STUDY INFORMATION SHEET FOR NHS QUALIFIED MENTAL HEALTH PRACTITIONERS (MHP)

Ethical Clearance Reference Number: 23/ES/0037

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Full title of project

Evaluating brief novel treatment for COVID-related Post-Traumatic Stress Disorder (PTSD) in the health and social care workforce: a pre-Randomised Control Trial (RCT) preparatory study. (Study short name: NHS PTSD Experimental Treatment Trial study (NHS PETT))

Invitation paragraph

I would like to invite you to participate in the NHS PTSD Experimental Treatment Trial (NHS PETT) study. This will involve you receiving training in a novel, effective PTSD treatment called Fast Imagery Reversal Script for Trauma-release (FIRST). You will then be asked to deliver the treatment to health and social care workers (HSCWs) who have been referred to the Staff Counselling and Wellbeing Service (SCaWBs), South London and Maudsley NHS Foundation Trust and are diagnosed with PTSD. Before you decide whether you want to take part, it is important for you to understand why the study is being conducted and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is Fast Imagery Reversal Script for Trauma-release (FIRST)?

FIRST is a possible new treatment for post-traumatic stress disorder (PTSD). It uses a process where the patient is asked to visualise in a way that is intended to be comfortable, non-traumatising, and non-intrusive. FIRST places less emphasis on recounting the actual trauma (therefore reducing the fears of engaging in therapy) and seeks to disrupt the memory that drives the PTSD. The treatment is offered in up to four weekly individual sessions of 90 minutes duration. Research has shown it can be delivered safely online. FIRST is a form of NLP (neurolinguistic programming) based therapy for PTSD that we strengthened and renamed though a previous research study (PETT 1) with military veterans affected by PTSD. PETT 1 evaluated the efficacy of the therapy for this study. FIRST, however, has not been used previously in any other research project.

What is the purpose of our study?

The purpose of our study is to develop a FIRST treatment route for health and social care workers (HSCWs) with PTSD and to understand what their employers consider to be important health benefits for their staff. Before we can proceed with a full randomised control study within the NHS we need to understand three things better: 1) Do staff want to receive treatment and participate in research and how? 2) Can FIRST training be successfully taught to a range of multi-professional

Mental Health Practitioners (MHPs) 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.

To help us undertake this research we aim to train and assess 4-6 MHPs in delivering FIRST to HSCWs who have been referred to KWSEL and have been diagnosed with PTSD.

Why have I been invited to take part?

You are being invited to participate in this project because you are an NHS MHP employed by South London and the Maudsley NHS Foundation Trust (SLaM). Participation is completely voluntary and you are free to participate in the study or decline and your decision will have no affect on your employment, promotion or any other benefits you may be entitled to.

What will happen if I take part?

You will be approached by the Programme Manager for Corporate Psychology and Psychotherapy who will tell you about the study, provide you with a participant information sheet and will answer any questions you may have. If you agree to take part we will ask you to sign a consent form via MS Forms. We will take no further data from you at this time.

Your training and supervision will be undertaken by Dr Lisa de Rijk, a neurolinguistic psychotherapist and international expert trainer in FIRST. She is also a co-applicant on the study. The training consists of a two-hour online group webinar where you will be introduced to FIRST and the study; this is followed by a 10-hour online self-directed learning package and two and a half days of online group training. You will then practice your skills for two weeks with each other and other colleagues during which time your competency in delivering FIRST will be assessed by the trainer and an external independent FIRST assessor, Ms Paola Scandurra. You will be supported throughout this process by the Programme Manager for Corporate Psychology and Psychotherapy.

Once competency has been assessed you will be asked to deliver the online FIRST therapy to 2-3 HSCWs who have been referred to SCaWBs and are diagnosed with PTSD. With agreement between yourself and your client the first therapy session with each of the 2-3 clients will be audio-visually recorded using the Microsoft Teams recording device. As soon as the session is completed you will be responsible for downloading the recording, password protecting it and saving it to the secure SLaM OneDrive folder. You will immediately delete the original recording from MS Teams. These recordings will be used to provide you with ongoing FIRST therapy supervision and support from Dr de Rijk and fidelity assessment by Ms Scandurra. They will be given viewing permissions to watch segments of each recording within the NHS OneDrive but will not be able to download or save the recordings. Once supervision has taken place your supervisor will ask you to permanently delete the recordings.

Once you have completed delivery of FIRST to 2-3 HSCWs we will invite you to take part in an exit interview. At that time, we will provide more information and seek your consent. If you would like to know more in advance, please let us know and we can provide you with the information sheet.

Do I have to take part?

Participation in the study is completely voluntary. You should only take part if you want to, and choosing not to take part will not disadvantage you in any way. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part. If you decide to take part we will ask you to sign a consent form via MS Forms using your NHS email account. You will be given a copy of this consent form to keep.

What are the possible risks of taking part?

We do not anticipate any risks for you participating in the study. However, should you become upset or distressed at any point during the training or delivery of the therapy you can ask for support from either your Clinical Lead or Dr de Rijk. You are free to withdraw from the study at any time although we may keep any data we have already collected from you up to that timepoint.

What are the possible benefits of taking part?

There are no intended direct benefits for you in taking part in the study. However, your experiences will help the researchers to understand how they could improve FIRST therapy training for a larger randomised control trial project and enhance the delivery of the therapy in the future.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name and contact details. People will use this information to do the research or to check your records to make sure the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to the Data Protection Officer: for SLaM, informationgovernance@slam.nhs.uk; for KCL, Olenka Cogias info-compliance@kcl.ac.uk).
- by ringing us on 020 7848 3620.

Data Protection Statement

If you would like more information about how your data will be processed under the terms of UK data protection laws please visit the link below:
https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research

What if I change my mind about taking part?

You are free to withdraw at any point of the study, without having to give a reason. Withdrawing from the study will not affect you in any way. If you choose to withdraw from the study we will retain the information you have provided so far.

How is the project being funded?

This NHS PETT study is being funded by the National Institute of Health Research (NIHR).

What will happen to the results of the project?

The results of the project will be summarised in a report for the funder (NIHR). Findings may also be published in academic journals and presented at internal conferences and seminars within King's College London and externally (nationally and internationally). If you would like to obtain a copy of the funder's report/publications please initial the consent form.

The results from this study, together with previous trials on FIRST, will support a funding application to test whether FIRST can be proven to be a successful treatment within the NHS.

Who should I contact for further information?

If you have any questions or require more information about the study, please contact:

Helen Winter
Consultant Clinical Psychologist
Programme Manager Corporate Psychology and Psychotherapy
South London and Maudsley NHS Foundation Trust
Maudsley Hospital
Denmark Hill
London SE5 8AZ
Helen.Winter@slam.nhs.uk

Professor Jackie Sturt
Professor in Behavioural Medicine in Nursing
Faculty of Nursing, Midwifery and Palliative Care
57 Waterloo Road
London
SE1 8WA
Jackie.sturt@kcl.ac.uk

What if I have further questions, or if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions, or, contact the study's principal investigator:

- Professor Jackie Sturt, 020 7848 3108, jackie.sturt@kcl.ac.uk

If you remain unhappy and wish to complain formally, you can do this through:

- SLaM Patient Advice and Liaison Service (PALS) on 0800 731 2864, pals@slam.nhs.uk

In the event that something does go wrong, and you are harmed during the research, you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Thank you for reading this information sheet and for considering taking part in this research.