Participant Information Sheet

Targeting distress reduction for patients experiencing distressing voices: A case series evaluating a novel intervention pathway (the Feeling Heard study)

You have been given this information sheet because you are being invited to take part in a research study. It is up to you to decide whether or not you want to take part. Before you decide, it is important that you know about the study. This information sheet will tell you about why the study is being done and what will happen if you decide to take part. Please take as much time as you need to read and understand this information: you can talk about it with other people if you want. If there is anything you don't understand you can speak to a member of the research team. You will find the team's contact details at the end of this information sheet.

Why is the project being done?

The National Institute for Health & Care Excellence (NICE) recommend Cognitive Behaviour Therapy (CBT) for the treatment of psychosis. However, the benefits of CBT for patients can be limited. This problem is being addressed by targeting CBT at one psychosis symptom at a time. A further problem concerns the availability of CBT, as few patients are offered this intervention due to the limited availability of therapists. This problem is being addressed by training more therapists to deliver CBT. We have developed a range of CBT interventions targeted at the single symptom of distressing voice hearing experiences; these interventions can be delivered by therapists with different levels of training. We want to see if it's feasible to offer these interventions in a sequence with interventions delivered by a combination of highly trained therapists and briefly trained therapists. This sequence of interventions will increase the choices of patients and has the potential to enhance benefits.

The purpose of this study is to find out if a sequence of CBT interventions delivered by psychologists with different levels of training can be helpful for patients who hear distressing voices.

This study is an educational project being conducted as part of a student's PhD. Findings of this study would provide helpful information and inform future research into using CBT for people who experience distressing voice hearing.

Why have I been invited to take part?

You have been invited to take part in the study because we understand that you have been given a diagnosis of psychosis and are currently distressed by hearing voices. Maximum of fourteen patients will take part in the study and will be offered the sequence of CBT interventions. All patients will continue to receive their usual care from their care team during the study.

Do I have to take part?

No, it is up to you to decide whether or not you want to take part. Even if you do decide to take part, you can change your mind at any time without having to give a reason. If you decide not to take part, or to stop taking part, this will not affect the care you receive from your care team. If you decide not to take part, no additional information will be collected and any information that has been passed to the research team will be deleted.

What will happen if I decide to take part?

If you decide to take part, you will meet with a researcher to complete an assessment to see if you are eligible to take part in the study. The researcher will be independent from your care team. In the assessment the researcher will ask you to complete a consent form, a questionnaire about your experience of voice hearing and a structured clinical interview.

Are there any reasons why I wouldn't be able to take part?

You cannot take part if you are under the age of 18, hear voices due to an organic cause (e.g., a brain disease such as dementia, or a brain injury) and/or have a primary diagnosis of substance misuse. Receiving this participant information sheet doesn't necessarily mean you will be able to take part in this study. The eligibility assessment will need to be carried out to determine if this study is right for you.

What will happen if I am eligible to take part?

If you are eligible to participate within the study, you will be asked to complete a further assessment with a researcher. This assessment will require you to complete some more questionnaires. After this assessment, you will receive a CBT intervention delivered by a briefly trained therapist. The therapy will involve eight weekly sessions and each session will last for up to an hour.

After this intervention you will have the opportunity to meet with a highly trained therapist for a consultation meeting. This meeting will help you decide what to do next and your choices will include:

- receive no further interventions
- receive another CBT intervention for distressing voices that will be delivered by a highly trained therapist

If you decide to receive another CBT intervention, this will be delivered by a highly trained therapist over 12 one-hour sessions.

Throughout the interventions you will be invited to monthly assessments with a researcher. A final assessment will be conducted when the intervention(s) have been completed.

You will still be able to continue with your usual care in addition to receiving the interventions.

Where would I have to go?

The meetings with a researcher and the intervention sessions will take place in a manner that is suitable for you, e.g., by phone, videocall or face-to-face (at the place where your care team is based).

What are the possible risks of taking part?

Each of the CBT interventions being evaluated within this study is beneficial when offered on its own. We want to see if the amount of benefit can be increased when the interventions are delivered in a sequence.

Your care team including your Lead Practitioner would know that you were taking part in the study.

Talking about voice hearing experiences can be helpful, though it can also sometimes feel difficult or distressing. The therapists will be trained in helping people with distressing voices and would help you to cope with any temporary increases in distress, should this occur. The researchers will be supervised by experienced therapists. You would also be free to access help from your care team, should you wish, and to drop out of the intervention and/or the study, if you wished. If needed, support could also be accessed from the following helplines:

- Sussex Mental Health Line - 0300 5000 1010 (24 hours)
- Samaritans – 116 123 (24 hours)
- Sane Line – 0300 304 7000 (16.30–22.30 daily)

What are the possible benefits of taking part?

By taking part in this study, you will be helping us to learn if CBT interventions for distressing voices are more beneficial when delivered in a sequential manner. This will help mental health services to make decisions about what interventions should be provided for people who hear distressing voices.

What happens when the research stops?

When the research project is finished, all participants will continue to receive their usual care from their care team.

If you have opted to be contacted about future research studies, your contact details will be held by the research team for 24 months. Only members of the research team will have access this data which will be stored within password-protected files on the secure and encryted computer system of Sussex Partnership Trust’s R&D Department.

What happens if something goes wrong?

It is very unlikely that there will be any adverse events associated with taking part in this research study. However, if you are harmed by taking part in this research study, there are no special compensation arrangements. If you are harmed by someone’s negligence, then you may have grounds for a legal action, but you may have to pay for it.

If you would like to make a complaint regarding your treatment and participation in this study please contact:

Sarah Styles
Research and Development Department
Sussex Partnership NHS Foundation Trust
0300 304 0088
researchmanager@sussexpartnership.nhs.uk.

If you would like to speak to someone independent of the research team, for more information or if something goes wrong, you can use the contact details below to speak to the Patient Advice and Liaison Service (PALS):

Patient Advice and Liaison Service
Swandean
Arundel Road
Worthing
West Sussex
BN13 3EP

Tel: **0300 304 2198**
Email: pals@sussexpartnership.nhs.uk

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your NHS number, name and contact details. 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.

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.

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 http://www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to Researchgovernance@sussexpartnership.nhs.uk, or
- by ringing us on 0300 304 0088.

What will happen to the result of the research?

The results of the study will be written-up as a report that will hopefully be published in a psychology journal. These results may also be presented at academic conferences. You will also be asked if you would like a copy of the results when completing the consent form.

Who is organising and paying for the research?

The research is funded by the South-East Network for Social Sciences (SeNSS) and sponsored by Sussex Partnership NHS Foundation Trust. The research is being carried out by researchers from Sussex Partnership NHS Foundation Trust and the University of Sussex.

Who has approved the research?

Research projects like this one can't go ahead without being approved by an NHS Research Ethics Committee. The Ethics Committee checks that the risks associated with the study have been reduced to a minimum and balanced against potential benefits. They also check that patients have been given enough information to make an informed choice about whether or not to take part. This study had been considered and approved by the North West - Preston Research Ethics Committee.

Where can I get more information?

For general information about taking part in research you can contact Sussex Partnership NHS Trusts' research and development department:

research@sussexpartnership.nhs.uk

If you need further information about this specific study, please contact a member of the research team. You can contact the team at any time using the following email address and/or phone number:

voices.clinic@sussexpartnership.nhs.uk
07825 753379

Next Steps:

If you are interested in taking part in the study, please allow yourself at least 24 hours to consider your decision before contacting the research team or before asking for a member of the research team to contact you. This is to ensure that you have had time to consider your decision.

Thank you for taking the time to read this information sheet.