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NHS COVID-related post-traumatic stress disorder (PTSD) experimental treatment trial

Submission date
05/10/2023

Recruitment status
No longer recruiting

Registration date
16/10/2023

Overall study status
Completed

Last Edited
16/10/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
High levels of Post-Traumatic Stress Disorder (PTSD) are reported in frontline health and social care workers (HSCW) who have worked through the pandemic. These levels of PTSD are comparable to those in military veterans who have been involved in warfare. Staff with PTSD present a patient safety risk due to high staff absences and mistakes. Currently the best treatment available for PTSD is lengthy, costly and 30% of people undertaking this treatment drop out before the end. New PTSD treatments are needed. We have developed a new Neurolinguistic Programming (NLP) treatment called Fast Imagery Reversal Script for Trauma-release (FIRST).
Our study aims to develop a FIRST treatment route for HSCW with PTSD and to develop an understanding of what their employers consider to be important health benefits for their staff. We are asking three questions: 1) Do staff want to receive treatment and participate in research and how? 2) Can NLP reconsolidation therapy training previously undertaken by veteran-charity therapists also be successfully taught to multi-professional mental health practitioners employed by the NHS? 3) What employer benefits are important to measure e.g. sickness-absence rates and/or mistakes made by staff while working.

Who can participate?
Health and social care workers over 18 years, working in NHS Trusts, Primary Care of Social Care between 1st March 2020 and 31st March 2021 covering the three UK waves of the pandemic.

What does the study involve?
The main purpose of the study will be to develop a funding application to undertake further research of FIRST to determine whether it works, how it works and is it safe compared to similar treatments. We propose a 3-phase study. Phase 1 will recruit a group of individuals directly affected by the pandemic including NHS and social care workers and patients and their families to discuss and answer the research questions. Phase 2 will train and assess four to six NHS qualified mental health practitioners in delivering FIRST. Phase 3 will deliver FIRST to twelve HSCW with PTSD to see if they will start therapy and take part as research participants.

What are the possible benefits and risks of participating?
We do not anticipate any risks for participants taking part in the FIRST therapy or exit interviews.

However, talking therapies require people to talk about a problem they are currently experiencing and this can feel uncomfortable or upsetting. Your therapist is specially trained to help you manage these feelings safely.
We cannot guarantee that you will benefit from participating in our study but current research suggests that your PTSD symptoms may improve if you complete the treatment. FIRST therapy is delivered in a shorter time than standard treatment offered by SLaM.

Where is the study run from?
King's College London (UK) and South London and Maudsley NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
October 2022 to March 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Prof. Jackie Sturt, jackie.sturt@kcl.ac.uk

Contact information

Type(s)
Scientific

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Integrated Research Application System (IRAS)
317339

Central Portfolio Management System (CPMS)
58296

National Institute for Health and Care Research (NIHR)
203566

Study information

Scientific Title
Evaluating a brief novel treatment for COVID-related Post-Traumatic Stress Disorder (PTSD) in the Health and Social Care workforce: a pre-RCT preparatory study

Acronym
NHS PETT

Study objectives
We can successfully recruit and train mental health practitioners working within the NHS to competently deliver FIRST therapy to health and social care workers within the NHS, and that these health and social care workers will present for, commence and complete FIRST therapy

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/10/2023, East of Scotland Research Ethics Service (EoSRES) (Tayside Medical Science Centre, George Pirie Way, Ninewells Hospital, Dundee, DD1 9SY, United Kingdom; +44 1382 383878; tay.eosres@nhs.scot), ref: LR/23/ES/0037

Primary study design
Interventional

Study design
Interventional non randomized

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-Traumatic Stress Disorder (PTSD)

Interventions
We are using a novel therapy called Fast Imagery Reversal Script for Trauma-release (FIRST) which is a possible new treatment for PTSD. FIRST draws on NLP (neurolinguistic programming) approaches and reconsolidation processes to deliver a therapy in which the person is asked to visualise in a way that is intended to be comfortable, non-traumatising, and non-intrusive. At no point is the person asked to describe the detail of the experiences that lead to their PTSD. The treatment is offered in up to four weekly individual session of 90 minutes duration.

As well as completion at baseline, participants will be asked to complete a series of questionnaires at completion of the FIRST therapy and at four weeks after their last FIRST session.
Participants will also be asked to take part in an exit interview for which they will have provided informed consent.
Interviews will last approximately 45 minutes and will take place online (via Microsoft Teams).

Intervention Type

Behavioural

Primary outcome(s)
To understand the feasibility and acceptability of FIRST therapy for HSCWs and MHPs. Feasibility and acceptability will be assessed via the qualitative exit interviews and will answer these questions:
1. Will HSCWs present for, commence and complete FIRST therapy.
2. Do HSCWs find FIRST therapy and referral processes acceptable.
3. Do they find the proposed outcome measures acceptable to consent to and complete?
4. Are research procedures acceptable?
5. How do the therapists (MHPs) experience (i) delivering FIRST and (ii) to HSCWs colleagues.
The exit interviews will take place at four weeks' post end-of-therapy delivery and qualitative content analysis will be applied to the data.

Key secondary outcome(s)
Mental health outcomes collected at baseline and four weeks' post end-of-therapy; and PCL-5 and GAD-7 will also be collected at completion of therapy (approx. four weeks' post baseline):
1. Post-traumatic Stress Disorder Checklist (PCL-5)
2. Work and Social Adjustment Scale (WSAS)
3. Patient Health Questionnaire (PHQ-9)
4. The General Anxiety Disorder (GAD-7)
5. The EuroQol five-dimensional five-levels (EQ-5D-5L)
6. The EuroQol-visual analogue scale (EQ-VAS)

Completion date
30/03/2024

Eligibility

Key inclusion criteria
1. Adults > = 18 years
2. Working in NHS Trusts, Primary Care or Social Care between 1st March 2020 and 31st March 2021 covering the three UK waves of the pandemic.
3. Prior, or new, diagnosis of PTSD determined by a PCL-5 score > 32. Confirmed by the Staff Counselling and Wellbeing Service or Post-Incident Pathway, within SLaM.

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Currently receiving psychological treatment for PTSD.
2. Not able to provide informed consent.
3. Unwilling to consent to video-recording of therapy sessions for supervisory purposes.

Date of first enrolment
01/11/2023

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
United Kingdom

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
United Kingdom
BR3 3BX

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be 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	Interview information sheet for NHS qualified mental health practitioners version 2.0	31/08/2023	16/10/2023	No	Yes
Participant information sheet	Study information sheet for NHS qualified mental health practitioners version 2.0	31/08/2023	16/10/2023	No	Yes
Participant information sheet	for Health and Social Care workers version 3.0	31/08/2023	16/10/2023	No	Yes