

# 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

<b>Submission date</b> 10/10/2024	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/10/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/10/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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](mailto:rebecca.e.rogers@kcl.ac.uk)

#### Study website

<https://www.inspirewellbeing.org/firstpett-project/>

## Contact information

#### Type(s)

Scientific, Principal Investigator

#### Contact name

Prof Jackie Sturt

**ORCID ID**

<http://orcid.org/0000-0003-1281-1401>

**Contact details**

James Clerk Maxwell Building  
57 Waterloo Road  
London  
United Kingdom  
SE1 8WA  
+44 20 7836 5454  
[jackie.sturt@kcl.ac.uk](mailto:jackie.sturt@kcl.ac.uk)

**Type(s)**

Public

**Contact name**

Ms Rebecca Rogers

**ORCID ID**

<http://orcid.org/0000-0002-5313-5705>

**Contact details**

James Clerk Maxwell Building  
57 Waterloo Road  
London  
United Kingdom  
SE1 8WA  
+44 7758353452  
[rebecca.e.rogers@kcl.ac.uk](mailto:rebecca.e.rogers@kcl.ac.uk)

## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Charity/Voluntary sector, Internet/virtual, University/medical school/dental school

## **Study type(s)**

Quality of life, Efficacy

## **Participant information sheet**

To follow

## **Health condition(s) or problem(s) studied**

Post-traumatic stress disorder in UK military veterans

## **Interventions**

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® 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 measure**

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

## **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 The Self-esteem scale at baseline and 20-weeks post-randomisation

## **Overall study start date**

01/02/2024

## **Completion date**

31/01/2028

# **Eligibility**

## **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 DMS-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 treatment group
10. Willingness for the therapy sessions to be video recorded
11. Access to the Internet

## **Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

100 Years

**Sex**

Both

**Target number of participants**

215

**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  $\geq 20$  or self-report of prescription or illegal substances dependence
5. An existing dissociative disorder as determined by scoring  $\geq 43$  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**

01/03/2025

**Date of final enrolment**

30/09/2026

**Locations**

**Countries of recruitment**

Northern Ireland

United Kingdom

**Study participating centre**

Inspire Wellbeing

Lombard Street

Belfast

United Kingdom  
BT1 1RB

## Sponsor information

### Organisation

King's College London

### Sponsor details

Strand  
London  
England  
United Kingdom  
WC2R 2LS  
+44 20 7848 7306  
ypri@kcl.ac.uk

### Sponsor type

University/education

### Website

<http://www.kcl.ac.uk/index.aspx>

### 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

**Publication and dissemination plan**

A report for the NIHR EME Programme will be produced and two Open Access publications to high impact journals on the trial and the mechanisms studies. NHS veteran, mental health and psychological trauma conferences will be targeted for national and international conference presentations. Dissemination plans are supported via KCL communications team's media engagement and a trial website and Twitter account. A dissemination event will be held with invited stakeholders including, the general public, NHS managers, charity managers, therapists, veterans and their families, UK policy makers and elected Members of Parliament. The event will also be available online to increase participation across the UK.

**Intention to publish date**

01/02/2029

**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**

Stored in publicly available repository, Available on request, Not expected to be made available