PROTOCOL

Full Title: An external pilot randomised controlled trial to evaluate the performance of a research protocol to compare the Reconsolidation of Traumatic Memories (RTM) intervention with Trauma-Focussed CBT delivered by charities for the treatment of post-traumatic stress disorder (PTSD) in ex-military veterans.

Short title: **P**TSD **E**xperimental Treatment **T**rial (PETT study)

Trial Registry

King's College London Research Ethics approval reference HR-18/19-11320 Dated 19.04.2019

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ISRCTN 10314773 https://www.isrctn.com/

RESEARCH TEAM

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1.2 Sub-contractors and service providers to the trial

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II. Dr Kevin Dyer, Consultant Clinical Psychologist, Clinical Lead of the Psychological Therapies Service and Dr James Hobson, Northern Health and Social Care Trust. Kevin.Dyer@northerntrust.hscni.net & James.Hobson@northerntrust.hscni.net
III. Dr Frank Bourke, Research and Recognition Project, New York, USA. frank.bourke@randrproject.com.

The PETT study has been funded by the Forces in Mind Trust (FiMT), a £35 million funding scheme run by the FiMT using an endowment awarded by The National Lottery Community Fund.

1.3 Research Staff

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1.4 Trial Steering Group (TSG)

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2) Dr Ben Carter, Senior Lecturer in Biostatistics, KCTU Mental Health Statistics Group Lead, Department of Biostatistics and Health Informatics, Institute of Psychiatry, Psychology & Neuroscience, King's College London.

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4) Dr Deirdre McManus, Consultant Forensic Psychiatrist, Traumatic Stress Clinic and London and South East Veterans' Mental Health Service, Camden and Islington NHS Trust. HMP Wandsworth, South London and Maudsley NHS Trust and Senior Clinical Lecturer, Institute of Psychiatry, Psychology and Neuroscience, King's College London.

1.5 Data Monitoring and Ethics Committee (DMEC)

1) Dr Sara Tai, Senior Lecturer in Clinical Psychology & Consultant Clinical Psychologist, CeNTrUM (Centre for New Treatments and Understanding in Mental Health), Division of Psychology and Mental Health, University of Manchester.

2) Andy Simpson, Research Manager, Royal British Legion.

3) Dr Justin Havens, Psychological Therapist, EMDR Europe Accredited Consultant, Chair Near West EMDR Region, FdA BA BEng MSc PhD MBACP (accred)

4) Trevor Murrells, PETT statistician, KCTU.

1.6 Research sites

Inspire clinical central office in Belfast (BT1 1RD) and its regional treatment venues located across Northern Ireland.

1. LAY SUMMARY

Post-traumatic stress disorder (PTSD) is a mental health condition affecting an important minority of people exposed to traumatic life experiences such as life-threatening violence or sexual threat. The latest evidence shows up to 17% of UK ex-military service personnel who have recently deployed in combat roles may have PTSD. Undiagnosed or untreated, PTSD increases hospitalisation, unemployment, places a strain on family relationships and poverty.

We initially proposed to conduct a small trial in Northern Ireland to see the feasibility of providing 60 veterans diagnosed with PTSD with a novel treatment approach. However, due to recruitment difficulties which resulted from the Covid-19 pandemic, and with approval from Forces in Mind Trust (and ethical approval from King's College London and Queen's University Belfast), the project team began to recruit veterans from across the UK to the PETT study on 01.10.2020. If this trial is successful, then a future larger trial across the UK will compare the new treatment with **Trauma Focused Cognitive Behavioural Therapy (TF-CBT**) – A Gold Standard treatment with proven effectiveness.

The novel treatment is Reconsolidation of Traumatic Memories (RTM) – A therapy developed in the USA. RTM is based on Neurolinguistic Programming (NLP) which is an approach that aims to understand language patterns and intentionally change them to enable someone to think and/or feel differently about something that had previously distressed them. It is widely used by UK veteran charities even though the treatment is untested in relation to its effectiveness in addressing the symptoms of PTSD. Studies of RTM with US veterans report low dropout rates with most participants PTSD symptom free at six-week follow-up. Within these studies, the majority of veterans who did not respond to RTM had active substance abuse problems. RTM appears quick to administer and demonstrates positive results and is well tolerated. However, there is a lack of data showing whether it may have the potential to also cause harm, deter future help-seeking, or be more costly than other, well established, treatments for PTSD.

Our charity partner, Inspire, will provide these treatments to study participants. People taking part will be randomly allocated to either TF-CBT or RTM therapy. Inspire have considerable experience and expertise in delivering psychological therapies to veterans with PTSD who served in Northern Ireland. Inspire therapists will be trained to deliver both interventions and will be supervised by experts in these therapies.

Within 28 months, we will:

- Train Inspire's therapists in TF-CBT and RTM treatments;
- Recruit and allocate 60 participants randomly to either treatment;
- Calculate how many veterans remain in the trial/treatment and understand reasons for drop-out;
- Collect questionnaire data at 6, 12, 20 and 52 weeks post randomisation;
- Determine the acceptability of the treatments and the research trial for participants and any barriers to participation.

Beneficiaries include:

- **Inspire's therapists** – Upskilled through training in the two treatments;
- **Veterans and their families** – Potential reduction in PTSD symptoms and identification of veteran and PTSD profiles for whom this treatment appears to work best/not work so effectively.
- **Veterans, their families, Research Partners and wider mental health sector** – Knowing whether a larger trial of RTM is justified and, if so, how a larger trial might best be undertaken;

- **Research Partners -** Upskilled by research involvement. Increased visibility of services within the veteran community and beyond.

2. BACKGROUND

The original PETT study was to be conducted in partnership with recruitment and treatment delivery partner, Inspire, who are based in Northern Ireland (NI)). However, as a consequence of the Covid-19 pandemic that developed throughout 2020 we soon realised that due to a huge reduction in referrals to NI charity organizations and veteran support services of veterans with suspected PTSD, unless we broadened our recruitment strategy to the whole of the UK we would be unable to recruit sufficient numbers of participants within our timescales. The opportunity to expand beyond NI to help overcome participant referral and conversion rate challenges was discussed with and received approval from FiMT (and later, ethical approval from KCL and QUB) in September 2020. The PETT study has since begun recruiting veterans from across the UK (from 1st October 2020). We continue to recruit participants from NI and our analysis will be able to support our original methodological rationale as well as the additional data from the rest of the UK.

For background detail and in our original proposal, Post-Traumatic Stress Disorder (PTSD) presents a significant burden to the veteran community negatively impacting function, physical health and family relationships (1-3). In Northern Ireland (NI) this is complicated further because of *The Troubles* which means veterans who served in Northern Ireland live in the community alongside the former perceived enemy, ex-combatants and may well continue to fear for their security which may deter help-seeking(4). The PTSD prevalence in NI's general population is 5% in any previous 12 months. This is comparable with 4.4% in the UK for the past month (5-7). It has an estimated annual economic cost of £172M (5). Rates of PTSD in some UK veterans, particularly those whose last deployment was in a combat role, is around 17% (8). In NI, veteran PTSD prevalence data is not yet available but it is expected to be high because of the context of *The Troubles* (9, 10).

NI veterans with mental health issues experience barriers to accessing NHS psychological services including reluctance to both register with a GP, and if they do, a reluctance to disclose their veteran status (9, 10). Additionally there are high levels of social exclusion, low confidence in NHS services and stigma (11, 12). Recent reports concluded veterans should be able to self-refer, access services through charities and encounter health professionals who are themselves veterans (11). Charities report experiencing increased referrals every year (13). Many such UK charities are too small to work with and we sought a charity partner with appropriate levels of clinical, information and financial governance to support a robust research evaluation. This led us to Inspire in NI. In NI providing bespoke healthcare access for veterans is challenging due to the lack of dedicated veteran NHS services (14) and waiting list treatment targets of 52 weeks, compared to 18 weeks elsewhere in the UK (4). This is unfortunate as evidence suggests that over time, untreated PTSD symptoms are unlikely to resolve although the associated psychological distress and psychosocial deficit increases (1). Recommended treatments for PTSD are TF-CBT and Eye Movement Desensitisation and Reprocessing (EMDR) (15) which ordinarily involves between 8 and 20 therapy sessions (16). NICE, however, recommends EMDR for PTSD only where the trauma is NOT combat-related (17). Furthermore, a review by Kar et al (2011) (18) reported up to 50% non-response rates to TF-CBT and high attrition is reported (19) and response rates to these treatments in veterans can be marginal (20). A need for new and/or improved interventions, trauma and non-trauma focused, for PTSD in veterans has been identified (20, 21). Neurolinguistic programming (NLP) is a treatment of choice for many charities delivering mental health support (22-27) because it therapeutically avoids the trauma focus (28), is quick to deliver and is without statutory regulation. The experimental RTM Protocol intervention is an

intervention based on Neurolinguistic Programming (NLP). NLP is a psychotherapeutic approach that seeks to understand and change a person's thinking and behaviour and proposes that the way we understand our world depends on which of our senses, vision, hearing, taste or touch are more dominant (29). A person's dominant sense is communicated mainly by what we say and how our eyes move. For example, a visual person may say *'I see what you mean'* whereas a person with a dominant hearing sense will say *'I hear what you say'*. The central hypothesis of NLP is that communication will be more effective, persuasive and therapeutic if it is tailored to match the preferred senses of the target person. There are a number of charities delivering NLP therapy to military veterans (22-27) in the absence of evidence for its effects and impacts (29).

Devolved Governments, the NHS veteran service and key charities are concerned about use of NLP-based therapy with veterans (30). In four small US veteran studies, the NLP-based Reconsolidation of Traumatic Memories (RTM) protocol offered possible treatment advantages (28, 31-33). Therapy completion was 88%, symptoms abated in three sessions, considerably fewer than up to 12-18 for complex PTSD. It was acceptable to and well tolerated by veterans, practitioner training was rapid and manualised and third sector delivery offered wider access therefore, adding to the choice of the armoury of effective therapies. On the other hand, because the US studies were under-powered there are many unknowns and it remains possible that, in some instances, RTM may potentially elicit a deterioration in clinical symptoms, deter future help-seeking, or be complex and costly to deliver at scale. Additionally, there are no pilot or feasibility data which currently exists (28, 31-33) to distinguish the impacts of RTM in veterans with complex PTSD as proposed by the International Classification of Diseases 11th revision (34).

Academic psychology has criticised NLP-based interventions for lack of a theoretically driven framework and little robust evidence of efficacy derived from gold standard RCT trials (35, 36). Despite anecdote of positive NLP effects from real world practice with veterans (22-26), a systematic review and Freedom of Information request (29) found no robust gold standard evidence of efficacy alongside some modest NHS expenditure on poorly-defined NLP activity. This absence of evidence is not absence of effectiveness. We are unclear whether the RTM protocol is effective, above all else does no harm and is value for money. It is essential, therefore, for the international veteran community to understand whether this treatment intervention for PTSD holds the potential for healing (equivalent to existing evidence-based treatments) that it promises by working towards a scientifically rigorous approach to its evaluation.

The current study has been designed to maximise the availability of both TF-CBT and RTM therapies to those most in need of treatment. The additional training that will be provided to Inspire therapists will increase the pool of therapists with the pre-requisite knowledge and skills to deliver TF-CBT in multiple and remote Inspire treatment centres outside of Belfast. Whether RTM eventually proves to be an effective treatment for PTSD or not, our study will leave a legacy of improved mental health trauma service provision across NI.

3. METHODS AND STUDY DESIGN

3.1 Aims and Objectives

To undertake a pilot RCT as a precursor to a fully-powered non-inferiority RCT. The pilot will determine rates of participant recruitment, randomisation, treatment and research attrition and completeness of outcome data prior to establishing whether a fully-powered non-inferiority RCT is feasible.

The external pilot RCT will:
1: Determine the rate of trial recruitment, retention in treatment and research, understand reason for drop out and determine completeness of outcome data assessed against progression criteria to determine if a fully powered trial is deliverable;
2: Undertake exploratory analyses of the outcome data to support a power calculation for a fully powered non-inferiority trial;
3: Understand the safety risks;
4: Establish an expanded mental healthcare capacity across Northern Ireland to enable both interventions to be delivered close to the veteran's home.

3.2 Research questions

a. Can Inspire therapists deliver both interventions according to their respective protocols?
b. Will statutory and charity sectors refer to an experimental NLP-based therapy and by which referral pathway?
c. What is the rate of presentation of veterans with diagnosed PTSD, comorbidity and Complex PTSD to Inspire in Northern Ireland (NI)?
d. What is the level of complete and missing data and on which outcomes?
e. Are the progression criteria met, specified as recruitment of 60 participants in 14 months; in each arm ≥70% of participants complete treatment; retention of ≥36 participants at 20 week follow-up?
f. How does the safety protocol (see appendix 1) detect and limit the consequences of adverse events and what are the clinical governance implications of this?
g. What is the per-participant cost of delivering RTM (including managing any adverse or serious adverse events)?

3.3 Stakeholder involvement

Two veteran charities have been involved in the development of the research questions and methods to support participant recruitment and retention. Charity members reported that NLP therapy is perceived as effective in the ex-service community, and consequently they thought our recruitment targets were realistic. The stakeholder group are advisers from the target population who have some experience of PTSD and who are currently well. They are not research participants but are patient and public involvement advisors. We will follow Involve guidelines on working with these stakeholders in relation to reimbursement for their time and expenses to participate.

We propose two stakeholder activities, a major one involving veterans and family members and a second involving veteran charities.

3.3.1 Veteran and family member stakeholders

Chérie Armour, Professor of Psychological Trauma & Mental Health, and her team will lead the engagement (PPI) with NI veteran communities. An Involvement team of 10 individuals who have experienced and recovered from PTSD and a significant other will be recruited via (Ret) Major Peter Baillie, Director of the UDR and Royal Irish Armed Forces After Care Service, Northern Ireland. This service has wide reach and we will recruit members from throughout the UK. Members will be offered £50 expenses for each of six involvement meetings. They will develop lay language surrounding the

NLP/RTM intervention, design study information methods to optimise transparency and reach, support project management challenges, review findings and support dissemination. See appendix 2 for full details.

We have designed stakeholder involvement with diversity and inclusion at the forefront of our planning. This funded involvement team will support the development of a web site, hosted by Inspire, which will use videos and written text to communicate study information consistently and transparently to the UK veteran community. It will take account of literacy, health literacy and mental health stigma issues that may challenge the target population. It will be veteran population-facing to encourage these communities to engage with it and to offer the widest possible reach and access to the research opportunity. The involvement of the UDR and Royal Irish Armed Forces After Care Service field teams in the involvement group will facilitate a great deal of person to person information flow through the regional communities with the project website as a backstop for ensuring core information is communicated consistently to potential participants and their families.

3.3.2 Charity sector stakeholders

We will establish a stakeholder group of four UK-based charity representatives to engage with electronically and in-person throughout the research to ensure the views of the veteran charity sector are represented. The two charities who initially approached us with interest in taking part in research, *Veterans at Ease* and *Healing the Wounds* will be invited to participate. A further charity has since approached us *Rock2Recovery*, and they will also be invited to participate. The fourth charity to be invited will be a major charity stakeholder in the UK such as *Combat Stress*. We are particularly interested in listening to the perspectives of smaller charities because they are the ones most often delivering unregulated NLP interventions that present both interest and a concern to the team. This group will meet by telephone conference on four occasions during the study. Meeting one will be to introduce them to the study and address any arising questions. It will close with an agreement of the focus of the three further meetings in relation to what issues the research team are experiencing that we may wish for their perspective on and the stakeholder interests in the ongoing study.

3.4 Ethical considerations

We propose the experimental evaluation of a novel psychological therapy in a vulnerable population and in the context of patient safety concerns from the community serving the target population. The ethical issues are therefore manifold and substantially centred around patient safety. Other ethical risks are whether full trial funding will be obtainable in the event of feasibility being demonstrated and patient safety risks determined to be acceptable, leaving a potentially effective therapy untested at scale. We have given careful consideration and consulted widely to establish these robust safety procedures to minimise any potential harm to participants.

To address the future funding issue, we have developed a careful project plan to maximise the likelihood of subsequent funding. Our exact choice of funder will be informed by upcoming deadlines and available themed calls in 2021. We outline two possibilities below. Upon successfully delivering on our external pilot study objectives we can apply to the HTA to undertake a phase III pragmatic trial as proposed above. The HTA have confirmed that this will be within their funding remit. Another option is to apply for an NIHR Programme Grant for Applied Research (PGfAR), a funding panel on which PI Sturt sits and is therefore well placed to develop a competitive application. We are the only UK (and possibly international) team able to undertake a programme of research to robustly

investigate the potential benefits and harms of NLP informed mental health interventions. A PGfAR could propose the phase III trial and several of the following work packages:

1) A Phase III trial as proposed above;
2) Determine the mechanisms and moderators by which RTM exerts its effect;
3) Undertake an MRI study to detect hypothesised neurological changes during the RTM treatment;
4) Update the PI's 2012 systematic review on the effect and impact evidence for NLP interventions;
5) Undertake a feasibility study of an NLP intervention identified in the systematic review update that shows greatest clinical potential;
6) Complete qualitative research to understand NLP delivery training needs, patient safety issues and NHS commissioning pathways for the delivery of the RTM protocol and other NLP-based interventions within the NHS and the third sector.

3.5 Participants and Setting

The study takes place in the United Kingdom where collaborator Inspire (formerly The Northern Ireland Association for Mental Health) deliver PTSD treatment (37). Eligible participants will be ex-military veterans presenting for treatment with a suspected diagnosis of PTSD or presenting for a second or subsequent time to services with a previously confirmed diagnosis of PTSD and where the participant has not responded to treatment. Eligibility will be determined during condition assessment and diagnosis by a consultant clinical psychologist in Inspire's clinical centre in Belfast who is fully qualified to confirm PTSD or complex PTSD diagnosis accordance to the DSM-5 using the Clinician Administered PTSD Scale (CAPS-5) and the ICD-TQ. The assessment will diagnose or confirm diagnosis. The first eligible 60 veterans who agree to participation and randomisation will be recruited into the study. From consent to final follow up, participants will remain in the research trial for 52 weeks.

The diagnostic interviews will be undertaken by a trained consultant clinical psychologist at Inspire for this study. The diagnostic interviews are not routinely conducted by the charity Inspire but they do conduct a comprehensive, psychological clinical assessment supplemented by validated self-report screening questionnaires which includes: the Post-traumatic Stress Disorder Checklist for DSM-5 (PCL-5), the Patient Health Questionnaire (PHQ–9), the Generalised Anxiety Disorder (GAD–7), Comprehensive Outcome and Routine Evaluation-Outcome Measure (CORE-OM), a Therapy Assessment form (TA) and an End of Therapy Form (EoT). Therefore, we have taken the approach to have all PTSD or complex PTSD diagnosis (acute and/or chronic) to be confirmed by a qualified consultant clinical psychologist at Inspire in NI. We will not ask participants to complete duplicate scales at our baseline data collection if they have already been collected at the assessment stage.

3.5.1 Inclusion criteria:

1) Adults ≥18 yrs. Women make up 10% of the UK Armed Forces and fewer than this experience combat-related roles. Therefore the majority of participants with a need for PTSD treatment will be males. However, the feasibility nature of this pilot requires that we understand whether the treatments and the research appeal to eligible female military veterans. We will therefore aim to recruit women to make up 10% of our sample.

2) UK military veterans from the Army, Royal Air Force of Royal Navy.

3) PTSD (acute or chronic) diagnosis determined by DSM-5 (38) using the Clinician Administered PTSD scale (CAPS-5) (39) during clinical assessment with an Inspire employed clinical psychologist.

4) Experiencing symptoms causing clinically significant distress or impact on social, occupational or other areas of functioning.

5) A history of exposure to one or more traumas.

6) Living or working in the UK.

7) Willingness to be randomised to either treatment.

3.5.2 Exclusion criteria:

1) Serving personnel.

2) Currently receiving psychological treatment for PTSD.

3) Currently has a comorbid DSM-5 mental health or personality disorder sufficiently severe as to intrude upon the participant's ability to cooperate with treatment.

4) Current dependence on alcohol as determined by an AUDIT 10 cut off of ≥20 (41) or self-report of prescription or illegal substances dependence.

5) Participants who had a suicide attempt within the past month at time of recruitment.

6) Not able to provide informed consent.

7) Self-reported medication changes in the previous four weeks.

8) Unwilling to consent to audio-recording of all therapy sessions as a minimum requirement.

9) Any other documented reason in which the assessing Clinical Psychologists determine that treatment for other mental health symptoms takes precedent over their PTSD at the time of assessment.

3.6 Sample Size

The proposed external pilot sample size takes into account published recommendations for pilot trials (42, 43) which propose a method for determining an external pilot RCT sample size in order to minimise the sample size for the main RCT. This sample size will support the calculation of confidence intervals around the proportion of eligible participants who agree to take part in the research, and the attrition rates from both the treatments and the research. Our proposed sample size is 60, 30 in each arm. Initially, we had a 1:1 randomisation ratio. However, with 50% of our target randomisation figures achieved due to therapist attrition in the TF-CBT delivery arm we sought statistical advice and decided to change the randomisation ratio to 2:1 in favour of the experimental RTM. This would allow us to continue to recruit at the level required to fulfil our recruitment targets specified by our funder.

Treatment seeking in the veteran population is low (44, 45) and response rates to PTSD research invitations are poorly reported (46, 47) . For example, Ulmer et al (2011) (48) screened 91 veterans with PTSD to recruit 22 participants to their pilot RCT. In a review of 7 randomised trials comparing TF-CBT with Eye Movement Desensitisation and Reprocessing, research and treatment attrition ranged from 8 – 58% with a mean of 29% (49). Taking these data into account, we propose to screen 180 people for eligibility, randomise 60 participants and expect an attrition of 30% and 50% (or lower) from the intervention and comparison respectively resulting in ≥ 36 participants with data at 20 weeks follow up. A screening sample of 180 would be sufficient to obtain a 95% confidence interval for a

proportion of ±8% or narrower, and a sample of 60 for a 95% confidence interval of ±13% or narrower, both with 99.9% probability calculated using SAS POWER (50)

3.7 Participant Recruitment

Potential participants will become aware of the study A) through Inspire's veteran mental health contracting organisations, a significant example being the RI & UDR Aftercare Service (ACS) and/or B) though our study public engagement work involving our traditional and online media announcements and those of veteran support organisations. Any eligible or ineligible person self-referring from a veteran support organisation will be encouraged, but not required, to inform that organisation of their engagement with the PETT team.

Pathway A: Described with reference to the Aftercare Service (ACS):

1. ACS caseworkers will inform clients with expressed mental health needs about the PETT study by sharing the PETT study invitation letter, a flyer containing a link to the information video, the PIS, the PCL-5 assessment form, a personal data processing consent form and a SAE. Interested potentially eligible participants return the completed forms to the research team via email or in the SAE. Due to Covid-19, ACS caseworkers are no longer conducting their assessments face-to-face so during this period and until face-to-face consultations are resumed they will now inform clients with expressed mental health needs about the PETT study during their phone consultations. They will share details about the study and signpost the potential participants to the study website for further information and provide contact details for the research team. In these circumstances, once a potential participant contacts the research team, a researcher will send them the flyer containing a link to the study information video, the participant information sheet, the PCL-5 assessment form and a personal data processing consent form via email. They will be invited to ask questions on the telephone or via email and if they wish to continue they will return the completed PCL-5 form and personal data processing consent form. They will also be given the opportunity to complete the PCL-5 and data processing consent form via a Qualtrics online link which can be sent to their mobile phone or email address.

2. On receipt the researcher will score the PCL-5. If the person scores $\geq$33, they will be given the opportunity to ask questions in person, electronically or over the phone. If they wish to proceed the researcher will undertake informed consent in person, electronically or over the phone. Consent will be recorded in writing by wet ink, electronically or audio recorded.

3. If the person declines to participate or if their PCL-5 score is $\leq$32 and therefore screened ineligible to take part, the researcher will inform them of this and ask permission to inform ACS so their caseworker can proceed with appropriate referrals. Alternatively, the person will be invited to inform their caseworker directly. All personal data on these people will be shredded/electronically deleted.

4. Each participant will then self-complete baseline data collection with researcher support as needed in person, electronically or over the phone.

5. An appointment will be made for them with the Inspire Clinical Psychologist within two weeks to have a confirmatory PTSD diagnostic interview.

6. Once eligibility is confirmed they will be computer randomised to a therapy group and commence therapy within two weeks.

7. Those not eligible will be referred back to ACS by Inspire.

Pathway B) For all other recruitment routes

1. All public engagement, traditional and online social media announcements relating to the PETT study will contain the information video link and email address pett@kcl.ac.uk.

2. Once a potential participant contacts the team they will be contacted by a named researcher who will offer the PETT study invitation letter, a copy of the PCL-5, a personal data processing consent form and the participant information sheet. They will be given the opportunity to ask questions and can complete the PCL-5 in person, over the phone or electronically. They will be made aware that if they experience distress in relation to completing the PCL 5, they can contact the researcher who can signpost them to support. Support organisations are also listed on the study invitation letter and in study emails.

3. If the person declines to participate or if their PCL-5 score is ≤ 32 they will be signposted to organisations, including Inspire and their GP, who they may wish to contact about further mental health assessment and treatment. In addition, if we know that they are currently being seen by a veteran charity organisation the person will be invited to inform the organisation or their caseworker directly. All personal data on these people will be shredded/electronically deleted.

4. If the person's PCL-5 score is ≥ 33 the researcher will proceed to undertake informed consent in person, electronically or over the phone. Consent will be recorded in writing by wet ink, electronically or audio recorded.

5. The participant will then self-complete baseline data collection with the researcher support if needed in person, electronically or over the phone.

6. Following informed consent and baseline data collection an appointment will be made for them with the Inspire Clinical Psychologist within two weeks to have a confirmatory PTSD diagnostic interview.

7. Once eligibility is confirmed they will be computer randomised to a therapy group and commence therapy within two weeks.

8. For those ineligible the Clinical Psychologist will discuss, and signpost to other therapeutic options. If the participant is been seen by a veteran charity organisation they will be invited to inform the organisation or their charity caseworker directly.

Inspire receive on average 10-15 referrals per month from ACS meeting our eligibility criteria. Screening, on average, 13 veterans every month for 14 months equals 182 potentially eligible participants. We realistically estimate that 4-5 of these 13 potentially eligible veterans will consent to join the study, therefore we will be able to recruit and randomise 60 participants in 15 months.

We will offer a £15 high street voucher as a *thank you* to all participants who complete each of the 6, 12, 20 and 52 week questionnaire booklets. The maximum voucher value will be £60 per participant.

The veteran community is well-networked, and messaging about the trial aims and procedures must be well thought out and transparent to limit misinformation affecting recruitment and consent to randomisation (see appendix 2 for Stakeholder engagement protocol).

3.8 Informed consent

The study informed consent process will begin during the recruitment process**.** The stakeholder involvement group will work closely with the UDR and Royal Irish Armed Forces After Care Service to develop project materials. These materials and the website will use lay language surrounding the two therapies and the study information to optimise transparency and reach to potential participants. The participation of the Aftercare service field teams in disseminating project information and signposting veterans and family members to the project website will result in many potential participants being well informed at the point of presenting for their informed consent meeting with the researcher. Following completion of PCL-5 assessment and signed informed consent, baseline data will be collected and PTSD eligibility confirmed after which they will be randomised.

3.9 Confidentiality and anonymity

Each participant's personal details will be linked to their study identifier in an excel spreadsheet that five members of the research team will have access to, (JS, CA, RR, JB and an Inspire named individual). Responsibility for managing this database will be held with the KCL researcher and the database will be held on a secure KCL server. All data collection and recording will be GDPR compliant and conform with Inspire's standardised risk assessment, escalation, management and safeguarding policies and procedures. We are aware of the particularly sensitive nature of mental health and military veteran status in this population.

Video-recordings of each therapy session, or at a minimum audio recording, will be undertaken to determine therapist competence, and consequently participant safety. If the therapy is taking place online, the therapist and participant will decide which video conferencing interface to use and with the participant's permission we will record the session using the online recording facilities within each interface. This is in adherence with Inspire's current governance regime. Once the session is completed the recording will be encrypted, password protected and saved to a secure computer folder. If the therapy is being delivered face-to-face we will use a video camera and stand with an SD card. The video is uploaded via the SD card onto to a secure and encrypted memory stick. Both the online and face-to-face recordings will be shared in person or via video-meeting via Zoom with their research clinical supervisor/s and up to four therapy peers during fortnightly group and individual clinical supervisions. Zoom is a web and video conferencing platform that is suitable for use in healthcare and is compliant with EU's GDPR and US's Health Insurance Portability and Accountability (HIPAA) [https://zoom.us/privacy]. The video-recording will not leave the therapist's possession and will not be shared digitally. The online recording or the SD card will be wiped clean following each clinical supervision. Participants will be able to specifically opt out of this on the consent form and consent to audio as an alternative. It is not safe to expose participants to experimental psychological interventions without objective evidence of what has been delivered. Our procedures have been developed to balance participant safety with confidentiality and anonymity.

3.10 Randomisation

King's College London Clinical Trials Unit (KCTU) will provide a computer randomisation service. Stratification will be undertaken on diagnosis of complex or simple PTSD to inform a full trial. Stratification will also occur on gender to ensure the sample of six female participants are allocated in equal number to each intervention group. Randomisation will occur once participants have completed the informed consent process, a diagnosis of PTSD has been confirmed, and baseline data collection is completed. Once baseline data collection is complete and recorded on the PETT trial database, an authorised individual will complete the online registration form and computer randomisation to

therapy A or B will be generated. All participants will be randomised within 30 days of the date of their first baseline outcome measurement. Therapy allocation will be communicated to the participant by Inspire and arrangements will be made for them to commence therapy within two weeks.

3.11 Interventions

3.11.1 Therapy A: Experimental Group – RTM Protocol

The experimental intervention is the Reconsolidation of Traumatic Memories protocol (RTM), an NLP based, non-traumatising intervention (28, 31-33) delivered in up to 5 x 90 -120 mins weekly sessions by a single trained therapist. The RTM Protocol is a brief cognitive intervention with minimal and non-traumatizing exposure to the original stimulus. The RTM protocol effectively rewrites the emotional elements of the memory by taking advantage of the phenomenon of reconsolidation (51, 52). The procedure is manualized and fully described by Gray & Liotta (2012)(53). Reconsolidation describes the reactivation of long term, otherwise permanent memories, by their evocation in certain contexts. When a memory is reactivated, it labilises, that is, it becomes subject to change. If the circumstances surrounding the memory remain the same, the memory remains unchanged; it is maintained in its current state. If circumstances have intensified, the impact of the memory may become worse; re-traumatization can add to the intensity of trauma memories. If the new circumstance provides evidence that a threat of negative emotional stimulus is no longer relevant, the strength of the affective charge may decrease.

The intervention proceeds as follows:

1. Evoke the trauma, with or without description (most NLP interventions can be completed content free).
2. Interrupt the re-emergence of the trauma as soon as the client begins to show physiological signs of its onset. Changes in breathing, skin colour, posture, pupil dilation and eye fixation are typical signs of memory access. As they appear, the state is to be broken by reorienting the client to the present, by changing the subject, redirecting their attention into a different sensory system, or firing off a pre-existing anchor. However it is accomplished, it is important to stop the development of the symptoms before they take control of the client's consciousness.
3. After a few minutes away from the trauma, ask the client to think of a time before the trauma when they were doing something pleasant in a safe, neutral context.
4. Instruct the client to imagine that they are sitting in a movie theatre and that they are watching that scene on the screen.
5. Have the client imagine that they can float out of that body (in the theatre) and into the projection booth, perhaps behind a thick window, where they can watch themselves, seated in the theatre, watching the safe, neutral picture.
6. Ask the client to imagine that the movie on the screen, watched by their dissociated body seated in the theatre, becomes a black and white movie of the trauma that runs from the safe place before the trauma to a safe place after the trauma.
7. From the perspective of the safe projection booth, have the client focus on the responses of the dissociated watcher in the theatre as THEY watch the movie.
8. Repeat the black and white movie process until the client can do it with no discomfort.
9. After completing the dissociated movies, have the client imagine floating down from the projection booth and stepping into their own body that is seated in the theatre. Having re-associated into that body, let them imagine getting out of the seat, walking to the movie

screen and stepping into the black and white image of the safe, neutral activity with which they ended the black and white rehearsal.

10. As the client steps into the movie screen, have them turn on the sound, colour, motion, smells and tastes of the safe neutral representation on the screen. Then, instruct them to experience a movie of the trauma in full sensory detail, BACKWARDS and very quickly (2 to 3 seconds). Let them end the movie with a still colour picture of themselves in the safe, neutral place from before the problem ever started.
11. Repeat the reversed representation enough times so that it is done easily and quickly, and the client has a sense of being comfortable. When the client can repeat the process easily with no experience of discomfort the process is finished.
12. Attempt to reactivate the trauma. Ask the client to go back to it, to think of things that normally brought the problem to life. Test for the trauma in as many ways as can be found.
13. If the client still has an experience of distress repeat the reversed movie several more times.
14. When the trauma cannot be evoked, the procedure is over.
15. A third level of new information may be introduced by having the client imagine that he or she is going through the trauma but something has changed so that the event is non-traumatizing. It may be a movie in which the subject is stunt player and all of the characters players, it might involve a new choice or train of events so that the subject was not traumatized. Three or four of these alternate scenarios may be worked through.
16. Attempt to reactivate the trauma. Ask the client to go back to it, to think of things that normally brought the problem to life. Test for the trauma in as many ways as can be found.
17. If the client still has an experience of distress repeat the reversed movie and alternate scenarios several more times.
18. When the trauma cannot be evoked, the procedure is over.

3.11.2 Therapy B: Comparison Group – TF-CBT

Trauma-Focused Cognitive Behaviour Therapy delivered over up to 18 x 60-90 minute weekly sessions delivered by a single TF-CBT trained therapist (15). TF-CBT is the gold standard for treating PTSD and is currently the first line of treatment recommended by NICE for PTSD (15). Research evaluating TF-CBT in adults with PTSD has established an empirical base supporting the efficacy of the intervention(19, 54, 55). A substantial number of RCTs in England and Northern Ireland have established the efficacy of TF-CBT in PTSD(56-59). These RCTs have shown very large effect sizes in treating PTSD symptoms and associated symptoms of depression and anxiety. TF-CBT for PTSD is a face-to-face therapy of up to 12 x 60 to 90-minute sessions that involves identifying the relevant appraisals, memory characteristics and triggers, and behavioural and cognitive strategies that maintain PTSD symptoms.

The cognitive model of PTSD developed by Ehlers and Clark (2000) (60) will be the model used in this study as it displays the largest treatment effect sizes and significant symptom improvements (56, 57, 61) suggesting why it is widely carried out and recommended in IAPT services (62, 63). This cognitive theory of PTSD addresses these symptoms by:

(A) modifying excessively negative appraisals of the trauma and/or its sequelae in maintaining the symptomatology of PTSD,

(B) reducing re-experiencing by elaboration of the trauma memories and discrimination of triggers in the development of PTSD, and

(C) dropping dysfunctional behaviours and cognitive strategies, particularly those related to avoidance of triggers for intrusive symptoms.

These are strategies that have the immediate aim of reducing one's sense of current threat but have the long-term effect of maintaining the disorder and are common in PTSD.

TF-CBT in this study will be delivered in up to 18 x 60 to 90-minute sessions each as recommended by NICE. The course and delivery of TF-CBT in this study for veterans with simple PTSD proceeds as follows (for complex PTSD, the same delivery may take up to 18 sessions):

Session 1:	• Treatment goals • Normalisation of PTSD symptoms • Identification of main intrusive memories • Initial identification of maintaining factors (appraisals, cognitive strategies such as thought suppression, rumination, hypervigilance, safety behaviours) and initial shared case formulation (to be revised throughout treatment) • Thought suppression experiment and instruction "letting memories come and go" • Rationale for trauma memory work
Session 2:	• Imaginal reliving or narrative writing to identify hot spots • Discussion of meaning of hot spots • Reclaiming your life: identification of areas to be reclaimed and initial steps
Session 3:	• If necessary, further imaginal reliving/narrative writing to identify hot spots • Identification of information that updates meaning of hot spots through: - identification of relevant information from other parts of the trauma or afterwards - cognitive restructuring (consideration of a wider range of evidence) Updating trauma memory with this information - bring hot spot to mind and hold in mind - use verbal reminders, imagery, incompatible sensations or actions to bring updating information simultaneously to mind
Session 4:	• Further discussion of meanings of hot spots, identification of updating information, and memory updating • Discrimination of triggers (then vs. now)
Session 5:	• Further discussion of meanings of hot spots, identification of updating information, and memory updating • Updated narrative • Discrimination of triggers (then vs. now)
Session 6:	• Work on maintaining behaviours, e.g. - Behavioural experiments: dropping safety behaviours and hypervigilance - Reduce rumination - Review of behaviours that interfere with sleep
Session 7:	• Site visit
Session 8:	• Further work on cognitive restructuring, updating memories (e.g. probe reliving), discrimination of triggers, and changing maintaining behaviours/cognitive strategies as needed

Session 9:	• Review progress in updating memories, discrimination of triggers, appraisals, and maintaining behaviours/cognitive strategies • Finalize updated narrative • Agree homework • Reclaiming your life assignments
Session 10:	• Reclaiming your life • Review progress in updating memories, discrimination of triggers, changing appraisals, and changing maintaining behaviours/cognitive strategies • Agree homework • Blue print
Session 11 & 12:	• Review of reclaiming your life assignments • Review progress in updating memories, discrimination of triggers, changing appraisals, and changing maintaining behaviours and agree further homework

Subject to the permission of participants, which will be checked at the start of each session, all intervention sessions in both therapy arms will be video recorded.

3.11.3 Therapists, their management and therapy training

Prior to training to deliver either intervention, Inspire employed psychological therapists will demonstrate the following:

a. Minimum of a Diploma in Counselling/Psychotherapy from the BABCP or the BACP or UKCP as a minimum.
a. Post-graduate CBT training meeting competency standards for accreditation with the BABCP.
b. Minimum of three years' post-qualifying supervised clinical practice with trauma clients.
c. Personal supervision records, reputable references, commitment to clinical supervision and on-going training.
d. Professional indemnity insurance.
e. Security cleared to Counter Terrorist Check level.

Psychological therapists delivering both interventions will continue to be managed by their employer, Inspire. In addition to the usual policies and practices of Inspire relating to clinical, information and financial governance, the therapists will receive project-specific professional development and support via their employer from EITHER table 1 or table 2.

Pre-trial assessment will be undertaken of candidate therapists by the RTM and the TF-CBT training leads. This will determine candidate therapist competency for undertaking the trial training. The training leads retain collaborative authority for selecting the trial therapists. This will reduce therapist variance across both arms. Therapists will complete a pre-training competency self-assessment (appendix 3) to include accreditations, qualifications and duration of experience in a therapeutic role. The trainers will together make assessments of the level of competency demonstrated on paper and allocate each therapist to 1 of 5 groups:

- Group A (level 1) consisted of newly accredited counsellors with limited experience of working with simple or complex PTSD, and a self-rating of competent across the majority of skills.
- Group B (level 1+) were counsellors who had been accredited for 5 years, including 5 years' experience of working with simple and complex PTSD. Self-rating spanned the competent and

proficient skills for generic counselling skills and novice or advanced beginner for CBT and NLP specific competencies.

- Group C (level 2) counsellors had minimum 8 years post accreditation experience and 9+ years' experience of working with simple and complex PTSD. Counsellors rated proficient in generic competencies and competent or proficient in CBT and NLP specific competencies.
- Group D (level 2+) counsellors had minimum 11 years post accreditation experience, a post graduate qualification and 10+ years' experience of working with simple and complex PTSD. Counsellors rated proficient in generic competencies.
- Group E (level 3) counsellors had minimum 10 years post accreditation experience, rated expert in generic and NLP/CBT competencies and had an additional professional registration to that of counselling or psychotherapy.

Individual therapists in group A will be randomly assigned to intervention group 1 or group 2 by the trial statistician. This process will be repeated for individual therapists in groups B to E to result in two balanced therapist groups with an equivalent level of core competencies, skills and experience. *Table 1*

Therapy A: RTM Protocol Training		**Hours per therapist**
1	Pre-course reading	4
2	Classroom teaching face to face by de Rijk	40
3	Successfully treat and undertake symptom assessments with 2 trauma patients with de Rijk observing therapy delivery live via skype and providing post therapy coaching	4
	Clinical Supervision	
4	Clinical supervision, using a mix of individual and group, 90-minute sessions via skype, will be provided to each therapist by Dr Lisa de Rijk. Approximately 20 sessions of clinical supervision per therapist will be undertaken depending upon how many participants in therapy simultaneously. A minimum of 2 supervision sessions will be individual. Online clinical supervision by video conferencing is feasible and effective compared to face to face supervision and is widely used (64-66).	20-30 hours (90 mins every 2 weeks for 25 weeks then monthly for the remaining intervention delivery period.)
5	**Expert observation and assessment by USA lead clinical psychologist (Total 8 hrs per therapist)**	
6	Observing 2 sections of RTM therapy sessions via video recording per therapist	3
7	Assess and coach RTM therapist during 4 x 1 hour skype sessions per therapist	4
8	Provide final written assessment per therapist on therapist competence and protocol fidelity	1

Table 2

Therapy B: TF-CBT Training		**Hours per therapist**
1	Classroom teaching face to face by an expert accredited in the Ehlers and Clark protocol (57) with experience in clinical care, education and research in testing the protocol. Therapists will learn, practice and have their competency assessed by the trainer.	24
2	**Expert observation and assessment by expert TF-CBT trainer who undertook training.**	
	Observing sections of video recorded TF-CBT therapy sessions by each therapist during clinical supervision to determine competence	3
3	**Clinical Supervision**	
	Clinical supervision, using a mix of individual and group, 90 minute sessions face to face or via skype, will be provided to each therapist by the TF-CBT trainer and/or their appropriate nominee. Approximately 20 sessions of clinical supervision per therapist will be undertaken depending upon how many participants in therapy simultaneously. A minimum of 2 supervision sessions will be individual. Online clinical supervision by video conferencing is feasible and effective compared to face to face supervision and is widely used (64-66).	20- 30 hours (90 mins every 2 weeks for 25 weeks then monthly for the remaining intervention delivery period.)

Inspire therapists routinely undertake mandatory monthly external clinical supervision and attend quarterly caseload management meetings to ensure treatment protocol adherence recommendations, monitor and review client progress and adhere to good governance. Bi-weekly meetings review contractual activity, new referrals, clinical issues and data recording/reporting. Communication is maintained through email, telephone and staff meetings.

3.11.4 Intervention fidelity

Both therapy A and B are protocolised and the respective protocols have been evaluated for fidelity across several studies (28, 31-33). Sections of two therapy session of the intervention received by each participant will be randomly selected for fidelity checking by therapists familiar with the intervention under consideration as specified in table 1 and 2. Videos, as opposed to audio-recording, are preferable because this is the only way we can calibrate the changes in the client, as described below:

In Therapy A the therapist teaches sensory acuity, i.e. being able to assess when a client is going into a sympathetic arousal state i.e. flight/fright or fight reaction. The RTM protocol is based on the principle that rapid dissociation from this state is key to enabling a reconsolidation of the memory. It is very difficult to calibrate this on voice alone, particularly as the arousal response may occur before the client gets to the point of speaking. Therapy A, being experimental, will be subjected to additional intervention fidelity processes aligned to clinical supervision. Table 1 rows 3 and 6-8 detail the approaches to therapy fidelity assessment. The lead psychologist from the USA team will assess the competence and protocol fidelity and this will be conducted via Zoom video conferencing which is a secure network. In addition, therapists will undertake approximately 20 hours of clinical supervision to strengthen their competency.

In Therapy B, video recording of therapy sessions is standard practice in all CBT training programmes and clinical trials because the inter-action between therapist and patient involves important non-verbal elements that cannot be reliably accessed via audio tape. For example, in trauma focussed

imaginal reliving sessions, the therapist must demonstrate ability to locate hot spots in the trauma memory that may be indicated by facial expression or body movements such as changes in posture or physical arousal. The competent use of imaginal re-living is a core element of the TF-CBT protocol. Therapy B will have fidelity assessed during training practice and throughout clinical supervision by way of sections of video recorded therapy sessions. The Cognitive Therapy Rating Scale will be used to assess therapist competence through approximately 20 hours of clinical supervision This is normal practice in delivering Ehlers and Clark TF-CBT protocol (57).

If the therapy is taking place online we will record the session using the online recording facilities within each video-conferencing interface. Once the session is completed the recording will be encrypted, password protected and saved to a secure computer folder. If the therapy is being delivered face-to-face we will use a video camera and stand with an SD card. The video is uploaded via the SD card onto to a secure and encrypted memory stick which only the therapist has secure access to. The SD card will be wiped clean following each data transfer to encrypted memory stick.

3.12 Outcomes

3.12.1 Socio-demographic and medical history variables

To understand who participates and to inform recruitment procedures for the full trial we will collect information on age, gender, education, ethnicity, occupational and marital status, duration of military service. Related to their PTSD history we will collect data on PTSD symptoms, previous confirmed PTSD diagnoses, number of traumas and previous treatment attempts and current and previous three months' self-report pharmacotherapy

3.12.2 Feasibility, acceptability, cost and safety outcomes

To determine feasibility we will collect data on numbers of eligible potential participants who are referred or self-refer for the study, the number of people who consent to participate and be randomised to either treatment and the number of people who remain in treatment and when people drop out and the number of people who remain in the research irrespective of whether they remain in treatment. We will calculate the cost of treatment by quantifying the number and duration of therapy sessions and by which therapist. This data will be collected by Inspire throughout the study duration using their Penelope data management system. We will include the cost of any patient safety measures used during treatment and up to the 20 week follow up point.

3.12.3 Health and Social Care Outcomes

We will assess health and social outcome using seven validated self-report questionnaires commonly used in mental health population studies. Data will be collected at baseline and 6, 12, 20 weeks and 52 weeks post-randomisation to assess participant burden, data quality and quantity and derive initial estimates of efficacy and effect size.

3.12.3.1 *PTSD Symptoms*

Post-traumatic stress disorder checklist for DSM-5 (PCL-5) (39, 67, 68) will be the likely primary outcome in our subsequent fully powered trial to assess symptoms of PTSD. The PCL-5 is a 20-item self-report measure that assesses the 20 *DSM-5* symptoms of PTSD. The PCL-5 has a variety of purposes, including monitoring symptom change during and after treatment, screening individuals for PTSD and making a provisional/probable PTSD diagnosis. The PCL-5 is a self-report measure that can be completed by patients in a waiting room prior to a session or by participants as part of a research study. It takes approximately 5-10 minutes to complete. Total PTSD symptom severity score (range - 0-80) is obtained by summing the scores for each of the 20 items. Preliminary validation work indicates a PCL-5 cut-off score of 33.

Evidence for the PCL for *DSM-IV* suggests that a 5-10 point change represents reliable change (i.e. change not due to chance) and a 10-20 point change represents clinically significant change (39). It was recommended to use 5 points as a minimum threshold for determining whether an individual has responded to treatment and 10 points as a minimum threshold for determining whether the improvement is clinically meaningful using the PCL for *DSM-IV*. In validation studies, the PCL-5 scores exhibited high internal consistency and the instrument was found to be a psychometrically sound measure of DSM–5 PTSD symptoms (69). The PCL-5 will be collected at the beginning of every therapy session in both groups. This data will be used to consider symptoms at the point of treatment attrition where this occurs and also contribute to operationalising the participant safety protocol (appendix 1).

3.12.3.2. *Rehabilitation*

The Work and Social Adjustment Scale (WSAS) (70) is a 5 item scale to assess the impact of the person's mental health on work, home, social and private leisure activities and interpersonal relationships. It has a 9-point assessment scale ranging from *Not at all* to *Very severely.* With internal scale consistency ranging from 0.7 to 0.9 and test-retest of 0.7 it is a valid and reliable scale for assessing impaired functioning in mental ill health (70).

3.12.3.3 *Process of Recovery*

The Quality of Process of Recovery scale (QPR) is a 15 item measure assessing recovery from psychosis or mental health problems and was collaboratively developed with service users (71). Since personal recovery self-defined and self-directed is something experienced rather than assessed by an expert, this self-report measure was deemed appropriate for this study as it reflects the wider aims of recovery including quality of life and social relationships. The questionnaire measures subjective recovery in two domains: intrapersonal functioning (17 items) and interpersonal functioning (five items). Each item is rated on a 5-point Likert scale ranging from 0 (Disagree strongly) to 4 (Agree strongly) with higher scores indicative of recovery. Respondents may score between 0 and 88. The subscales have good internal consistency and test–retest reliability over short periods. Cronbach's alpha coefficients for the intrapersonal and interpersonal scales for this sample were $\alpha = 0.94$ and $\alpha = 0.66$, respectively.

3.12.3.4 *Emotional Distress*

The Patient Health Questionnaire (PHQ) is a 9-item self-administered diagnostic instrument for depression. It scores each of the 9 mood-related DSM-IV criteria as "0" (not at all) to "3" (nearly every day) (72). Scores represent: 0-5 = mild, 6-10 = moderate, 11-15 = moderately severe, and 16-20 = severe depression. It is widely used to assess mood in UK general practice and IAPT services.

The General Anxiety Disorder (GAD 7) is a 7-item scale to assess for anxiety. It is used in primary care and mental health settings as a screening tool and symptom severity measure for the four most common anxiety disorders (Generalized Anxiety Disorder, Panic Disorder, Social Phobia and Post Traumatic Stress Disorder). Scores of 5, 10, and 15 are taken as the cut off points for mild, moderate, and severe anxiety, respectively. When used as a screening tool, further evaluation is recommended when the **score** is 10 or greater (73).

3.12.3.5 *Health status*

EQ5D-5L (74) is a two-page questionnaire with page consisting of the EQ-5D descriptive system and page 2 the EQ visual analogue scale (EQ VAS). Page one comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has five levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The participant indicates their health state by ticking the box next to the most appropriate statement in each of the

five dimensions. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state. The EQ VAS records their self-rated health on a vertical visual analogue scale, where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'. The VAS can be used as a quantitative measure of health outcome that reflect the patient's own judgement. The EQ-5D-5L has been validated in a diverse patient population in six countries including eight patient groups with chronic conditions. The measurement properties of EQ-5D-5L were superior to its predecessor EQ-5D-3L in terms of feasibility, ceiling effects, discriminatory power and convergent validity.

3.12.3.6 *Health and social-services utilisation*

FolATED (75) is a 31 item administered questionnaire or structured asking about number of contacts with general practice, social services, mental health services and other agencies during the past specified period. It is hosted by DIRUM, an open-access database of resource-use questionnaires for use by health economists involved in trial-based economic evaluations. Funded by the Medical Research Council Network of Hubs for Trial Methodology Research, DIRUM offers a unique (and permanent) web address for each resource use measure for citation in papers and reports. DIRUM also provides a repository of methodological papers related to resource use and cost measurement (76).

3.12.4 Acceptability of both treatments

Qualitative interviews will be undertaken with 20–30 participants from both RTM and TF-CBT groups. The interviews aim to determine the acceptability and feasibility of participating in the trial and the treatment they received. We will aim to interview 2-3 participants who chose to withdraw from the treatment, 2-3 who chose to withdraw from the trial and the remainder from those who completed the treatment and who completed at least the 12-week follow up. Interviews will be undertaken in a venue of the participant's choosing that is safe for the participant and the researcher. This could be face-to-face, over the telephone or online. Participants are asked to give specific consent to be approached for an interview on the consent form. Interviews will be analysed using thematic content analysis.

3.13 Data Collection

Socio-demographic and medical history variables will be obtained from Inspire's clinical records following the completion of eligibility, informed consent procedures, baseline data collection and diagnostic confirmation assessment. Each participant's demographic and medical history data will be entered onto the study database hosted on the King's College London secure server. Data will be entered by a researcher or a trained Inspire administrator and a participant identification number will be generated.

Feasibility, acceptability, cost and safety outcomes will be collected by the QUB researcher by monitoring when and why participants drop out of either intervention or the research study. Costs of therapy data will be recorded by both TF-CBT and RTM therapists based on £75.00 per session for the number, duration and location of therapy sessions per participant and collated by the researcher. Therapy location data will be collected to incorporate therapist travel into the delivery costs. The independent clinical psychologist will inform the researcher when any participant makes contact, the frequency and duration of these contacts and the outcome.

Health and Social Care Outcomes will be collected via a series of validated questionnaires. Following completion of informed consent procedures and prior to randomisation, baseline data will be

collected from the participant with follow up taking place at 6, 12, 20 and 52 weeks post randomisation. Data collection will be undertaken either in person (aligned to a therapy appointment where they coincide), over the telephone (with paper copies having been sent via post in advance), or electronically (by secure web data collection software or email). The participant can choose their preferred method at each follow up point. Paper questionnaires, with participant identifiers, will be scanned and sent via encrypted email from Queen's University Belfast to the King's College London Trial Manager. Electronically completed surveys will be sent by encrypted email in the same way. Data will be entered into a project specific eCRF database supported by KCTU and hosted on the KCTU server. Follow up data will be acceptable if it is completed/collected 10 working days either side of the official follow-up date at 6, 12 and 20 weeks and within one calendar month at 52 week follow up. Data arriving outside of these time period will be classed as missing for the purpose of analysis.

3.14 Statistical Data Analysis

We will calculate rates of recruitment, willingness to participate, proportions of participants with PTSD and complex PTSD, intervention and research drop-out rates. Estimates of variability (standard deviation) of outcome assessments will be used to inform the sample size calculation for the future fully powered non-inferiority RCT. We expect to use a non-inferiority margin for PCL-C of five. A similar conservative margin was proposed by Foa *et al* (2018) (77) for PCL-5 based on Monson *et al* (2008)(78). Prior to making this calculation the main study outcome(s) will be examined to see whether they conform reasonably well to a normal distribution. If not a transformation of the data will be considered. SAS procedure POWER (50) will be used to calculate the sample size estimate for a comprehensive follow-on non-inferiority RCT (42). Exploratory analyses will enable the standard deviation of changes in pilot outcome assessments to be calculated using appropriate statistical methods (e.g. random effects regression models).

Because the change of randomisation ratio took place mid-way through the trial when 50% of the target number of randomisations had already occurred on a 1:1 ratio, the analysis of participant data before (1:1 ratio) and following (2:1 ratio) the allocation change will need be undertaken separately.

The study will use King's CTU standardised operating procedures as appropriate, as follows:

1. Data monitoring committee
2. Statistical analysis plan
3. Statistical documentation retention
4. Statistical QA
5. Sample size calculation
6. Protocol review and blinding
7. Statistical reports
8. Data manipulation following data extraction

We will follow the CONSORT guidance for pilot and feasibility trials and for intervention studies and the TIDieR checklist (79, 80).

3.15 Project Management and Investigator Expertise

Our research brings together a unique collaboration of academic, charity, NLP training and public involvement organisations who are expertly placed to safely deliver and evaluate the RTM therapy and the research protocol. Sturt, Greenberg, Grealish and Murrells (King's College London, King's Clinical Trials Unit) and Armour (Queen's University Belfast) will lead the research evaluation, with their combined expertise in veteran populations, mental health, behavioural sciences and clinical trials. Inspire (formerly The Northern Ireland Association for Mental Health) is our charity partner and

clinical provider. Inspire has robust clinical, financial and information governance policies and procedures in place to conduct this study. Armour (Queen's University Belfast) will deliver the public involvement activity, to ensure the views of veterans and their families are represented throughout the research design and delivery. The RTM protocol therapist training and quality assurance will be undertaken by international NLP expert, Lisa de Rijk of Awaken Consulting. The TF-CBT protocol therapist training and quality assurance will be undertaken by Josh Kreft, CBT/EMDR Therapist and Service Manager, Military Veterans' Service.

3.15.1 Study Management

The co-principal Investigators, Sturt and Greenberg, will assume overall responsibility for the research. The Study Group (SG) will hold fortnightly virtual meetings between the King's team and the QUB team. Sturt and Grealish support a 60% project manager/researcher at KCL. Armour supports a 60% researcher based at QUB respectively to formally recruit and undertake most of the data collection. These meetings will have standing agenda items relating to recruitment, data completion, intervention commencement and the detection and management of adverse events. Other team members will attend by request of the PI as required. Sturt has experience of developing and delivering complex interventions and working with others to undertake data collection in multiple and remote research sites around the country and internationally. The team has been assembled largely using good communication methods across considerable geographical distance and the detailed project management and governance arrangements are robust to monitor activity to time, budget and protocol and to be flexible and adaptable to necessary changes. All investigators have roles and responsibilities that will keep them in at least bi-weekly contact with the project leads and the researchers. We have costed in 20 individual flights and overnight stays for the London/England team to have a physical presence in Belfast, commencing in the early stages of the project when the collaborative relationships are consolidating.

The whole research team will form the Project Management Group (PMG), consisting of investigators, collaborators, two members of our public involvement group, and representatives of a four-member charity stakeholder group. The PMG will meet quarterly in months 0, 4, 8, 12, 16, 20, 24 and 28 over the 28-month study duration. We will offer virtual meeting arrangements to maximise attendance. We will establish a stakeholder group of 4 UK-based charity representatives to engage with electronically and in-person throughout the research to ensure the views of the veteran charity sector are represented.

3.15.2 Data Monitoring and Ethics Committee (DMEC)

We have established a TSG and DMEC which have agreed to meet jointly on four occasions during the trial. The DMEC will review the unblinded data with the study statistician with regard to participant safety. They will then report to the TSG with any recommendations to take forward.

3.15.3 Participant Safety and Risk Management

Participant safety will be a standing agenda item of each fortnightly King's-QUB meetings. We additionally propose to fund an independent, Northern Ireland based, trauma-experienced Clinical Psychologist for up to 50 hours in total for the 18 months of the RTM intervention delivery and follow-up period. This Independent Clinical Psychologist will provide an independent safety net for participants and their family if they become concerned about a participant's mental health. No such events have been identified in the five USA trials of RTM so we believe this time allocation will be sufficient for this purpose. This Clinical Psychologist will also have independent access to the DMEC chair.

3.15.4 Data management

A web based electronic data capture (EDC) system has been designed, using the InferMed Macro 4 system. The EDC will be created in collaboration with the trial analyst/s and the CI and maintained by the King's Clinical Trials Unit for the duration of the project. It will be hosted on a dedicated secure server within KCL.

The CI or delegate will request usernames and passwords from the KCTU. Database access will be strictly restricted through user-specific passwords to the authorised research team members. It is a legal requirement that passwords to the EDC are not shared, and that only those authorised to access the system are allowed to do so. If new staff members join the study, a user-specific username and password must be requested via the CI or delegate (e.g. Trial Manager) from the KCTU team and a request for access to be revoked must be requested when staff members leave the project. Study site staff experiencing issues with system access or functionality should contact the CI or delegate (e.g. Trial Manager) in the first instance.

No identifiable data beyond participant initials and age at consent will be entered on the EDC or transferred to the KCTU. No data will be entered onto the EDC system unless a participant has signed a consent form to participate in the trial. Source data will be entered by a researcher or Inspire nominated individual, typically within eight days of data collection by authorised staff onto the EDC by going to www.ctu.co.uk and clicking the link to access the MACRO 4 EDC system. A full audit trial of data entry and any subsequent changes to entered data will be automatically date and time stamped, alongside information about the user making the entry/changes within the system.

The CI team will undertake appropriate reviews of the entered data, in consultation with the project analyst, for the purpose of data cleaning and will request amendments as required.

At the end of the trial, the site PI will review all the data for each participant and provide electronic sign-off to verify that all the data are complete and correct. At this point, all data can be formally locked for analysis.

Upon request, KCTU will provide a copy of the final exported dataset to the CI in .csv format and the CI will onward distribute as appropriate.

4. PROJECT OUTPUTS

4.1 Impact

The major impact of this research will be the submission of a funding application for the full non-inferiority RCT. We will begin the development of this full application as soon as 50% of our target sample have completed the intervention and 12-week follow up. This will give us sufficient evidence to deploy our traffic light progression criteria towards a full trial funding application.

We consider that the best interests of people living with PTSD will be served if the fully powered RCT is designed to engage with the NHS. The NIHR South London Research Design Service has confirmed that our proposed phase III trial is within the funding remit of two NIHR research programmes: Health Technology Assessment (HTA), and Programme Grants for Applied Research (PGfAR). These programmes are currently participating in the **Promotion of good mental health and the prevention or treatment of mental ill health NIHR** themed call**.** These programmes focus on clinical intervention

delivery by NHS and non-NHS providers and therapists. We propose the following population (P), intervention (I), comparison (C) and outcome (O) plan for a phase III trial:

P - Military veterans and ex non-military uniformed services

I - RTM protocol

C - TF-CBT

O - PTSD symptoms assessed by the Post-traumatic stress disorder checklist for DSM-5 (PCL- 5) and functional capacity as assessed by the Work and Social Adjustment Scale (WSAS)

4.1.1 Fully powered trial progression criteria

See appendix 4.

4.2 Dissemination

The proposed study is an external pilot RCT and we expect one major peer-reviewed paper to be developed from this study for publication in an open access journal. Funding has been requested for this purpose. This paper will present the pilot evidence relating to the intervention delivery and the research protocol performance. The target journal for this will be the BMC Open Access journal *Pilot and Feasibility Studies*. A further paper may be developed to propose a logic model for the RTM protocol intervention for submission to *Journal of Traumatic Stress* (Impact Factor 2.72) or *Psychological Trauma: Theory, Research, Practice and Policy* (Impact factor 2.30). NHS veteran and mental health conferences will be targeted for conference presentation and the INVOLVE conference to discuss our project outcomes/outputs through an Involvement lens.

Appendix 1: Participant safeguarding protocol

Our experimental therapy, RTM protocol, has been delivered without serious adverse event in five USA studies involving over 120 veterans (28, 31-33, 53). Nonetheless, it is important to have a robust safety protocol for this vulnerable group of UK participants for its first exposure to a UK population. The following comprises our safety protocol for all participants in the trial, throughout the trial, and specifically for all participants randomised to the experimental RTM group. It addresses lines of responsibility and accountability, definitions relating to safety, escalation and safeguarding procedures in the event of notable clinical deterioration with or without an escalation in risk, alongside ensuring the safe and effective management of participants who are ineligible to enter the trial.

1.0 Lines of responsibility and accountability

1.1 From the point at which a potential participant is handed over to Inspire for eligibility assessment through to the point of discharge, Inspire have responsibility and clinical governance accountability for the participant's mental health and wellbeing and including their own safety and where relevant the safety of others and including the safeguarding of children and vulnerable adults.

1.2 From the point of discharge from Inspire therapy to the point of 52 week follow, up or withdrawal from the trial, the participant's GP holds responsibility and accountability for the participant's mental health and wellbeing and this includes their safety.

1.3 Participant safety will be a standing agenda item on every fortnightly King's- QUB research team meeting.

1.4 Data Monitoring and Ethics Committee (DMEC) will meet four times during the trial comprising three trauma experts, a veteran welfare expert and an independent statistician. The DMEC terms of reference will operate according to the King's Clinical Trials Unit Standard Operating Procedures. The research team will report any participant safety issues to the DMEC within 48 hrs of each fortnightly King's and Queen's meeting.

2.0 Definitions related of safety

2.1 Mental health safety - symptom severity, deterioration is assessed using the PCL-5 self-report screening questionnaire (39, 67, 68) completed by the participant at the beginning of every therapy session until discharge. Any existing or emergent safeguarding and or vulnerable adult concern will be assessed and monitored at each session with proportionate action taken in accordance with legislative reporting requirements.

2.2 Mental health safety is assessed using the PCL-5 self-report screening questionnaire completed by the participant at the following time points following discharge; 6 weeks post randomisation which is likely to be post discharge in the RTM group and during therapy in the TF-CBT group; 12 weeks post randomisation; 20 weeks post randomisation and 52 weeks post randomisation.

2.2.1 The named researcher will review all incoming follow up PCL-5 scores within 72 hrs of receipt.

2.3 PTSD Adverse Events are defined as a ≥10 point rise in the self-report PCL-5 since the previous therapy session or a 15 point rise from baseline or the maximum score of 80 being reached and/or relapse into alcohol and/or substance misuse at a hazardous level which integrated with the clinical judgement of the treating therapist will determine the action taken

2.4 PTSD Serious Adverse Events are defined as hospital admission for mental ill-health, self-harm, suicide and attempted or completed suicide.

3.0 Safety net procedures for between therapy and follow up time points

3.1 All participants will be offered a *Contact Card* at the point of randomisation. This will list the contact details of services to call 24/7 if they feel they need to talk with someone about their mental health outside of their therapy session and throughout their trial participation. Contact details will include Lifeline, Samaritans, their GP and where appropriate their Aftercare case worker and Inspire's 24/7 helpline.

3.1.1 For participants in therapy, the therapist will record participant self-reports of all contacts being made in the therapy safety log.

3.1.2 For participants in follow up, the researcher will note such self-reports in the data collected and ask the participant for details. Details, if provided, will be recorded in the researcher's participant safety log.

3.1.3 The unblinded researcher will review the therapy database weekly to determine if any activity has been logged in the previous 7 days.

3.2 The RTM therapy is experimental and, in contrast to TF-CBT, does not carry evidence of treatment effects and safety issues. Therefore an additional participant safety feature is provided for this group and their family members. An additional contact number for an Independent Clinical Psychologist (ICP) will be provided.

3.3 The ICP is funded for ½ an hour a week for any RTM participant or their family member to contact them by telephone with concerns for participant mental health safety and or vulnerable adult and or safeguarding concerns.

3.4 Where the ICP identifies a need to escalate their concern regarding either the mental health care or safeguarding and vulnerable adult of a participant and or their immediate family member they will take action themselves and encourage the participant to take action. These actions are specified as:

3.4.1 Advise the participant to make contact with their GP

3.4.2 Advise the participant to contact a family member

3.4.3 Where possible the ICP will speak with a family member to signpost them to the GP for escalation

3.4.4 The ICP will independently inform the participant's GP within 2 hours to alert them to the participant's need for mental health escalation and safeguarding.

3.4.5 If the participant is still in therapy they will inform and update the participant's Inspire therapist within a minimum of 24-hours and in advance of the next scheduled therapy session

3.4.5.1 The therapist will inform the named researcher

3.4.6 If the participant has completed or dropped out of therapy early (unplanned ending) with Inspire and are in follow-up they will inform the named researcher

3.4.7 They will keep a log of the incident, the clinical concerns noted and the actions taken.

3.4.8 The ICP will have weekly email contact with the named researcher to report any safety logs and or safeguarding concerns in the previous 7 days.

3.5 The ICP will have independent access to the Data Monitoring and Ethics Chair (DMEC) chair to whom they will report any serious adverse events.

4.0 Care escalation procedures in the case of adverse event

4.1 If at point of referral or during the course of treatment, Inspire therapists become concerned about the welfare of any participant or immediate family member they will escalate their concerns through Inspire's standardised risk assessment, escalation, management and safeguarding policies and procedures. Where necessary they will contact the participant's GP to mobilise referral to crisis response, NHS primary or secondary care. Likewise, if a safeguarding and vulnerable adults concern is identified this will be escalated, acted on and reported to the relevant statutory body – safeguarding team.

4.1.1 The PCL- 5 along with Core-10 will be completed at each therapy session. If ≥10 point rise in PCL-5 score occurs since the previous therapy session, or 15 point rise from baseline, or the maximum score of 80 is recorded on the PCL-5 alongside an escalation in risk "flagged" using CORE-10, they will use their clinical judgement to assess whether escalation is appropriate.

4.1.2 Any ≥10 point rise in PCL-5 score that occurs since the previous therapy session, or 15 point rise from baseline, or the maximum score of 80 is recorded on the PCL-5, will be detected by the unblinded member of the research team who will inform the DMEC chair within 3 working days.

4.2 If a participant's PCL-5 score rises by ≥10 points from the previous follow up, or 15 point rise from baseline, or the maximum score of 80 is recorded on the PCL5, the unblinded researcher will make contact with the participant within six hours of noting the rise in score and encourage them to contact their GP and/or their case worker. They will advise the participant that the researcher will need to contact the participant's case worker (or GP if no case worker) to alert them to the rise in PTSD symptoms.

5.0 Care escalation procedures in the case of serious adverse event

5.1 A serious Adverse Event that occurs during therapy will be investigated by Inspire according to their standardised clinical protocols and clinical governance framework

5.1.1 The serious adverse event will be investigated by Inspire's clinical lead or delegated representative using Inspire's standardised SAE procedures - template and within an agreed time-frame contingent on the nature and seriousness of the event.

5.1.2 The completed investigation report will include recommendations, shared learning and corrective actions each to be completed within a specified time frame, presented to and signed off by the Inspire CEO – Board alongside being shared with the DMEC chair for review.

5.2 A Serious Adverse Event that occurs following discharge from Inspire but whilst in the trial will be investigated by one of the study senior investigators (i.e. Sturt, Greenberg, Armour) using Inspire's SAE investigational policies and procedures. Inspire protocols and timeframes will be used. The investigational report will be submitted to the DMEC chair.

5.3 The DMEC chair will be notified within 24 hrs of the research team being notified of all serious adverse events.

6.0 Ineligible participants

6.1 Inspire Associate Consultant Clinical Psychologists will determine whether each potential participant meets the inclusion and exclusion criteria. They will use Inspire's standardised risk assessment, escalation and management guidelines, and safeguarding policies and procedures to adhere to Inspire's clinical governance framework and ensure that:

6.2 Those considered ineligible for the study will be safely signposted to alternative specialist voluntary or statutory services

6.2.1 Those referred by MoD Aftercare Service will be discharged back to MoD Aftercare Service to put in place a bespoke care plan to safely meet their identified needs.

6.3. For anyone ineligible, but assessed as high risk, the GP will be contacted to, where necessary, mobilise crisis response and potential referral to NHS primary or secondary care.

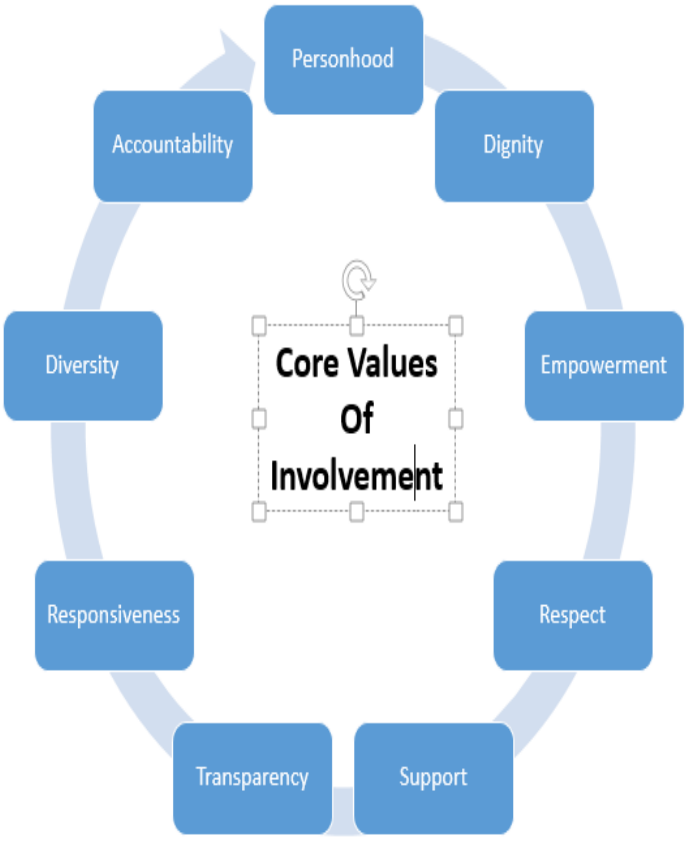
6.3.1 If referred by MoD Aftercare – the field worker will also be mobilised to make follow up contact with the individual.

6.4 Where safeguarding and vulnerable adult's concerns are identified this will be escalated, acted on and reported to the relevant statutory body – safeguarding team.

6.5 For any individual deemed at immediate high risk and who is unable to keep themselves safe, emergency services will be contacted directly.

Appendix 2: Stakeholder involvement team

Overview and Core Values

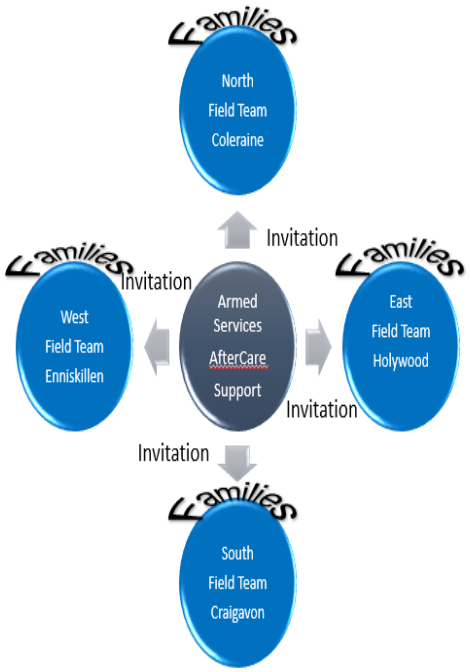


The 'Involvement' aspect of the research will be facilitated by co-applicant Chérie Armour's team.

We propose that the involvement of Service or ex-Service personnel and their families (hereafter referred to as 'The Involvement Team') would take the form of six two-hour meetings at appropriate points during the research.

- Chérie Armour would act as a Facilitator to the Involvement Team. She would also administer the remuneration (vouchers or cash) for Involvement Team members.

INVITING VETERANS TO BE PART OF 'INVOLVEMENT TEAM'



Recent (November 2017) direct discussions between the Facilitator, Gavin Megaw (Customer Relations Manager, Inspire) and (Ret) Major Peter Baillie, (Director of UDR and Royal Irish (HS) Armed Forces After Care) confirm that it be very straightforward to attract the following individuals to make up the 'Involvement Team':

- 4 to 5 veterans from NI (i.e. males and females who have experienced PTSD but who are no longer in need of active treatment for it); plus,
- one adult significant other of such individuals.

This process will be very straightforward because the Armed Forces After Care Service already has excellent direct links to families of veterans via the Case Workers who head up each of the four 'Field Teams' operating in different parts of NI: (N) Coleraine, (S) Craigavon, (E) Holywood and (W) Enniskillen. These Case Workers report directly to Peter Baillie.

Our proposed approach to populating the Involvement Team is therefore to:

- Co-create, with Peter Baillie, a brief (maximum two A4 pages) invitation pamphlet, for issue to the Case Workers in each of the four Field Teams. This pamphlet will summarise:
    - the overall purpose of the research overall;
    - the separate, but related, role of the Involvement Team;
    - the nature and duration of commitment;
    - the characteristics of the people we are looking for re the Involvement Team – i.e. 4-5 veterans from NI (i.e. males and females who have experienced PTSD but who are no longer in need of active treatment for it); plus, one adult significant other of such individuals;
    - key issues for Involvement Team members re confidentiality, security etc;
    - logistics / proposed meeting places / dates etc;
    - remuneration arrangements (e.g. £50 voucher/cash etc) per person per meeting; and,
    - a very brief application form (to be submitted to Peter Baillie by a specified closing date) if someone is interested in being considered for membership of the Involvement Team.

- We will explain that places are limited (five veterans, five adult significant others). We would strive for at least one veteran per Field Team.

- The first applicant from each Field Team to meet the criteria, will be appointed to the Involvement Team.

- If oversubscribed, we will create a waiting list. This will also give us a pool of people to call upon in case any of the members of the Involvement Team needed to drop out at any stage during the project.

- All applications will be acknowledged and all applicants will be notified (within seven working days of the closing date) re whether they had 1) been appointed to the Involvement Team, 2) been added to the waiting list or 3) not met the criteria for either.

MEETING 1: ORIENTATION

Key meeting to establish trust and agree working arrangements.

Facilitator (and potentially Peter Baillie and Gavin Megaw as well) will meet with the appointed members of the Involvement Team to:

- Confirm, agree and document core intention of involvement;
- Confirm the nature and duration of commitment;
- Confirm and agree core principles / values / ethos of all Involvement activities;
- Listen to and respond to needs of participants and significant others, including:
    - Concerns / fears / anxieties;
    - Creating and sustaining a sense of safety:
        - personnel involved;
        - locations;
        - language / terminology;
        - confidentiality;
        - personal data;
        - clear and timely information; and,
    - Confirming priorities within needs.
    - Motivation and personal goals re wishing to become part of the Involvement Team.
    - Confirm the talents and skills amongst the members of the Involvement Team;
    - Confirm how the Facilitator might best serve the Involvement Team as the work proceeds.
- Agree how to proactively and appropriately resource members of Involvement Team;
- Agree logistics / meeting places etc and remuneration arrangements (e.g. £50 voucher/cash etc);
- Agree how and when records of meetings will be made, kept and distributed etc;
- Agree the scope of the remaining 5 Involvement meetings and how email and communication etc would operate between Involvement Team Members between meetings.

MEETING 2: DEVELOPING MATERIALS

Facilitate Involvement Team to review and/or develop and/or refine a range of research-related materials such as:

- Participant Information Sheets and consent forms;
- Documentation and approaches to raise awareness of the research;
- Video design and script to provide study information;

- Answers to FAQs for prospective research participants / significant others;
- Study information webpage design.

MEETING 3: CONDUCT OF RESEARCH

- Facilitate Involvement Team to identify how prospective research participants and / or their significant others could benefit from (or could have benefited from) further information on the research.
- Catalogue all such information needs identified.
- Address the information priorities during the meeting.
- Ensure that other information needs identified are delegated to, and addressed by, an appropriate member of the Involvement Team and / or wider Research Team.

MEETING 4: EVALUATION

- Facilitator to share key findings and conclusions from the research with the Involvement Team.
- Facilitate the Involvement Team to suggest how the findings and conclusions from the research could be:
  - communicated even more clearly; and,
  - Described / presented in an even more meaningful / impactful way.

MEETING 5: DISSEMINATION

- Facilitator to share with the Involvement Team the preliminary proposals for the dissemination of the research findings and conclusions.
- Facilitate the Involvement Team to provide their views on how the dissemination activities might be further optimised.

MEETING 6: REFLECTION

- Facilitator to facilitate the Involvement Team to reflect on their own journey of involvement during this research, noting:
  - What they found most helpful;
  - What they found least helpful;
  - What they would like to be done differently next time;
  - The single most important positive thing they consider they have gained from their experience; and,
  - Whether or not they would recommend being a member of the Involvement Team to others, and why.

Appendix 3. Therapist assessment tool

Name	
Accreditation Body	
Profession	Counsellor/Psychotherapist/Psychologist *delete where appropriate
Date accredited	
Main therapeutic modality	
Other therapy training	
Years working with Simple PTSD	
Years working with Complex PTSD	
Other Professional qualifications e.g. Social Worker; Nurse etc	

Methodology used for therapist competency groupings

Therapists were asked to complete a self-assessment profile of therapist competence (Blackburn et al, 2001 (81)).

Additional demographics were collected of

- Professional Accreditation body
- Date of accreditation
- Main therapeutic modality(s)
- Other Therapeutic training
- Therapeutic experience of simple PTSD (years)
- Therapeutic experience of complex PTSD (years)
- Other Professional qualifications

No therapist was known to the Rater and data were sorted by level of competence self-rating resulting in 4 groupings. When the groups were reviewed and additional experience of working with complex PTSD and length of time since initial accreditation were factored in, 5 groups emerged.

Group 1 (level 1) consisted of newly accredited counsellors with limited experience of working with simple or complex PTSD, and a self rating of competent across the majority of skills.

Group 2 (level 1+) were counsellors who had been accredited for 5 years, including 5 years' experience of working with simple and complex PTSD. Self-rating spanned the competent and proficient skills for generic counselling skills and novice or advanced beginner for CBT and NLP specific competencies.

Group 3 (level 2) counsellors had minimum 8 years post accreditation experience and 9+ years' experience of working with simple and complex PTSD. Counsellors rated proficient in generic competencies and competent or proficient in CBT and NLP specific competencies.

Group 4 (level 2+) counsellors had minimum 11 years post accreditation experience, a post graduate qualification and 10+ years' experience of working with simple and complex PTSD. Counsellors rated proficient in generic competencies.

Group 5 (level 3) counsellors had minimum 10 years post accreditation experience, rated expert in generic and NLP/CBT competencies and had an additional professional registration to that of counselling or psychotherapy.

Self assessment

This self assessment table has been adapted from Blackburn et al (2001) (81) for the competency rating scale. The skill set is a generic therapeutic skill set identified by IAPT.nhs.uk.

Skill	**Novice**	**Advanced beginner**	**Competent**	**Proficient**	**Expert**
Knowledge and understanding of mental health problems					
Knowledge of, and ability to operate within, professional and ethical guidelines					
Knowledge of a model of therapy, and the ability to understand and employ the model in practice					
Ability to engage the client					
Ability to foster and maintain a good therapeutic alliance, and to grasp the client's perspective and 'world view'					
Ability to deal with emotional content of session					
Ability to manage endings					
Ability to undertake generic assessment (relevant history and identifying suitability for intervention)					
Ability to make use of supervision					
Pacing and leading and able to put client into a positive state by altering your own state					
Able to calibrate change in state of a client					
Elicitation of structures of present state					
Elicitation and assessment of associated vs dissociated trauma story					
Able to conduct a Symptoms of Distress Scale assessment in vivo					
Utilisation of anchoring techniques					
Utilisation of submodalities (finer distinctions of internal imagery) to effect change in clients					
Able to assist clients to dissociate and associate to and from states					
Able to identify trauma hot spots					

Appendix 4. Progression criteria to a full non-inferiority RCT

Project Outcomes	Measure of Success	Nature and number of Beneficiaries	Timescale
Outcome 1: Known rate of trial recruitment, retention in treatment and research and completeness of outcome data assessed against our green traffic light progression	In 14 months we identify 180 eligible participants	180 study participants	Months 5-18
	Consenting and randomised participants n = 60	60 study participants	Months 5-18
	Treatment drop out: RTM protocol Intervention drop out ≤ 30% TF-CBT intervention drop out ≤ 50%	≥36 study participants	Months 5-21
	Research attrition: Research follow up retention 36 participants at 20 weeks	36 study participants	At end of project
Outcome 2: Exploratory analyses of the outcome data to support a power calculation for a fully powered non-inferiority trial.	Baseline data set is complete for 90% of participants	54 study participants	Months 5-18
	12 week follow up data set is complete for 70% of study participants	42 study participants	Months 8-21
	20 week data set is complete for 50% of participants	30 study participants	At end of project
Outcome 3: Known safety risks and ameliorations of RTM therapy	A trial adverse and serious adverse event definition and safety protocol is developed which identifies all participants at risk; monitors and refers according to Inspire and research project-specific statutory care pathways; contains adverse events (e.g relapse, hospital admission, suicide and attempted suicide) across the 20 week follow-up period and documented clinical actions taken to mitigate participant risk	All 60 trial participants	Month 2
	All adverse and serious adverse events and ameliorations recorded and every event discussed at the bi-weekly research team meeting.	All 60 trial participants	Month 5-23
	A log of every adverse, serious adverse event and clinical and research team actions in response	All 60 trial participants	At end of project

Outcome 4: Establishment of expanded mental health care capacity across Northern Ireland to enable both interventions to be delivered within 20 miles of the veteran's home.	A minimum of 5 Inspire therapists will complete the 20 hour masterclass and be assessed as proficient in delivering protocoled TF-CBT	The beneficiaries of an expanded professional mental health capacity across Northern Ireland would be extensive. Hitherto, TF-CBT has only been available to veteran members of the Armed Forces aftercare service in Belfast which for the majority of veterans was too far to travel weekly for 8-12 weeks.	Month 4
	A minimum of 5 different Inspire therapists will complete the 70 hr RTM training and be assessed as proficient in delivering the RTM protocol		Month 4
	Inspire therapists attend two – four weekly clinical supervision sessions		Month 21
	≥50% of randomised participants to the TF-CBT arm remain in treatment when delivered closer to home		At end of project

Appendix 5: Data source and input responsibilities for trial database

MACRO Database form	Data source	Person entering data into database	Baseline	6 weeks	12 weeks	20 weeks	52 weeks	Comments
TRIAL DATABASE (BLINDED)								
1.Registration	Consent form	Person taking consent or FTR	X					
2.Eligibility	CP records	CP or FTR	X					
3. Socio-demographic	*Baseline Outcome Data Booklet*	BR	X					
4.PTSD history	CP records	CP or FTR	X					
5.Status form	Follow up contacts	BR		X	X	X	X	
6.PCL-5	- Inspire assessment records or *Baseline Outcome Data Booklet* - *Follow-up Outcome Data Booklet*	CL/CP/UBR/BR	X CL/CP	X Th/UBR/BR	X Th/UBR/BR	X BR	X BR	
7.WSAS	- *Baseline Outcome Data Booklet* - *Follow-up Outcome Data Booklet*	BR	X	X	X	X	X	

The PETT study has been funded by the Forces in Mind Trust (FiMT), a £35 million funding scheme run by the FiMT using an endowment awarded by The National Lottery Community Fund.

8.EQ-5D-5L	- *Baseline Outcome Data Booklet* - *Follow-up Outcome Data Booklet*	BR	X	X	X	X	X	
9.Adapted Folated	- *Baseline Outcome Data Booklet* - *Follow-up Outcome Data Booklet*	BR	X	X	X	X	X	
10.PHQ9	- Inspire assessment records or *Baseline Outcome Data Booklet* - *Follow-up Outcome Data Booklet*	CL/CP/UBR/BR	X	X	X	X	X	
11.GAD7	- Inspire assessment records or *Baseline Outcome Data Booklet* - *Follow-up Outcome Data Booklet*	CL/CP/UBR/BR	X	X	X	X	X	
12.QRP	- *Baseline Outcome Data Booklet*	BR	X	X	X	X	X	

	- Follow-up Outcome Data Booklet							
13.Randomisation	Eligibility (2)	BR	X					
14. Ongoing MH meds	*Follow-up Outcome Data Booklet*	BR		X	X	X	X	NB: These questions risk unblinding the BR. Therefore BR does not look at or enter Questionnaire 8 data. This data is passed to UBR who will enter the data in the Therapies database.
15.Alternative therapies log	*Follow-up Outcome Data Booklet &/or* Inspire records	BR		X	X	X	X	NB: These questions risk unblinding the BR. Therefore BR does not look at or enter Questionnaire 8 data. This data is passed to UBR who will enter the data in the Therapies database.
16.Adverse Events log	Therapist database &/or ICP &/or GP &/or participant See comments	BR/UBR	Ongoing throughout trial					<u>During therapy</u> from Inspire &/or ICP &/or from participant in Questionnaire 8 in *Follow-up Outcome Data Booklet* . <u>During follow up</u> from Participant in Questionnaire 8 in *Follow-up Outcome Data*

								Booklet and/or from GP or ICP.
17. Withdrawal	Follow up contacts	BR		X	X	X	X	
18. PI database signoff	Completed database	PI & Trial manager (JS/RR)				X	X	
THERAPIST DATABASE (UNBLINDED)								
Therapy registration	Consent form & registration on blinded trial database	UBR	Ongoing throughout trial					NB: Should be monitored closely (by unblinded researcher AMG) to make sure data is transferred carefully from trial database to therapy database and vice versa.
Therapy log	Therapist records	Therapist/UBR						

CP = Clinical Psychologist

Th = Therapist

Cl = Counsellor

BR = Blinded researcher

UBR = Unblinded researcher

FTR = From these Records

ICP = Independent Clin Psych

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