INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number HR/DP-23/24-41529

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Full title of study
Efficacy and mechanisms evaluation of FIRST therapy vs waiting list control for Post-Traumatic Stress Disorder (PTSD) in UK military veterans.

Short title
The FIRST PETT study.

Invitation paragraph
King's College London are seeking to trial a new psychological therapy for post-traumatic stress disorder and we would like to invite you to take part.

- The trial is called FIRST PTSD Experimental Treatment Trial (FIRST PETT), and,
- The therapy's full name is Fast Imagery Reversal Script for Trauma-release (FIRST).

Before you decide whether you wish to take part we want to tell you more about what is involved and why we are doing the research.

Please read through the following information and if you want to, please discuss it with your family and friends and GP. If there is anything that is not clear, or, you want more information on any part of it, please just let us know.

What is the therapy?
FIRST is a possible new treatment for PTSD. It is a therapy which is intended to be comfortable, non-traumatising and non-intrusive. Your therapist will teach you all the steps of the process which will begin with you thinking about picture-based stories around everyday events before you move on to working with the trauma memory. During the therapy you will be asked to picture scenes that led up to your traumatic experience but at no point will you be asked to describe the detail of these experiences. The treatment takes place over 3-4 weekly sessions that last approximately 90 minutes.

We have previously worked with ex-servicemen and women affected by PTSD in a smaller trial and have also tested FIRST with health and social care workers working in the NHS. Using our findings from this earlier study we have improved and strengthened the therapy.

What is the purpose of the study?
We will be recruiting 215 military veterans from the United Kingdom to take part in this study. The participants will be randomly allocated to receive either:

a) the FIRST treatment immediately, or
b) to be placed on a waiting list to receive the FIRST treatment after twenty-four weeks.

We want to find out if FIRST therapy can reduce PTSD symptoms, how it works and whether it can be recommended as a standard NHS treatment option in the future.

Why have I been invited to take part?

You are being invited to take part in this study because you are:

- An ex-serviceman or woman of the Royal Navy, British Army or Royal Air Force
- You are living or working in the United Kingdom
- You are at least 18 years old
- You have a diagnosis of, or, you think you may have PTSD (this can be a result of event/s that have taken place either within your military service or outside of it).

What do I do next?

If you are interested in taking part, you can contact us through our website, or, by email and one of our research team will get back in touch by telephone or email to explain more about the study and answer any questions your may have.

How will you know if I have PTSD?

If you decide you would like to take part, we will ask you to sign an online data consent form. Signing this form gives permission for us to look at the answers you give to the two online screening questionnaires we will email you and which will tell us more about your mental health symptoms. Once these have been completed and if they indicate that you may be experiencing PTSD you will be invited to undertake a more detailed eligibility confirmation screening.

Before this takes place the research team will answer any questions you may have and once you are ready we will ask you to sign an online consent form and provide us with your age, sex and ethnic group. We will then arrange an online appointment with one of our assistant psychologists.

The assessment will last approximately 90 minutes. If this assessment confirms that you are likely to be experiencing PTSD symptoms and are ready and able to undertake therapy we will ask you if you still wish to take part in the study and if so, you will join the trial. There is a small chance that your assessment may be observed by the assistant psychologists' supervisor. This observation is to check that they are doing everything correctly. The supervisor will introduce themselves to you at the beginning of the session but will then sit to the side and you will not be able to see them. If you don't want your assessment to be observed, please tick the box on the consent form.

Some people may not be suitable for the study immediately due to personal circumstances or other health problems. Unfortunately, substance misuse or dependency may exclude you from this trial but if these are treated effectively you may be able to join the study a few months' later. Other reasons you may not be eligible to take part could include recent changes in prescribed medication, serious self-harm in the previous month or currently undertaking psychological treatment for your PTSD from another provider.

We are also unable to provide you with a formal diagnosis of PTSD for use outside of the study but all participants will be offered the FIRST therapy.

What happens once I take part?

Once you have joined the trial you will be asked to answer some questions about yourself, your PTSD, your mood and how you feel about your life at the moment. These questionnaires have

been used in other research trials and will include the PCL-5 to find out more about your PTSD symptoms, the Work and Social Functioning scale to assess how you are adjusting to daily living, the PHQ-9 to look at any depression symptoms, the EQ5D-5L which measures quality of life and the Rosenberg self-esteem scale. Examples of questions include: "In the past two weeks, how often have you been bothered by any of the following problems, 'Little interest of pleasure in doing things?', 'Feeling down, depressed, or hopeless", 'Trouble concentrating on things, such as reading the newspaper or watching television'" (from the PHQ-9) and from the Rosenberg self-esteem scale, "Please indicate on a scale from Strongly agree to Strongly disagree, 'At times, I think I am no good at all', 'I am able to do things as well as most other people', 'I wish I could have more respect for myself'". Completing these questionnaires will take approximately 60 minutes. You will also be asked if you wish to take part in some thinking and reasoning activities that will allow us to see if any changes take place in your memory and attention after having FIRST therapy. During the activities you will be asked to read or remember information that will appear on your screen and then answer some questions soon afterwards. These tasks will take place online, will last up to 60 minutes and the research team will be available to support you if necessary.

Once these are completed you will then be randomised into one of two treatment groups. This is decided by a computer system and you have a 50:50 chance of being in either group. You will not be able to change the group that you are allocated to.

(1) Group one will receive FIRST therapy immediately (an appointment will be arranged for you to begin therapy within three weeks);
(2) Group two will receive FIRST therapy in 24-weeks' time (you will be given the date and time of your therapy appointment when you are put into this group).

Whichever group you are placed in we will send your contact details and a summary of your eligibility assessments to Inspire, a mental health charity located in Northern Ireland (https://www.inspirewellbeing.org/). The details about you will be securely looked after by Inspire and only essential people that need to arrange your therapy appointments and look after you properly will have access to it. All the therapists working in our trial are contracted with Inspire and have been fully vetted with counter-terrorist clearance.

We will also ask you to give us details of your GP but we will not contact them without your permission unless we believe you or someone else is at serious risk of harm. We will never do this without informing your first.

If you would like to choose a friend or family member that we can talk to about the study and who can be told the dates of your therapy sessions to remind you when they are taking place, we are happy to do this. We will ask you to indicate this on the consent form and then you will ask them to contact us via our email. This is completely voluntary and you can ask us to remove their name at any time.

The therapy:
FIRST therapy will take place online via Microsoft Teams. Each FIRST therapy session will last approximately 60-90 minutes.

All your therapy sessions 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 into King's secure OneDrive by your therapist and the original recording deleted.

Small sections of these recordings 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, to make sure that therapist is delivering the treatment safely to you. The recording of your therapy session will not be used for any other purpose. As soon as supervision and auditing has been completed the recording will be permanently destroyed. We will never keep any of the recordings for longer than three months.

Questionnaires/activity tasks:
As well as the questionnaires we send you when you first join the trial, we will ask you to complete a couple of the questionnaires at six and 12 weeks after you join the trial, and the original full set of questionnaires will be sent again at 20-weeks. Those in group one will also be asked to repeat the larger set at 52 weeks. Questionnaires can be completed online or over the telephone with one of the research team, whichever way you prefer.

Participants in both groups will be asked to repeat the thinking and reasoning tasks at 12-weeks.

Participants in both groups will be invited to undertake a second shorter Assistant Psychologist's online assessment where they will be asked questions to see if their PTSD symptoms have decreased. This will take place at 20-weeks and should last approximately 45 minutes.

All participants will receive a £15.00 shopping voucher for completing each set of questionnaires at six, twelve and 20 weeks and an additional £15 if they agree to take part in the follow-up AP online assessment (£60.00 in total) and those in group one an additional £15.00 at 52 weeks (£75.00 in total).

Do I have to take part?
Participation is completely voluntary. You should only take part if you want to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

What are the possible risks of taking part?
We do not anticipate any risks for you participating in the FIRST therapy. 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.

All participants will be given a 'contact card' with details of emergency contact numbers in case you need to speak to someone about your mental health outside of office hours. These include the Samaritans (telephone 116 123) and the NHS mental health helpline at **https://www.nhs.uk/service-search/mental-health/find-an-urgent-mental-health-helpline**.

If your mental health was to deteriorate significantly during any point of the study and we had serious concerns about your safety, then we would be obliged to involve your GP to decide how best to manage your condition. We would always let you know before we did this. If this were to happen while you were undertaking therapy, your therapist along with their supervisor would discuss the best steps to take and would include you in any decision-making as appropriate.

If during your therapy sessions or at any other time during the study you were to disclose information about any past, current or future serious illegal activities we may be obliged by law to

inform the appropriate authorities. We would discuss this with you prior to taking action. If, however, we believed there was an immediate risk to yourself or others we would need to act urgently and would not necessarily be able to talk to you first.

A possible disadvantage of taking part is that we ask you to fill in several questionnaires which may take some time. While we would like you to complete all of the questionnaires on each occasion, it is your choice not to answer any questions 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 on the NHS. If you take part our research on FIRST therapy may help other veterans and civilians with PTSD in the future.

As a thank you for completing the questionnaires you will receive a £15 voucher at each questionnaire follow up which means if you complete the study you will be paid a total of £60 for your time if you are in group one, or, £45 if you are in group two.

How will we use information about you?

We will need to use information from you for this research project. Each participant's personal details will be linked to a study code number and recorded in an encrypted and password protected online excel sheet that only three members of the research team will have access to. This file will be held on a secure KCL server. This will allow us to keep the personal information you provide separate from the answers in your health questionnaires.
The information you provide for us in the questionnaires will be entered into the King's Clinical Trials Unit's secure database using your allocated code number. There will be no other information included that could identify you, e.g. your name.

Information you discuss during your treatment sessions will only be available to your therapist and their supervisor. No information that you discuss in your treatment sessions, or your questionnaire data, will be passed to your GP or other NHS health professionals that you engage with. Your therapist will record in clinical notes:

- The times and dates of their meetings with you;
- An overview only of your mental health and wellbeing following every session;
- Your PTSD symptom score.

If you tell us anything that makes us think that you or anyone else is at risk of harm we will have to share this information with your GP. However, we would always discuss this with you before we spoke to anyone else.

The therapy recordings will need to show your face but they will be encrypted and stored using your study code. The recordings will always be kept separate from any other identifiable information we are holding on you. We will not keep the recordings any longer than is absolutely necessary to adhere to therapy fidelity and audit requirements. Once this is confirmed the

recordings will be immediately destroyed. The only three people who will view the recordings are your therapist, their supervisor, Dr Lisa de Rijk, and the study fidelity supervisor, Paola Scandurra.

Once the trial is completed we will delete all identifiable information about you such as your name and contact details. However, we will ask if you would like to receive updates on the trial and a copy of the final study report. If you give us consent for this we will hold your contact details up until we can send you the final report after which we will delete them. If you do not provide consent your personal details will be deleted permanently.

In all our published reports and papers our findings are presented in charts, graphs and tables using numbers and percentages. We do not refer to individual participant's results so all participants remain completely anonymous.

As per university policy, our work may be checked to ensure we are following all data protection laws. Anonymous research data will be held for 10 years in KORDS, King's research data repository.

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

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

- by asking one of the research team at firstpett@kcl.ac.uk
- by sending an email to the Data Protection Officer for KCL, Olenka Cogias info-compliance@kcl.ac.uk)
- by ringing us during office hours 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. You are able to withdraw your data from the study up until the end of the final 20-week data collection expected on 31 January 2027 after which withdrawal of your data will no longer be possible as the database will be locked for analysis.

How is the project being funded?

This FIRST PETT study is being funded by the National Institute of Health Research, Efficacy and Mechanisms Evaluation Programme and the Forces in Mind Trust.

What will happen to the results of the study?

When the study is completed, the results will be written up for publication in a scientific journal and in a report for our two funders (NIHR and FiMT). Findings will also be presented at internal conferences and seminars within King's College London and externally (nationally and internationally). Within these reports and presentations, no participant will be identifiable. 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:

Professor Jackie Sturt
Professor of Behavioural Medicine in Nursing
Florence Nightingale Faculty of Nursing, Midwifery and Palliative Care,
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What should I do 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, jackie.sturt@kcl.ac.uk, telephone, 020 7848 3108

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information: The Chair of the Psychiatry, Nursing and Midwifery Research Ethics Subcommittees, King's College London by emailing: rec@kcl.ac.uk

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