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# PTSD Experimental Treatment Trial (PETT): Comparing two talking therapies for the treatment of post-traumatic stress disorder in UK military veterans

**Submission date**
17/09/2019

**Recruitment status**
No longer recruiting

**Registration date**
01/10/2019

**Overall study status**
Completed

**Last Edited**
16/10/2023

**Condition category**
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Current plain english summary as of 19/04/2021:
Background and study aims
Post-traumatic stress disorder (PTSD) is a mental health condition that can affect people who have experienced a traumatic event in their life. Previous research has shown that up to 17% of UK ex-military service personnel who have recently been active in combat roles may have PTSD. If this is left undiagnosed or untreated, PTSD can lead to hospitalisation, unemployment and poverty and can put a strain on family relationships.
This study aims to investigate whether 60 military veterans in the United Kingdom will join the study and be happy to be randomly allocated on a 2:1 ratio to either of our two therapy treatments: Reconsolidation of Traumatic Memories (RTM) and Trauma-Focused Cognitive Behaviour Therapy (TF-CBT). It aims to find out if veterans will complete treatment and fill in the research questionnaires throughout the study. Another aim is to develop procedures to ensure veterans are safe when having either treatment. All the information will be collected and analysed to help to set up a larger trial to see whether RTM should be offered as a routine treatment for PTSD.

Who can participate?
Participants can be men or women, 18 years or older, who live or work in the United Kingdom. They will be UK military veterans of the Army, Royal Air Force or Royal Navy who have received a diagnosis of post traumatic stress disorder (PTSD) by one of the study's clinical psychologists at the charity Inspire's offices in Belfast.

What does the study involve?
This study will compare a new therapy treatment called Reconsolidation of Traumatic Memories (RTM) with an existing treatment called Trauma-Focused Cognitive Behaviour Therapy (TF-CBT). Participants will have an assessment with an experienced clinical psychologist who works at Inspire to confirm whether they have PTSD and are eligible for the study. Once they have joined they will complete their baseline outcome measures and then be randomly allocated to one of

the two therapy groups on a 2:1 randomisation ratio favouring the experimental treatment RTM:
Group 1 will receive RTM. This involves up to four weekly treatment sessions with each treatment session lasting up to 90 minutes.
Group 2 will receive TF-CBT. This involves up to 12 weekly treatment sessions, each lasting up to 1 hour.
In addition to the therapy, participants will be asked to complete questionnaires at 6, 12, 20 and 52 weeks after randomisation. This can be done in person, over the phone or online. When the treatment has ended, 15 to 20 of the participants will be invited to have an interview with a researcher to see what they thought about taking part in the study and the treatment they received.

What are the possible benefits and risks of participating?
By taking part in the study, the PTSD symptoms of the participants may get better and they may be contributing to future improvements in treatments offered to veterans suffering from the same condition. However, all talking therapies require people to talk about a problem and this can be uncomfortable or upsetting. They may uncover unpleasant memories of an event that had been forgotten. TF-CBT is known to be effective in reducing or removing the symptoms of PTSD. In contrast, it is not known if RTM may lead to increased symptoms of PTSD. This research will help answer that question.

Where is the study run from?
The recruitment and assessment of participants will take place online from the Inspire head office in Belfast, Northern Ireland with the therapy sessions being delivered online due to the impact of the COVID-19 pandemic.

When is the study starting and how long is it expected to run for?
June 2019 to April 2022

Who is funding the study?
Forces in Mind Trust (UK)

Who is the main contact?
Jackie Sturt
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Previous plain English summary:

Background and study aims
Post-traumatic stress disorder (PTSD) is a mental health condition that can affect people who have experienced a traumatic event in their life. Previous research has shown that up to 17% of UK ex-military service personnel who have recently been active in combat roles may have PTSD. If this is left undiagnosed or untreated, PTSD can lead to hospitalisation, unemployment and poverty and can put a strain on family relationships.
This study aims to investigate whether 60 military veterans in Northern Ireland will join the study and be happy to be randomly allocated to either of our two therapy treatments: Reconsolidation of Traumatic Memories (RTM) and Trauma-Focused Cognitive Behaviour Therapy (TF-CBT). It aims to find out if veterans will complete treatment and fill in the research questionnaires throughout the study. Another aim is to develop procedures to ensure veterans are safe when having either treatment. All the information will be collected and analysed to help to set up a larger trial to see whether RTM should be offered as a routine treatment for PTSD.

Who can participate?
Participants can be men or women, 18 years or older, who live or work in Northern Ireland. They will be UK military veterans of the Army, Royal Air Force or Royal Navy who have received a diagnosis of post traumatic stress disorder (PTSD) by one of the study's clinical psychologists at the charity Inspire's offices in Belfast.

What does the study involve?
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Group 1 will receive RTM. This involves up to four weekly treatment sessions with each treatment session lasting up to 90 minutes.
Group 2 will receive TF-CBT. This involves up to 12 weekly treatment sessions, each lasting up to 1 hour.
In addition to the therapy, participants will be asked to complete questionnaires at 6, 12, 20 and 52 weeks after randomisation. This can be done in person, over the phone or online. When the treatment has ended, 15 to 20 of the participants will be invited to have an interview with a researcher to see what they thought about taking part in the study and the treatment they received.

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By taking part in the study, the PTSD symptoms of the participants may get better and they may be contributing to future improvements in treatments offered to veterans suffering from the same condition.
However, all talking therapies require people to talk about a problem and this can be uncomfortable or upsetting. They may uncover unpleasant memories of an event that had been forgotten.
TF-CBT is known to be effective in reducing or removing the symptoms of PTSD. In contrast, it is not known if RTM may lead to increased symptoms of PTSD. This research will help answer that question.

Where is the study run from?
The recruitment and assessment of participants will take place at the Inspire head office in Belfast, Northern Ireland with the therapy sessions being delivered within 20 miles of the recipient's home or workplace.

When is the study starting and how long is it expected to run for?
June 2019 to April 2022

Who is funding the study?
Forces in Mind Trust (UK)

Who is the main contact?
Jackie Sturt
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# Contact information

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Scientific

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## Additional identifiers

### EudraCT/CTIS number
2019-001880-60

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
26.02.19 version 1.0

# Study information

## Scientific 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

## Acronym
PETT

## Study objectives
We will conduct a small trial in Northern Ireland (updated 19/04/2021: the United Kingdom) to assess the feasibility of providing 30 veterans diagnosed with PTSD with Reconsolidation of Traumatic Memories (RTM), a novel treatment approach. We will compare this new treatment with 30 veterans undertaking Trauma-Focused Cognitive Behavioural Therapy (TF-CBT). This pilot RCT is 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.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 26/03/2019, King's College London Research Ethics Office (Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo RD, London, SE1 9NH, UK; +44 (0)207 848 4020; rec@kcl.ac.uk), ref: HR-18/19-11320

## Study design
Single-centre external pilot randomized controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Community

## Study type(s)
Treatment

## Participant information sheet
See study outputs table

## Health condition(s) or problem(s) studied
Post-traumatic stress disorder (PTSD)

## Interventions

Using King's College London Clinical Trials Unit's computer randomisation service, 60 participants will be allocated on a 2:1 ratio to either Reconsolidation of Traumatic Memories (RTM) or Trauma-Focused Cognitive Behavioural Therapy (TF-CBT) (Randomisation ratio changed from 1:1 to 2:1 on 19/04/2021). Those allocated to RTM will receive up to four 90- to 120-min weekly sessions by a single trained therapist. Those allocated to TF-CBT will receive up to 12 60- to 90-min weekly sessions delivered by a single trained therapist.

Therapy A: Experimental Group – RTM Protocol
The experimental intervention is the Reconsolidation of Traumatic Memories protocol (RTM), an NLP-based, non-traumatising intervention delivered over up 4 x 90- to 120-min 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. 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 a 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.

Therapy B: Comparison Group – TF-CBT
Trauma-Focused Cognitive Behaviour Therapy delivered over up to 12 x 60- to 90-min weekly sessions delivered by a single TF-CBT trained therapist. TF-CBT is the gold standard for treating PTSD and is currently the first line of treatment recommended by NICE for PTSD. Research evaluating TF-CBT in adults with PTSD has established an empirical base supporting the efficacy of the intervention. A substantial number of RCTs in England and Northern Ireland have established the efficacy of TF-CBT in PTSD. 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-min 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) will be the model used in this study as it displays the largest treatment effect sizes and significant symptom improvements suggesting why it is widely carried out and recommended in IAPT services. This cognitive theory of PTSD addresses these symptoms by: modifying excessively negative appraisals of the trauma and/ or its sequelae in maintaining the symptomatology of PTSD, reducing re-experiencing by elaboration of the trauma memories and discrimination of triggers in the development of PTSD, and 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 12 x 60- to 90-min sessions each as recommended by NICE. The course and delivery of TF-CBT in this study for veterans with PTSD proceeds as follows:
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 the 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

Follow takes place at baseline, 6, 12, 20 and 52 weeks post-randomisation

### Intervention Type
Behavioural

### Primary outcome measure
1. Feasibility will be assessed using the following outcome measures:
1.1. Numbers of potential participants who are referred or self-refer to the Clinical Psychologists for eligibility assessment
1.2. The number of people who consent to participate and are randomised to either treatment
1.3. The number of people who remain in treatment
1.4. The time when people drop out
1.5. The number of people who remain in the research irrespective of whether they remain in treatment.
2. The cost of treatment will be assessed using the following outcome measures:
2.1. The number and duration of therapy sessions and the therapist used
2.2. The cost of any patient safety measures used during treatment and up to the 20-week follow up point.

### Secondary outcome measures
All secondary outcome measures will be used at baseline and then 6, 12, 20 and 52 weeks post-randomisation.
1. PTSD symptoms assessed using the PTSD checklist for DSM 5 (PCL-5). This is the likely primary outcome in the subsequent fully powered tria.
2. Impact of the participants' mental health on work, home, social and private leisure activities and interpersonal relationships assessed using the Work and Social Adjustment Scale (WSAS)
3. Recovery from psychosis or mental health problem assessed using the Quality of Process of Recovery scale (QPR)
4. Depression assessed using the Patient Health Questionnaire (PHQ), a self-administered diagnostic instrument
5. Anxiety assessed using the General Anxiety Disorder score sheet (GAD-7)
6. Health status assessed using the EQ5D-5L, a two-page questionnaire with page one consisting of the EQ-5D descriptive system and page two the EQ visual analogue scale (EQ VAS)
7. Health and social services utilisation in terms of number of contacts with general practice, social services, mental health services and other agencies during the past specified period assessed using the FolATED (Use of health and social-service questionnaire), which is a 31-item administered questionnaire
8. Acceptability of both treatments assessed using qualitative interviews with 15-20 participants in both RTM and TF-CBT groups to determine the acceptability and feasibility of participating in the trial and the treatment they received

### Overall study start date
24/06/2019

### Completion date
23/06/2022

## Eligibility

### Key inclusion criteria
Current inclusion criteria as of 19/04/2021:
1. Adults aged ≥18 years
2. UK military veterans from the Army, Royal Air Force or Royal Navy

3. PTSD (acute or chronic) diagnosis determined by DSM-5 using the Clinician Administered PTSD scale (CAPS-5) during clinical assessment with an Inspire (trial's participating partner) 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 United Kingdom
7. Willingness to be randomised to either treatment

Previous inclusion criteria from 05/11/2019 to 19/04/2021:
1. Adults aged ≥18 years
2. UK military veterans from the Army, Royal Air Force or Royal Navy
3. PTSD (acute or chronic) diagnosis determined by DSM-5 using the Clinician Administered PTSD scale (CAPS-5) during clinical assessment with an Inspire (trial's participating partner) 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 Northern Ireland and within 20 miles of one of Inspire's treatment centres which are spread across remote NI
7. Willingness to be randomised to either treatment

Previous inclusion criteria:
1. Adults aged ≥18 years
2. UK military veterans from the Army, Royal Air Force or Royal Navy
3. PTSD or complex PTSD diagnosis (acute and/or chronic) according to DSM-5 using the Clinician Administered PTSD Scale (CAPS-5) and the ICD-TQ determined during clinical assessment with an Inspire (trial's participating partner) employed consultant 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 Northern Ireland and within 20 miles of one of Inspire's treatment centres which are spread across remote NI
7. Willingness to be randomised to either treatment

## Participant type(s)
Patient

## Age group
Adult

## Lower age limit
18 Years

## Sex
Both

## Target number of participants
60

## Total final enrolment

### Key exclusion criteria
Current exclusion criteria as of 05/11/2019:
1. Serving military 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 addiction to alcohol or illegal substances as determined by an AUDIT 10 cut-off of ≥20
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 4 weeks
8. Unwilling to consent to audio-recording of all therapy sessions as minimum requirement

Previous exclusion criteria:
1. Serving military 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 addiction to alcohol or illegal substances as determined by an AUDIT 10 cut-off of ≥20
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 4 weeks
8. Refusing to be audio recorded, which is required for treatment fidelity and data analysis

### Date of first enrolment
14/10/2019

### Date of final enrolment
30/06/2021

## Locations

### Countries of recruitment
Northern Ireland

United Kingdom

### Study participating centre
**Inspire**
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**Sponsor type**
University/education

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**ROR**
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# Funder(s)

**Funder type**
Charity

**Funder Name**
Forces in Mind Trust

**Alternative Name(s)**
FiM Trust, FiMT

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United Kingdom

# Results and Publications

## Publication and dissemination plan

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. 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.

Manuscripts will be prepared between 01/08/2021 and 30/06/2022.
Updated 19/04/2021: Manuscripts will be prepared between 01/10/2021 and 01/10/2022.

## Intention to publish date

01/12/2022

## Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version V6 | 31/03/2021 | 20/04/2021 | No | Yes |
| Protocol file | version V5 | 31/03/2021 | 20/04/2021 | No | No |
| Results article | | 13/10/2023 | 16/10/2023 | Yes | No |