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Efficacy and mechanisms evaluation of Fast Imagery Reversal Script for Trauma release therapy vs waiting list control for post-traumatic stress disorder in United Kingdom military veterans

Submission date
10/10/2024

Recruitment status
Recruiting

Registration date
11/10/2024

Overall study status
Ongoing

Last Edited
30/10/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Post-Traumatic Stress Disorder (PTSD) is a mental health condition which can follow experiencing or witnessing events such as threatened or actual death, serious injury or sexual violence. PTSD rates in the general population are 4% but in military veterans can be 17% or higher. There are approximately two million UK veterans of which 13% are female sex, 50% over 70 years and 2% from an ethnic minority group. Some veterans find it difficult to seek NHS therapy, because it is lengthy and discussing the trauma is too upsetting. Charities and NHS decision-makers agree that new PTSD therapies are required that better meet veterans' needs. Neurolinguistic Programming (NLP) is a brief talking therapy for people with mental health symptoms used by some veteran charities. During the COVID pandemic, we undertook a small trial comparing an NLP therapy with NHS therapy via video call with 60 veterans with PTSD. We found that NLP therapy was able to reduce PTSD symptoms in three sessions. We improved the NLP therapy and have renamed it Fast Imagery Reversal Script for Trauma-release (FIRST®).

We will conduct a large trial to test whether FIRST® can successfully treat PTSD. The project aims to 1) confirm FIRST® works as well as the pilot NLP therapy 2) test whether online delivered FIRST® is effective in reducing PTSD symptoms and 3) understand what happens to thinking patterns, following FIRST®, to understand how it reduces PTSD symptoms

Who can participate?
We will recruit 215 male and female UK military veterans with self-reported PTSD symptoms, aged 18 years and above. We will work with a specialist social media company to a) advertise our study and b) attract a diverse group of veterans to take part.

What does the study involve?
Interested veterans will complete four questionnaires to confirm that they have PTSD. They will

then be invited to a PTSD and general mental health assessment to see if they are well enough to undergo therapy. If they are eligible to join the study, veterans will be randomly allocated to either receive three or four sessions of online delivered FIRST® immediately, or to receive FIRST® 20 weeks later, with their current medical care plan continuing in the meantime.

Ongoing participant commitment
Participants will complete questionnaires to assess PTSD symptoms, mood, anxiety, quality of life and how they function in their social and working life, and thinking tasks to understand how FIRST® works. Questionnaires will be completed before therapy begins and at 6, 12 and 20 weeks. The group receiving FIRST® initially will complete the questionnaires one year following therapy to see if PTSD symptoms change over time.

What are the possible benefits and risks of participating?
Benefits: we cannot guarantee that participants will benefit from taking part in the study but current research suggests that their PTSD symptoms may improve after completing the treatment. All participants will receive FIRST® and it is delivered in a shorter time than standard treatments offered on the NHS. Taking part in the study may help other veterans and civilians with PTSD in the future.
Risks: we do not anticipate any risks for participants taking part in the study. However, all talking therapies require people to talk about a problem that they are currently experiencing, and this can feel uncomfortable or upsetting. Participants may uncover unpleasant memories of an event that had been forgotten; however, the therapists are specially trained to help participants manage these feelings safely.

Where is the study run from?
The study is being run from King's College London (UK) with FIRST® therapy being delivered by Inspire Wellbeing, our mental health charity partner. Inspire therapists are experienced in delivering therapy online, are trained in delivering FIRST® and will be monitored to ensure they deliver it correctly.

When is the study starting and how long is it expected to run for?
February 2024 to January 2028

Who is funding the study?
The study is jointly funded by the National Institute for Health and Care Research (NIHR) and the Forces in Mind Trust (FiMT) (UK)

Who is the main contact?
Rebecca Rogers, Trial Manager, King's College London, rebecca.e.rogers@kcl.ac.uk

Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
In UK military veterans (P) the remotely delivered Fast Imagery Reversal Script for Trauma release Protocol (I), compared to waiting list control (C) is clinically and statistically effective in reducing post-traumatic stress disorder symptoms by the minimal clinically important difference (O) at 20 weeks (T)

Acronym
FIRST® PETT

Study objectives

In UK military veterans (P) the remotely delivered FIRST® Protocol (I) compared to waiting list control (C) is clinically and statistically effective in reducing PTSD symptoms by the minimal clinically important difference (O) at 20 weeks (T).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/07/2024, King's College London Health Facilities (Blue) Research Ethics Subcommittee (Research Ethics Office, 3rd Floor, 5-11 Lavington Street, London, SE1 0NZ, United Kingdom; -; rec@kcl.ac.uk), ref: HR/DP-23/24-41529

Study design
Parallel group single masked (outcome assessor) 1:1 randomized controlled superiority trial

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life

Health condition(s) or problem(s) studied
Post-traumatic stress disorder in UK military veterans

Interventions
Current interventions as of 20/10/2025:
FIRST® is a brief intervention delivered in 3 to 4 x 90 minute sessions by a FIRST® therapist via videocall. FIRST® rewrites the emotional elements of the memory. FIRST® therapy will be delivered over a minimum of three days and a maximum of four weeks. The two factors determining this are a) there must be one sleep cycle between each therapy session and b) scheduling of therapy sessions for the participant and the therapist. Therapy sessions will be delivered remotely, and our therapy delivery and clinical governance partner and collaborator is Inspire; a mental health charity located in Northern Ireland (https://www.inspirewellbeing.org/) who delivered all therapies remotely in the feasibility trial. Inspire therapists are experienced in working remotely with cross-UK and Republic of Ireland military veterans since online mental health assessment and therapy became mainstream therapeutic provision during the COVID-19 pandemic. For an efficacy trial this third sector organisation offers a more ideal setting for the following reasons: a) the flow of participants through the trial is controllable because there are many fewer competing interests than within the NHS; b) Inspire, due to their Northern Ireland location, have considerable expertise in working with military veterans and other populations with occupationally-related PTSD; and c) they have robust clinical governance procedures which are adaptable to being supplemented with FIRST® therapy-specific clinical supervision.

Participants will be randomised after eligibility assessment and baseline data collection and will be randomly allocated to either receive three or four sessions of online delivered FIRST® immediately, or to receive FIRST® 24 weeks later, with their current medical care plan continuing in the meantime. Randomisation will take place via a web-based randomisation service run by the King’s Clinical Trials Unit.

Previous interventions:
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Participants will be randomised after eligibility assessment and baseline data collection and will be randomly allocated to either receive three or four sessions of online delivered FIRST® immediately, or to receive FIRST® 20 weeks later, with their current medical care plan continuing in the meantime. Randomisation will take place via a web-based randomisation service run by the King's Clinical Trials Unit.

Intervention Type
Behavioural

Primary outcome(s)
PTSD symptom severity assessed by the post-traumatic stress disorder checklist for DSM-5 (PCL-5) collected at baseline, 6-weeks, 12-weeks and 20-weeks post-randomisation

Key secondary outcome(s))
Current secondary outcome measures as of 20/10/2025:
1. Assess the impact of the participant's mental health on work, home, social and private leisure activities and interpersonal relationships, assessed by the Work and Social Adjustment Scale (WSAS) collected at baseline and 20 weeks post randomisation
2. Depression assessed by the Patient Health Questionnaire (PHQ-9) collected at baseline, 6 weeks, 12 weeks and 20 weeks post-randomisation
3. Health status assessed by the EQ5D-5L at baseline and 20 weeks post-randomisation
4. Self-related self-esteem assessed by the Self-esteem scale at baseline and 20 weeks post-randomisation
5. Symptom severity assessed by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) at baseline and 20 weeks post-randomisation
6. PTSD complexity assessed by the ICD-11 Trauma Questionnaire (ICD-TQ) at baseline and 20 weeks post-randomisation

Previous secondary outcome measures:
1. Assess the impact of the participant's mental health on work, home, social and private leisure activities and interpersonal relationships, assessed by the Work and Social Adjustment Scale (WSAS) collected at baseline and 20 weeks post randomisation
2. Depression assessed by the Patient Health Questionnaire (PHQ-9) collected at baseline, 6 weeks, 12 weeks and 20 weeks post-randomisation
3. Health status assessed by the EQ5D-5L at baseline and 20 weeks post-randomisation

4. Self-related self-esteem assessed by the Self-esteem scale at baseline and 20 weeks post-randomisation

Completion date
31/01/2028

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 20/10/2025:
1. UK-based military veterans from the Royal Navy, British Army, and Royal Air Force
2. Aged >18 years
3. Currently living or working in the UK
4. Ability to read and speak English
5. PTSD diagnosis determined by the DSM-5 using the Clinician Administered PTSD scale (CAPS-5)
6. Experiencing symptoms causing clinically significant distress or impact on social, occupational or other areas of functioning
7. Self-reported history of exposure to one or more traumas
8. Willing and able to provide informed consent
9. Willingness to be randomised to a treatment group
10. Willingness for the therapy sessions to be video recorded
11. Access to the Internet

Previous key inclusion criteria:
1. UK-based military veterans from the Royal Navy or Royal Marines, British Army, Royal Air Force
2. Aged >18 years
3. Currently living or working in the UK
4. Ability to read and speak English
5. PTSD diagnosis determined by the DSM-5 using the Clinician Administered PTSD scale (CAPS-5)
6. Experiencing symptoms causing clinically significant distress or impact on social, occupational or other areas of functioning
7. Self-reported history of exposure to one or more traumas
8. Willing and able to provide informed consent
9. Willingness to be randomised to a treatment group
10. Willingness for the therapy sessions to be video recorded
11. Access to the Internet

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
Current key inclusion criteria as of 30/10/2025:

1. UK-based military veterans from the Royal Navy, British Army, and Royal Air Force
2. Aged >18 years
3. Currently living or working in the UK
4. Ability to read and speak English
5. Meet the diagnostic criteria for PTSD and/or clinically important symptoms impacting on social, occupational or other areas of functioning as determined by DSM-5 using the Clinician Administered PTSD scale (CAPS-5)
6. Self-reported history of exposure to one or more traumas
7. Willing and able to provide informed consent
8. Willingness to be randomised to treatment group
9. Willingness for the therapy sessions to be video recorded
10. Access to the Internet

Previous key exclusion criteria as of 20/10/2025:

1. Currently receiving psychological treatment for PTSD
2. 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
3. Participant has attempted suicide within the past month at time of recruitment or has had multiple previous attempts which are deemed clinically likely to happen again during the course of the trial
4. Participant is currently self-harming or has experienced a serious episode of deliberate self-harm which required medical intervention within the past month
5. Current dependence on alcohol as determined by an AUDIT cut-off of ≥20 or self-report during clinical interview
6. Self-report of current dependence on prescription or illegal substances as determined during clinical interview
7. Self-reported medication changes in anti-psychotic and anti-depression medication in the previous four weeks
8. Participant has an existing dissociative disorder that moderately-severely or severely impairs function as determined by the Assistant Psychologist during administration of the CAPS-5 assessment
9. Any other documented reason in which the assessing assistant psychologists, in consultation with their clinical supervisor, determine that treatment for other mental health symptoms takes precedent over their PTSD at the time of assessment

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Previous key exclusion criteria:

1. Currently receiving psychological treatment for PTSD
2. 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

3. Participants who have had a self-reported suicide attempt within the past month
4. Current dependence on alcohol as determined by an AUDIT cut off of ≥20 or self-report of prescription or illegal substances dependence
5. An existing dissociative disorder as determine by scoring ≥43 on the Dissociative Experiences Scale
6. Self-reported medication changes in anti-psychotic and anti-depression medication in the previous four weeks
7. Any other documented reason in which the assessing assistant psychologists, in consultation with their clinical supervisor, determine that treatment for other mental health symptoms takes precedent over their PTSD at the time of assessment

Date of first enrolment
01/11/2025

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Inspire Wellbeing
Lombard Street
Belfast
United Kingdom
BT1 1RB

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available immediately following the end of the study due to IP considerations. We advise researchers to contact the trial manager, rebecca.e.rogers if they are interested in requesting our data. However, once this is resolved the data will be stored in a publicly available repository (KORDS / https://kcl.figshare.com/).

IPD sharing plan summary
Available on request, Not expected to be made available, Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	version 3.0	22/08/2025	20/10/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes