Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

University of BRISTOL

PARTICIPANT INFORMATION SHEET

Project Title: Trauma-focused therapy for people at-risk of psychosis

We would like to invite you to take part in a study. Before you make a decision about whether you want to take part or not, we would like to tell you a bit about it. One of our researchers will go with you through this information sheet at the first face-to-face meeting, and answer any questions you may have. Please ask us if there is anything that is unclear.

What is the purpose of this study?

Many people at risk of psychosis have had traumatic (extremely upsetting) experiences during their lives. Sometimes memories of these experiences can lead to people hearing voices or seeing things, or developing paranoid ideas, which are the most common symptoms of psychosis. This study is part of a PhD project. It aims to investigate whether it is possible to prevent psychosis in people who are thought to be at risk by using a talking therapy called Eye Movement Desensitization and Reprocessing (EMDR). This therapy helps people deal with traumatic memories by changing how these are stored, and changing any unhelpful negative beliefs that have been caused by the event (e.g. “It was my fault”). Please see the attached leaflet for more information about EMDR.

Why have I been invited?

You have been invited to take part in this study because you may have been experiencing mild symptoms which suggest that you may be at risk of developing psychosis in the future. We aim to recruit 40 people into this study.

Do I have to take part?

No. It is up to you whether or not you take part. If you decide to take part and change your mind later, you can withdraw at any point and without giving a reason. This would not affect the standard of care you receive. However, we would be interested in understanding more about your reasons, as this will help us plan other studies in the future.

What will happen to me if I decide to take part?

If you decide to take part you will be invited to a face-to-face meeting with a researcher to establish if the study is suitable for you. The meeting will be arranged at your convenience either in the Early Intervention Services within the Avon and Wiltshire NHS Trust or at your home. If you want, you can have someone with you when you talk to the researcher.

At this meeting the researcher will tell you more about the study, and you can ask any questions you have about taking part. The researcher will also ask you to fill out two questionnaires about upsetting events you may have experienced in your life and one questionnaire about how these experiences affect you now. This will take about 15 minutes. Your answers will be used to determine if you are eligible to take part in the study. If you are not eligible, you will be thanked for your time and the reasons why you cannot take part will be explained to you.

If the study is suitable for you and you want to take part, you will then be asked to sign a consent form and fill out a questionnaire booklet which will include questions on your symptoms, mood, general functioning, health status, medication and drug use. The researcher will also ask you a few questions about your symptoms. This will take about 60 minutes.

You will then be randomly allocated to receive either EMDR or treatment as usual (TAU). Random allocation is similar to tossing a coin. You cannot pick which group you go into, this will be decided randomly by a computer. We do this because we want to ensure that you have an equal chance of being allocated to either group.

If you are placed in the EMDR group, you will then be offered up to 12 sessions of EMDR therapy. There will be one session per week, with each session lasting approximately 90 minutes, and they will be held at the Early Intervention Services within the Avon and Wiltshire NHS Trust (AWP). With your permission, we will audio-record the sessions. This is so that an assessor (i.e. EMDR consultant/trainer) can listen to a sample of recorded sessions to check the therapist is delivering the treatment as intended. No one other than the EMDR consultant will have access to your recorded sessions. Recordings will be deleted as soon as they have been assessed. You will receive a copy of the recordings so that, if you want, you can listen to your therapeutic sessions when you go home. This will help you remember what you discussed with your therapist. However, you do not have to agree to your sessions being audio-recorded to take part in the study. If you are placed in the TAU group, you will receive the standard care which NHS provides for people at-risk of psychosis.

There will be 3 follow-up appointments for everyone who takes part in the study: at 4, 8 and 12 months after randomisation. At these appointments, you will be invited to a face-to-face meeting with a researcher who will ask you about your symptoms and will ask you to complete a questionnaire booklet which will include questions on your symptoms, mood, general functioning, health status, drug use, medication and use of health services. At 12 months post-randomization we will also access your clinical records from primary and/or secondary care to see what kind of symptoms you experienced and how often you used medical services over the last year. These meetings will take place in the Early Intervention Services or at your home and will take about one hour. The researcher will not be aware of the treatment group that you are in and you will be asked not to tell them.

At the end of your treatment you might be invited to take part in an interview, although you may choose not to if you prefer. You will be given the choice of being interviewed in person or over the phone. The researcher will ask you about how it felt to be part of the study and your views of the treatment you have received. The interview will last up to one hour and with your permission it will be audio recorded. The interview will then be typed up and anonymised so that no one will be able to identify you.

At the end of the study you will continue with the usual care which NHS provides for people at risk of psychosis.

What will happen if I don't want to carry on with the study?
You may withdraw at any point during the study without giving a reason. This will not affect the standard of care you receive. If you withdraw from the study, we will use the data collected from you, up to the point you decided to withdraw.

What are the possible disadvantages of taking part?
If you take part in this study, during treatment or when completing questionnaires, you might be asked about your past experiences. You might find this upsetting. However, all therapists delivering treatment in the study will be experienced therapists and you can choose not to answer a question if you want. The assessments will be carried out at a time and place that suit you best, and you can take a break whenever you need to do so.

What are the possible benefits of taking part?
By taking part in this study, you will help us better understand how to manage individuals who are at risk of developing psychosis. At the end of the study, we will send you a summary of the results.

Will my taking part in the study be kept confidential?
All the information you give as part of the study will be kept confidential and will not be shared with anyone outside the research team. We will ask for your consent to inform your GP/Psychiatrist about your participation in this study. We will not discuss any of the information you give us with your GP or Early Intervention Team unless you tell us something that makes us very worried about the risk to yourself or other people, and even then we would only do this after discussing it with you first. In exceptional circumstances we may need to break confidentiality and inform your GP or Early Intervention Team without your consent if we believe the risk of harm is very high. Results from the study will be published in medical journals, but no individuals or places will be identifiable from this.

Who is organising and funding the research?
This research is being organised by researchers at the University of Bristol. This study is funded by the National Institute for Health Biomedical Research Centre and has been reviewed and given a favourable opinion by the South-West Exeter Research Ethics Committee.

Storage of Information
Your data will be anonymised and stored for 20 years. You will be assigned an identification number which will replace your name in all the documents. All your data will be secured against any unauthorized access.

Expenses and payments
You will be reimbursed for the travel expenses you incurred on travelling to the baseline and follow-up assessments, and you will also be offered £10 for your time at each follow-up assessment.

What if there is a problem?
We do not anticipate any problems occurring for people who participate in this study. However, 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. You can speak directly to Daniela Strelchuk who is responsible for the conduct of the study on xxxx or email

daniela.strelchuk@bristol.ac.uk or you can also talk to Stan Zammit, the lead researcher on the study on 0117 33 14007 or email stan.zammit@bristol.ac.uk

If you remain unhappy and wish to complain formally, you can do this formally through the NHS complaints procedure at: Avon and Wiltshire Partnership Mental Health Trust Complaints Department, Jenner House, Langley Park, Chippenham SN15 1GG. Tel: 01249 468261 or Freephone (from landline): 0800 073 1778

Although extremely unlikely, if during the study you are harmed by someone else's negligence, then you may have grounds for legal action for compensation against the University of Bristol but you may have to pay your legal costs.

If you would like more information

Please contact Daniela Strelchuk who is responsible for the conduct of the study on xxx or email daniela.strelchuk@bristol.ac.uk. You can also speak to Professor Stanley Zammit who is the lead researcher on the study, on 0117 33 14007 or email stan.zammit@bristol.ac.uk.

Thank you for taking the time to read this information. Please contact us if you have any questions or anything else you would like to discuss about the research.