful effects were made on symptom severity. This suggests evidence of the efficacy of both conditions in alleviating symptoms for current-serving members and veterans with PTSD.

Comorbid health issues improved

Comorbid mental health issues are common in military personnel and veterans with PTSD. Although PE therapy was not designed to directly target depression and anger, both MPE and SPE groups demonstrated significant reductions in these areas following therapy, with no difference between the groups. Secondary measure effect sizes from baseline (T1) to 12 weeks (T3) and 12 months (T4) were smaller in comparison to the PTSD measures (CAPS-5, PCL-5); however, it is notable that significant improvement was reported on all measures (with the exception of the WHODAS disability rating).

From T1 to T3, both treatment groups had a small to medium effect on anger. A medium effect size was reported for anxiety and depression measures from T1 to T4. SPE showed a greater effect than MPE on anxiety and disability when comparing change from T1 to T3, which is likely due to the recency of treatment in SPE; however, both treatment groups showed similar effect size improvements for quality of life, depression, and anger.

The amelioration of comorbid depressive symptoms (Aderka et al., 2011; Eftekhari et al., 2013; Nacasch et al., 2010), general anxiety (van Minnen et al., 2015) and anger (Cahill et al., 2003; Ford et al., 2018) following SPE treatment were previously reported. More recent studies have shown similar effects of massed or rapid PE on anxiety and depression (Hendriks et al., 2017; Zwetzig et al., 2021). However, to our knowledge, this trial is the first to report a reduction in anger severity following MPE. Of note, reductions in anger, although significant, were smaller than those observed in PTSD and depression. Previous research using trauma-focused CBT has demonstrated residual anger despite meaningful reductions in PTSD severity (Ford et al., 2018; Zayfert & DeViva, 2004), which may be due to distress tolerance (Morabito et al., 2019). Further research is necessary. However, this finding is significant given that a recent study reported three in four Australian military personnel and veterans have significant anger problems (Cowlshaw et al., 2022) and other studies using trauma-focused PTSD treatment have observed little to no improvement in anger (Schnurr & Lunney, 2019; Zayfert & DeViva, 2004).

Fewer treatment dropouts in MPE

Although MPE and SPE were equally efficacious in reducing PTSD symptoms, with gains observed as early as four sessions into therapy in the SPE group, our findings indicate that treatment dropout, or treatment non-completion, was almost four times lower in MPE compared to SPE. In unpacking the reasons for dropout (where possible), out of the 12 participants who dropped out of the SPE group, 25.0% ($n = 3$) cited personal issues as the reason for leaving therapy (such as balancing therapy with family, work, medical treatment, and other commitments). In contrast, none of the MPE participant dropouts cited other commitments or personal issues as the reason for leaving therapy. It has been argued that MPE can address distraction, avoidance, and demotivation that occurs between therapy sessions (Sherrill et al., 2020). It is possible that the reduced time commitment required may circumvent a significant proportion of potential dropouts from therapy and the potential for other competing demands to occur in the therapeutic window. It is also possible that by engaging daily with a therapist, there is a greater sense of support and commitment to the process. Indeed, recent qualitative research in the US has shown that veterans believe the structure of MPE limits distractions and avoidance, reinforces engagement, and enhances motivation (Sherrill et al., 2020).

With a population that is often challenged to find large blocks of time for therapy, alongside the fact that this trial was a real-world RCT, the effectiveness of MPE combined with the extremely low dropout rates observed in this study present a compelling argument for national adoption and rollout. It is noteworthy that even the more elevated dropout rate of 18.5% in SPE is significantly lower than the 30.0% dropout rates reported in US veteran trials of PE (e.g., Katz et al., 2014; Yehuda et al., 2014; Yuen et al., 2015). It is also worth observing that treatment dropout is often used as a crude proxy for treatment acceptability (Imel et al., 2013). Therefore, our findings indicate that MPE may be a more acceptable way to engage in and complete therapy for military personnel and veterans.

Limitations

The outcomes of this report should be considered in relation to two key limitations. First, PE therapy is not necessarily suitable for all presentations of trauma. The RESTORE trial included individuals with a diagnosis of PTSD according to the CAPS-5 and a military-related trauma, and while all individuals in the trial met inclusion criteria, PE therapy may not be the most suitable form of trauma-focused therapy for some, given other mental health and lifestyle factors (e.g., depression, anxiety, social supports). For example, a recent study of MPE in veterans found a small proportion of patients who did not maintain treatment gains were likely to report persistent depressive symptoms (Burton et al., 2022). Second, due to certain trial inclusion criteria, while highly inclusive of severe PTSD, significant comorbidity and co-occurring life stressors, the sample may not be representative of all current-serving and ex-serving personnel seeking treatment in a health service setting (Yehuda & Hoge, 2016). For example, the trial excluded participants who did not meet the criteria for a PTSD diagnosis; however, previous research showed that individuals with subclinical presentations can respond to exposure-based therapy, even demonstrating a greater reduction compared to individuals with PTSD diagnosis (Korte et al., 2016).

Implications

The RESTORE trial provides the first Australian evidence to show that MPE across 2 weeks provides the same reduction in PTSD symptom severity as 10 weeks of therapy and that treatment gains are maintained at 12 months.

This trial demonstrated that the equivalent ‘dose’ of PE therapy within a shorter duration is equally effective as the standard, longer duration form of the therapy for both PTSD and common comorbid mental health issues. Further, individuals undertaking MPE were 3.5 times less likely to drop out of therapy than those who undertake the longer SPE therapy, with rates as low as 4.8%. In combination, these findings have extremely important implications for individuals experiencing trauma while employed with the military, including those who are currently serving personnel and may not have the capacity to attend 10 weeks of therapy sessions.

Unlike other international PE studies, the RESTORE trial was multi-site and multi-therapist. This trial provided therapy in a real-world setting at Defence mental health centres and Open Arms clinics, with the assistance of 38 trained therapists who also provided therapy to clients outside the trial. Unlike the setting of research clinics and the use of researcher-therapists (e.g., Foa et al. [2018], who used three clinicians to provide PE therapy for over 350 participants), this trial had high ecological validity, closely replicating the setting in which military members and veterans may receive PE therapy outside a trial.

Further, the RESTORE trial had very high face validity given the outcomes achieved within the broad bounds of the trial inclusion criteria. The trial tolerated those with very complex mental health needs and challenging life circumstances and was not designed to include only those with the most straightforward presentation of PTSD. The trial engaged with individuals who had experienced PTSD for over 30 years, had multiple, complex mental health issues alongside their PTSD, were experiencing very tough times in their personal life, were treatment naive, and had tried multiple PTSD treatments. The range of participants within the trial genuinely reflected the reality of matters with which individuals cope in advance of and during therapy.

Results from the RESTORE trial do indeed represent real people with real mental health problems and complexities. As such, it is apparent that, for current and ex-serving Australian military members, MPE and SPE are effective evidence-based treatments.

Additional considerations

During the trial and in observing participant progress and outcomes, the project team determined several factors to consider when implementing MPE into the health service system. These factors are:

- clinician openness to learning and their confidence in implementing the treatment influences the therapeutic relationship with the client and the treatment outcomes
- MPE is a manualised therapy and, therefore, adherence to the protocol, including the specific requirements of each session, is highly important
- a variety of therapist qualifications are suitable, but access and attendance to regular supervision with a PE expert is key to ensuring therapists feel supported and confident.

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Appendix

Table A1. List of RESTORE therapists

Therapist	Organisation	Location
Alexandra Howard	Phoenix Australia	Melbourne
Alison Kaine	Defence	Canberra
Andres Leal	Open Arms	Adelaide
Annie Smith*	Open Arms	Cairns
Belinda Connolly	Open Arms	Sydney
Brodie Cooper	Open Arms	Rockingham
Charlotte Rubow	Open Arms	Brisbane
Charmaine Knox	Open Arms	Townsville
Cherie Blanchard	Open Arms	Perth
Chris Fountain	Private Practitioner	Perth
David Said	Defence	Sydney
Deidre Searcy	Defence	Adelaide
Douglas Brewer	Private Practitioner	Perth
Gesima Olney	Open Arms	Darwin
Giselle Larkins	Open Arms	Rockingham
Greg Gardner	Open Arms	Adelaide
Greg Iselin	Open Arms	Brisbane
Helen Rayner*	Open Arms	Brisbane
Jane Nursey	Phoenix Australia	Melbourne
Jessica Kennedy	Open Arms	Canberra
Jacqueline Costello*	Defence	Sydney
Julia Tockar	Private Practitioner	Sydney
Julie Mastrodomenico	Private Practitioner	Brisbane
Karla Milner*	Open Arms	Hobart
Kate Inglis	Private Practitioner	Canberra
Katelyn Kerr	Private Practitioner	Brisbane
Professor Kim Felmingham	Phoenix Australia	Melbourne
Dr Kristi Heffernan	Private Practitioner	Sydney
Lauretta Lewis	Open Arms	Brisbane
Lee Brient*	Open Arms	Devonport
Linda Hopkinson	Open Arms	Darwin
Loretta Poerio*	Open Arms	Canberra
Louise Cotton	Open Arms	Darwin
Louise Du Chesne	Open Arms	Melbourne
Mark Gribble	Open Arms	Canberra
Marlene Anderson	Private Practitioner	Townsville
Melissa McCormick	Open Arms	Townsville

Micah Bernoff	Open Arms	Brisbane
Michelle Gregory	Open Arms	Darwin
Dr Mike Barry	Private Practitioner	Canberra
Natalie Hanily	Defence	Brisbane
Dr Natalie Matthews	Defence	Adelaide
Nicole Sadler	Phoenix Australia	Canberra
Dr Paul Kemp	Private Practitioner	Adelaide
Piers Hardiman	Open Arms	Melbourne
Rosalind Fidge	Defence	Townsville
Sandro Positano	Open Arms	Adelaide
Sarah Hampton	Private Practitioner	Brisbane
Scott Bevis	Open Arms	Darwin
Shonagh Valentine	Open Arms	Townsville
Srishti Yadav	Private Practitioner	Sydney
Dr Stephen Rayner	Defence	Rockingham
Tom Locke	Open Arms	Perth
Dr Tony McHugh	Private Practitioner	Melbourne
Zoe Moore	Open Arms	Brisbane

* Therapists who received training but were not added to the randomisation lists.

Table A2. List of RESTORE assessors

Assessor	Location
Amanda Haselgrove	Adelaide
Jess McLellan	Townsville
Dr Kim Murray	Melbourne
Kirsteen Moss	Sydney
Lynette McKee	Darwin
Maya Manning	Perth
Nicole Prendergast	Brisbane
Dr Tarni Jennings	Brisbane

Note. All assessors were private practitioners except for the Melbourne assessor, who was from Phoenix Australia.

Table A3. List of RESTORE Chief Investigators (CIs)

CIs	Organisation	Role
Professor David Forbes	Phoenix Australia	Chief Investigator A
Professor Meaghan O'Donnell	Phoenix Australia	Chief Investigator B
Professor Richard Bryant	University of New South Wales	Chief Investigator C
Dr Stephanie Hodson	Open Arms	Chief Investigator D
David Morton	Defence	Chief Investigator E
Professor Malcolm Battersby	Flinders University	Chief Investigator F
Professor Andrew Forbes	Monash University	Chief Investigator G

Table A4. List of all RESTORE project team members (past and current)

RESTORE project team	Role
Dr Lisa Dell	Project Lead
Professor Peter Tuerk	Clinical oversight
Dr John Cooper	Psychiatric oversight (ex-serving members)
Dr Duncan Wallace	Psychiatric oversight (current-serving members)
Dr Alyssa Sbisa	Project manager (current)
Dr Julia Fredrickson	Project manager (past)
Dr Holly Knight	Project manager and intake officer (past)
Dr Tracey Varker	Project manager (past)
Dr Winnie Lau	Senior clinician and intake officer (current)
Amanda Pearce	Intake officer (current)
Dr Kim Murray	Intake officer (current)
Dr Kari Gibson	Intake officer (past)
Professor Mark Creamer	Intake officer (past)
Dr Richard Cash	Intake officer (past)
Anne-Laure Couineau	Intake officer (past)
Dr Andrea Putica	Intake officer (past)
Isabella Freijah	Research assistant (current)
Juhi Khatri	Scheduling assistant (past)
Caleb Stone	Scheduling assistant (past)
Dan Redman	IT support