Participant Information Sheet

Study title: STOP - Successful Treatment of Paranoia: Replacing harmful paranoid thoughts with better alternatives

Funder: Medical Research Council (MRC)

Study site: Institute of Psychiatry, Psychology & Neuroscience (IoPPN)
King's College London
De Crespigny Park
Denmark Hill
London SE5 8AF

Site investigator: Professor Jenny Yiend/ Dr. Pamela Jacobsen

REC reference: 21/LO/0896

You are being invited to take part in a research study at the IoPPN. Before you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read this information sheet carefully and decide if you would like to take part or not.

What is the study about?

Paranoia is a symptom of a number of mental health conditions, including psychosis, and can lead to suffering in work, family and social interactions. Recent thinking suggests that treatments might work better if they focus on one symptom at a time rather than trying to treat the entire illness in one go.

This study tests a mobile app therapy for paranoia called STOP. STOP is a self-managed treatment that has been developed by combining research on biases in paranoia with tried and tested techniques that can change these biases.

STOP involves reading text that could be understood in a paranoid way (such as the stare of a stranger which could be viewed as harmful). The app encourages people to make a

different meaning (such as the stare being viewed as harmless) by using word tasks and questions.

Results from a previous study suggested that a 6-session version of this treatment reduced paranoid interpretations and may reduce paranoia symptoms. Now we want to test a 12-session version which has been enhanced with graphics, animations and audio to make it more user-friendly and engaging. This trial will show us whether there are any benefits of STOP and, if so, how long they last.

Why have I been invited to take part?

You have been invited to take part because you are an adult over the age of 18 and have said that you experience distressing paranoid thoughts. You may have been told about the study by your mental health team or you may have read about the study and got in touch.

Do I have to take part?

No. Participation is entirely voluntary, which means it is up to you to decide whether or not to take part. If you do decide to take part, but later change your mind, you are free to withdraw at any time, without giving a reason, but we will keep information about you that we already have. If you decide not to take part in the study, or later withdraw from the study, this will not in any way affect the normal care you receive.

How do I know if I can take part in the study?

If you experience paranoid thoughts and find these distressing, then you may be eligible to take part. We will check this with you by asking you a few questions about your mood, current treatment and symptoms. It will include hearing descriptions of some short scenarios and telling us what you think they mean by making ratings of sentences we give you (e.g. “on a scale of 1-4, where 4 is very similar, how similar is this next sentence, to the scenario before”).

What will happen to me if I take part?

1. ***Consent***. If you are eligible and decide to take part, you will first be asked to sign a consent form (you will be given a copy to keep along with this information sheet).
2. ***Initial assessment***. Next you will complete the first research assessment, completing questionnaires about your current difficulties, your general well-being and levels of paranoia. This should take around one hour.
3. ***Random allocation***. If you are eligible for the study, you will be randomly allocated to one of three different procedures of varying lengths, some of which we think may help reduce symptoms of paranoia. Random allocation means by chance, a bit like flipping a coin. This means that you have an equal chance of receiving each procedure. This is to make sure the study is a fair test. Once you have been randomised, a researcher will help you to schedule your sessions. Everyone will schedule 12 sessions, but the actual amount of STOP therapy you receive during those 12 sessions will vary according to which procedure you are randomly allocated to. You may be allocated to the 'control group' procedure, which means the sessions are not expected to have any therapeutic benefit.
4. ***Procedures.*** There will be three sets of STOP materials – one for each of the three procedures. STOP consists of 3-line scenarios that are a bit like very short stories. After reading each scenario, participants complete missing words and answer a question about that scenario. The scenarios will be different in content depending on which procedure you receive (1, 2 or 3) and the number of scenarios within each procedure is also different. At each session, we will also ask you how you feel when in some typical social situations (e.g., taking public transport or hearing a group of strangers laugh) and ask you to do some simple word tasks, like creating sentences from jumbled words.
5. ***Final assessment and follow-ups.*** After you have finished all the sessions, the researchers will ask you to complete the same questionnaires and tasks as you did at the start. We will then contact you 18 and 24 weeks after you first registered on the trial to ask you to complete the questionnaires again.

6. ***The treatment and care that you receive will not change if you take part in the study.*** Throughout your involvement in the study all the other care and treatments that you receive will remain the same unless changed by your care team.

Will I be compensated for my time?

Yes, as a reimbursement for your time you will be paid after each of the 4 assessments. You will receive £20 after each assessment and an additional £20 after you complete the final assessment 24 weeks after you first started the study. This means that in total you could receive £100 reimbursement for your time. Reimbursement for travel expenses will be made available, where appropriate.

What are the possible disadvantages and risks of taking part?

The main disadvantage is the possible inconvenience and time commitment required to take part. In addition, the procedures themselves may not be helpful. The procedures will involve talking or thinking about feelings, thoughts or experiences which may be upsetting at times. This is a completely normal part of assessment, and our researchers are very experienced in keeping this to a level you can manage. There are no right or wrong answers and you do not have to answer any questions that you do not want to. You are free to ask the researcher to move on to another subject, skip tasks in the app, or stop the session altogether if you find any of the procedures upsetting. No major adverse effects are anticipated for participants in the study, but we will monitor your well-being throughout the trial by regular check-in phone calls with a trained researcher. It is unlikely that anything in the study would cause any distress; however, if it does you can report it during these calls or contact a member of our research team at STOPclinicalsupport@kcl.ac.uk. If you require more urgent support (for example, you are experiencing feelings of suicide or self-harm), please do not hesitate to contact our study helpline at 07897408675 to connect with a member of our clinical team.

What are the possible advantages or benefits of taking part?

Any of the procedures may have some benefit for symptoms of paranoia, anxiety and depression. The information we collect during the study will help us know whether this is the case and if so, develop the treatment further so that it will be helpful for people in the future.

Will my responses be confidential?

Yes. Everything you tell us will remain completely confidential, within the limits of the law (namely the Data Protection Act). If you tell us anything that puts yourself or someone else at risk of serious harm, or reveals criminal activity, then we must break confidentiality and inform your care team or the relevant authorities. We will discuss this with you first. All information collected from you will be kept confidential and identified only by a unique code that will not personally identify you. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will inform your clinical team/GP of your involvement in the research.

If an adverse event occurs during the study, the relevant regulatory authorities (such as the Medicines and Healthcare products Regulatory Agency, or MHRA) may need to access your study data or medical records to investigate it further.

In case of a reported adverse event or technical issue, basic information about the device you use to complete the STOP sessions (e.g., app version) will be collected from the app to assist with troubleshooting and product improvements. More details can be found in the STOP app Privacy Notice.

An online survey platform (i.e., Qualtrics) will be used to gather some data. Their privacy statement can be viewed here: https://www.qualtrics.com/privacy-statement/.

If you have further questions, please refer to the following website for more information on KCL's statement of the Use of Personal Data in Research: https://www.kcl.ac.uk/research/support/rgei/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research and the King's privacy notice can be viewed here https://www.kcl.ac.uk/terms/privacy.

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, age, gender, ethnicity, clinical diagnostic information and contact details. We may also retrieve data relating to any treatment as usual you receive from local services, which may include pharmacotherapy and/or psychological therapies, from your patient file. People will use this information to do the research or to check your records to make sure that 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.

You will be asked to enter personal data into the STOP mobile app, and researchers will enter data that you provide into an online platform linked to the app. These data will be accessible only to members of the research team and to the software company (Avegen) who have developed and are hosting the app for the duration of the study. You will be asked to read and agree to Avegen's Terms and Conditions and Privacy Policy before using the app.

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 https://www.kcl.ac.uk/research/support/rgei/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research
- by asking a member of the research team
- by sending an email to Albert Chan at info-compliance@kcl.ac.uk (Data Protection Officer, King's College London)

What will happen to the results of the research study?

The research should be completed by the end of 2025. The results of the study will be published in an academic journal and summary findings will be published on the study website https://www.stoptrial.co.uk/. You are welcome to have a copy of the results of the study once it is completed, if you wish. Please let the researchers know. The information (data) collected during this study will also be saved in a publicly available repository called the UK Data Archive so that it may be used by other researchers.

Who is organising and funding the research?

This research is being done as part of a grant awarded by the Medical Research Council (MRC) to Professor Yiend. King's College London is the lead sponsor of the research. South London and Maudsley NHS Foundation Trust (SLaM) is the co-sponsor for the research.

Who has reviewed the study?

This research was reviewed and funded by the Medical Research Council (MRC). People with experience of using mental health services have provided advice on study approaches and documents so that the study will be carried out in the best possible way. All research in the NHS is also looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion (approved) by the London-Stanmore Research Ethics committee on 14/01/2022.

What should I do if I have questions or concerns about the research?

There is a designated study helpline (tel: 07897408675), which you can contact at any time to reach a member of the study team. You should use this number if you feel that that study is affecting you adversely in anyway, for example if your mood appears to be getting worse as a result of taking part in the sessions. You can also find this number on the help page in the STOP mobile app.

If you have a non-emergency concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Alternatively, you can contact the project supervisor, Professor Jenny Yiend (jenny.yiend@kcl.ac.uk), at King's College London on 07977978655.

If you have any questions and would like to speak to someone independent of the study, then please call your nearest Patient Advice and Liaison Service (PALS) office: https://www.nhs.uk/service-search/other-services/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363. If you remain unhappy and wish to complain formally, you can do this through the 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).

For any questions relating to data protection, please contact the Data Protection Officer(s): Albert Chan, info-compliance@kcl.ac.uk (KCL).

This project is supported by the Medical Research Council (Grant Ref: MR/V027484/1)