INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number HR-18/19-11320

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of study

PTSD Experimental Treatment Trial (PETT study): Comparing two talking therapies for the treatment of post-traumatic stress disorder in UK military veterans

Invitation Paragraph

I would like to invite you to participate in this research project which is comparing two treatments for Post-Traumatic Stress Disorder (PTSD) for military veterans. We will compare a new treatment called Reconsolidation of Traumatic Memories (RTM) with an existing treatment called Trauma-Focused Cognitive Behaviour Therapy (TF-CBT)**.** Before you decide whether you want to take part, it is important for you to understand why the research 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 Reconsolidation of Traumatic Memories (RTM)?

The RTM 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 5 x weekly individual sessions of 90-120 minutes each session. Research in the USA found PTSD symptoms going away after 2 or 3 sessions.

What is Trauma-Focused Cognitive Behaviour Therapy (TF-CBT)?

TF-CBT is the recommended treatment across the world for PTSD treatment. It involves up to 18 x weekly individual sessions over the course of 3 months. The treatment aims to reduce the patient's sense of current threat by:

1) identifying and changing a person's feelings of threat due to the original trauma/s and/or its aftermath,

2) giving detail to the trauma memory and identifying triggers to the intrusive memories returning, and

3) reducing the use of thinking and behaviour patterns that have not been helpful to the person and that often maintain the problem.

The PETT study has been funded by the Forces in Mind Trust (FiMT), a £35 million funding scheme run by the FiMT using an endowment awarded by The National Lottery Community Fund.

What is the purpose of the study?

The purpose is to see if 60 military veterans in the United Kingdom will join the study and be happy to be allocated randomly to either RTM treatment or the more established TF-CBT treatment. We want to find out if veterans will complete treatment and fill in the research questionnaires to see if the treatment was effective for them. We also want to develop procedures to ensure veterans are safe when having either treatment. All the information will be collected and analysed to help us to run a larger trial to see whether RTM should be offered as a routine treatment for PTSD.

Why have I been invited to take part?

You are being invited to participate in this study because you meet the inclusion criteria of the study, which include:

- Military veterans of the Army, Royal Air Force or Royal Navy
- Living or working in the United Kingdom
- 18 years old or over
- A diagnosis of, or the person suspects they may have, PTSD

What will happen if I take part?

If you decide to take part you will be asked to complete a questionnaire to assess your mental health symptoms. If you have many symptoms of PTSD you will be invited to join the study. A researcher will contact you and help you to complete several questionnaires about you, your PTSD, your mood, how you feel about your life at the moment and any recent medical and social worker appointments. The questionnaire will be shared with Inspire and you will then be given an appointment to have an assessment with an experienced clinical psychologist contracted to Inspire. This will either take place at the Inspire offices in Belfast or online. The assessment will confirm whether you have PTSD and are eligible for the study. Some people may not be suitable for the study immediately if they have other untreated mental health or substance abuse – dependency problems. If these are treated effectively you may be able to join the study a few months later.

You will then be told which treatment group you have been randomly allocated to. All therapists have counter terrorist clearance. There is a 2:1 chance that you will receive the RTM treatment over the TF-CBT. This means you have a 66% chance of being in the RTM treatment group and a 33% chance of being in the TF-CBT treatment group:

(1) Group one will receive RTM. This involves up to 5 weekly treatment sessions, and each treatment session lasting up to 90-minutes.

(2) Group two will receive TF-CBT. This involves up to 18 weekly treatment sessions, each lasting between 60 and 90 mins.

If you agree, we will video record all treatment sessions to make sure the therapist is treating you in the correct way. Small sections of your videos will be watched by your therapist's

clinical supervisor and occasionally up to four other therapists also involved in the study. They will be used to support the training of the therapists and make sure they are delivering the treatment safely to you. Video recording is much better for therapist training but if you don't want this, we can audio record instead.

We will ask you to complete questionnaires again 6 weeks after the approximate time you start treatment and again 12, 20, and 52 weeks later. We can provide some help for you with this. You can complete these questionnaires in person, over the phone or online as you prefer. A researcher or Inspire administrator may access your Inspire clinical records to collect information about your health during the study but the conversations between yourself and the therapist remain confidential.

Three months after you complete the study we may ask to interview you about your experiences of the treatment, and of the research. It is up to you whether you decide to take part in this interview with a researcher. The interview will be audio-recorded and can be in person, over the telephone or by email.

Do I have to take part?

Participation is completely voluntary. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your care from Inspire will not be affected in any way if you decide to leave the treatment or the research.

What are the possible risks of taking part?

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.

TF-CBT is known to be effective in reducing or removing the symptoms of PTSD. In contrast we do not know if RTM may lead to increased symptoms of PTSD. Our research will help answer that question.

All participants will be given a 'contact card' containing the details of the key members of the study team during office hours. It will give you 24/7 contact numbers in case you need to speak to someone about your mental health out of office hours. 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.

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 this research but current research suggests that your PTSD symptoms may improve if you complete the treatment that you are allocated to. If you take part it may help other veterans and civilians with PTSD in the future. As a thank you for completing the questionnaires you will receive £15 voucher at each questionnaire follow up which means you will be paid a total of £60 for your time if you complete the study.

Data handling and confidentiality

Your data will be processed in accordance with the General Data Protection Regulation 2016 (GDPR). All information about you will only be shared within the research team. Your name and contact details will be linked to a study identifier personal to you. This linking information, that can identify you, will be kept in a locked cabinet at a secure Queen's University Belfast, King's College London and Inspire building to which only five members of the research team have access and your confidentiality will be assured. You will have a study identifier for the purposes of analysing the questionnaires.

Besides your therapist, the only people who will have access to your name and contact details will be

- Prof Cherie Armour from Queen's University and her research assistant
- Prof Jackie Sturt from King's College London and her research assistant
- One member of the Inspire team

Your anonymised health and questionnaire data will be directly input 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.

If your therapy sessions take place face-to-face video or audio recordings will be made by your therapist's camera and stored on an encrypted memory stick. If your therapy takes place remotely, i.e. online via a phone, tablet, laptop or computer, your therapist will video or audio record the session and store an encrypted recording on their own device. This will not leave their possession and your therapist will destroy the recording after every session with their supervisor.

If you agree to a follow-up interview, the audio-recording will be stored digitally on a King's College London encrypted device and transferred to a secure server at Queen's University Belfast and King's College London. Your interview will be typed into a transcript by a transcriber contracted to King's College London who will be bound by confidentiality agreements by the college. Your name and all identifying details will be removed during transcription. The audio-recording will then be destroyed.

You may ask that we do not record your interviews, or stop recording at any time, that would be fine. This will not affect your participation in the study or your treatment from Inspire.

Information you discuss during your treatment sessions will only be available to your therapist and their supervisor. However, the therapist is required to inform your GP and/or care coordinator that you are receiving psychological treatment as part of a research project. 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 and your care coordinator. However, we would always discuss this with you before we spoke to anyone else.

All anonymised information about will be kept for five years in case we need to check it.

Data controllers for King's College London and Queen's University may ask to see your information to make sure the research team are following the data protection laws.

Data Protection Statement

The data controller for this project will be King's College London (KCL). The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a 'task in the public interest'. You can provide your consent for the use of your personal data in this study by completing the consent form that has been provided to you.

You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability. Questions, comments and requests about your personal data can also be sent to the King's College London Data Protection Officer Mr Albert Chan info-compliance@kcl.ac.uk. If you wish to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk.

What if I change my mind about taking part?

You are free 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 are able to withdraw your data from the study up until 30th September 2021 after which withdrawal of your data will no longer be possible due to the fact that the database will have been locked for analysis. If you choose to withdraw from the study we will ask for your consent to use the data that you have provided to the point of withdrawal.

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 report to the research funder. We will develop a summary and send it to you using your confidentially stored contact details. Within these reports, no participant will be identifiable. We will use the results to develop a larger trial across the UK to prove whether RTM is effective in treating PTSD in veterans.

Who has reviewed the study?

This research has been looked at and endorsed by experts in military mental health and including veterans and veteran charities on behalf of the research study funder, Forces in Mind Trust. It was also looked and approved by an independent group of people called the Research Ethics Committee at King's College London and Queen's University Belfast to ensure your safety, rights, well-being and dignity are fully protected. REF: HR-18/19-11320

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

If you have general research study questions please contact:

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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.