

INFORMATION SHEET FOR HEALTH AND SOCIAL CARE WORKERS (HSCWs)

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 (NHS PETT study))

Invitation paragraph

I would like to invite you to participate in the NHS PTSD Experimental Treatment Trial (NHS PETT study). This involves participating in a novel, effective PTSD treatment called Fast Imagery Reversal Script for Trauma-release (FIRST) and a semi-structured exit interview. Before you decide whether you want to take part, it is important for you to understand why the study is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me 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 PTSD. It uses a process where the person is asked to visualise in a way that is intended to be comfortable, non-traumatising, and non-intrusive. At no point will the person be asked to describe the detail of the experiences that lead to their PTSD. The treatment is offered in up to four weekly individual sessions of 90 minutes duration. 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 a) undertake FIRST therapy to ascertain whether it is effective and acceptable for Health and Social Care Workers (HSCWs) and b) to participate in an exit interview, to understand your experience of participating in the NHS PETT study and FIRST therapy.

We hope to develop a FIRST treatment route for health and social care workers with PTSD and to develop an understanding of what their employers consider to be important health benefits for their staff.

Why have I been invited to take part?

You are being invited to participate in this project because you are a health or social care worker who was employed during the Covid pandemic and you have been diagnosed with PTSD by a Mental Health Practitioner (MHP) through the Staff Counselling and Wellbeing Service (SCaWBs) or Post-Incident Pathway. MHPs are trained to assess and support people with common mental health problems in the self-management of their recovery.

What will happen if I take part?

If you decide to take part we will give you the opportunity to ask any questions you may have and then ask you to sign a consent form using MS Forms and complete some questionnaires about yourself, including information about your mood and how you feel about life at the moment. These online forms will take between 25-35 minutes to complete and your responses will be recorded within the WriteUpp NHS secure record patient system that is used within SCaWBs, South London and Maudsley NHS Foundation Trust (please follow this [link](#) to SLaM's personal information and data protection policy).

The therapy sessions:

We will arrange for you to take part in FIRST therapy (up to four weekly sessions) delivered by a MHP working within SCaWBs. These will take place online via Microsoft Teams. Each FIRST therapy session will last 90 minutes. Your first therapy session will be audio-visually recorded using Microsoft Teams recording facilities and we will seek your consent for this. The recording will be encrypted and uploaded in the NHS secure OneDrive folder by your therapist and the original recording deleted. Segments of this recording will be viewed by your therapist's clinical supervisor, Dr Lisa de Rijk, who is a member of the research team and an independent FIRST assessor, Ms Paola Scandurra, for supervisory purposes only. The recording of your therapy session will not be used for any other purpose. As soon as supervision has been completed the recording will be permanently destroyed.

Questionnaires:

You will also be asked to complete a series of questionnaires at the completion of your FIRST therapy and at four weeks after your last FIRST therapy session. Your questionnaires will be collected by the clinical team at SCaWBs and once the data has been pseudonymised, it will be stored within the NHS secure OneDrive folder. The study's Trial Manager, will be given access to this pseudonymised data and she will download and save it directly into a King's College London electronically secure online database. This database will only be accessed by members of the research team to add data and analyse it.

Interview:

You will also be asked to take part in an exit interview. Interviews will last approximately 45 minutes and will take place online (via Microsoft Teams). With your consent, the interview will be recorded via Microsoft Teams recording facilities. In the interview you will be asked questions about why you chose to take part in the NHS PETT study, and your experiences of therapy, the research procedures and the questionnaires used. To support your answers you will be provided with a range of emotional words both positive and negative (for example, happy, curious, anxious, encouraged, nervous, empowered, powerless) to help you explore your thoughts and views

related to your experiences. This is known as emotional touchpoint methodology. If at any point of the interview you wish to pause and take a break, or, to stop the interview completely, that is absolutely fine.

If you would like to attend the exit interview with one family member or friend for emotional support, you are welcome to do so. You do not need to inform the interviewer that you will be attending with a supportive person in advance. The information that you provide will be kept confidential and we ask that your family member or friend also keep the information disclosed in the interview confidential.

The exit interviews focus on your experiences of the FIRST therapy sessions and your participation in the research study. We therefore do not expect you to discuss current practice. However, should you raise issues related to malpractice of NHS staff we will be legally obliged to break confidentiality to report these issues. However, we will discuss this with you in advance.

If you agree to a follow-up interview, the MS Teams' recording will be downloaded into the encrypted and secure King's College London server. The original recording will be deleted. Any accompanying notes will be kept locked in a secure location. To analyse the interviews in detail, we will need to transcribe them (type up the full text of the interview word by word). If you agree, we will send the recording to a transcription company (outside of the University), who will do this task while maintaining confidentiality. The recordings will be uploaded to their secure transcription service, approved by both King's College London and South London and Maudsley NHS Foundation Trust's Research and Development Office. Your name and all identifying details will be removed during transcription. The audio-recording will then be destroyed.

With your consent we will notify your GP that you are taking part in this trial and we will send them a copy of this information sheet.

The clinical team at SCaWBs will be in contact with you throughout your participation in the study both at the end of the therapy sessions and after the study interview. If further support for you is required you will continue your treatment following the usual SCaWBs or Post-Incident clinical pathways.

Do I have to take part?

Participation in the FIRST therapy sessions and the exit interview is completely voluntary. You should only take part if you want to, and choosing not to take part will not disadvantage you in anyway. 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 an online consent form via MS Forms and you will be given a copy of this consent form to keep. To ensure that you are the person signing the consent form we will send the consent form via MS Forms to your NHS email account. Once you have signed and submitted the form we will contact you to confirm your participation in the study.

If you decide to take part and later change your mind, you are free to withdraw from the study at any stage. Your care from SCaWBs or the Post-Incident Pathway will not be affected in anyway if

you decide to leave the treatment or the study. If you decide to withdraw we will retain any data that you have already provided us with.

What are the possible risks of taking part?

We do not anticipate any risks for you participating in the FIRST therapy or exit interviews. However, all talking therapies require people to talk about a problem that they are currently experiencing, and this can feel uncomfortable or upsetting. You may uncover unpleasant memories of an event that had been forgotten. Your therapist is specially trained to help you manage these feelings safely.

Should you become upset, distressed or the FIRST therapy does not work for you, you will be referred back to SCaWBs to continue your treatment pathway. If you should become upset in your exit interview whilst sharing your experiences of the FIRST therapy or of your participation in the NHS PETT study you will be asked if you would like to stop the interview and continue at a later time, or, withdraw from the interview altogether. If you feel you need additional support, the interviewer will inform your existing SCaWBs Clinical Lead who will assess your needs.

All participants will be provided with SLaM's 24-hour helpline, a dedicated Samaritans' telephone number for health and social care workers and details of the out-of-hours peer support service, Solidarity in Crisis. If your mental health was to deteriorate significantly during any point of the study and we had serious concerns about your safety your therapist would notify the Clinical Lead of SCaWBs who would make a clinical decision on what action to take next. This may involve notifying your GP but we would make you aware of this before it happened.

A possible disadvantage of taking part is that it takes time to complete the study questionnaires. Whilst we encourage you to complete all of the questionnaires on each occasion, it is your choice not to answer any question if you feel uncomfortable.

What are the possible benefits of taking part?

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 treatments offered by SCaWBs.

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

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. You will be referred back to the clinical team at SCaWBs who will continue your treatment pathway. 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](https://www.nihr.ac.uk) (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

Dr Emma Rowland,
Phase 3 lead for NHS PETT study,
Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care,
King's College London,
Waterloo Campus,
James Clerk Maxwell Building,
SE1 8WA
Emma.Rowland@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.