Participant Information Sheet
(patient participants)
(Version 1.0 – 18/10/21)

Increasing access to Cognitive Behavioural Therapy (CBT) for psychosis patients: a randomized controlled trial evaluating brief, targeted CBT for distressing voices delivered by Assistant Psychologists

This study is funded by the National Institute for Health Research for Patient Benefit (study number 203241)

You are being invited to take part in the above study. To help you decide whether you would like to take part, it is important that you understand why the study is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear. You may like to discuss it with others, but it is up to you to decide whether to take part.

Equality & Diversity statement

We strive to ensure that our research materials are as accessible and inclusive as possible regardless of age, disability, gender, ethnicity, religion or sexual orientation. If you have any individual needs concerning this information sheet e.g. larger print, printed on yellow paper, or a different language for instance, please speak to the research assistant (see the end of this information sheet for contact details).

Why is the study being done?

The National Institute for Health & Care Excellence (NICE) recommend CBT for the treatments of psychosis, but only a minority of people with psychosis have the chance to receive CBT. CBT is not available to the majority of people with psychosis because it can be quite long and needs to be delivered by highly trained therapists.

The purpose of this study is to find out if a shorter version of CBT delivered by briefly trained therapists can be helpful for people who hear distressing voices. We will evaluate this form of CBT by comparing it to a control group who will receive no additional interventions.

The findings of this study will 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 are currently distressed by hearing voices. In total, 130 people will take part in the study; 65 will receive the shorter version of CBT delivered by briefly trained therapists in addition to their usual care and 65 will be in a control group who will continue to receive their usual care.

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. Your decisions will not affect the care you receive from your care team.

What will happen if I decide to take part?

If you decide to take part, you will meet with a research assistant to complete a first assessment to see if you are eligible to take part in the study. The research assistant will be independent from your care team. In the assessment the research assistant 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 any of the following reasons apply to you:

- under the age of 18
- hear voices due to an organic cause (e.g., a brain disease such as dementia, or a brain injury)
- have a primary diagnosis of substance misuse
- have completed a full course (minimum of 16 hours) of CBT for psychotic experiences during the past year

Receiving this participant information sheet doesn't necessarily mean you will be able to take part in this study. The first assessment will need to be carried out to determine if you are eligible to take part.

What will happen if I am eligible to take part?

If you are eligible to participate in the study, you will be asked to complete a second assessment with a research assistant. This assessment will require you to complete some more questionnaires. After this assessment, you will be allocated to one of the two groups within the study; one group will receive the shorter version of CBT delivered by briefly trained therapists in addition to their usual care and another group will receive only their usual care. The allocation to different groups is completely random, and no one in the research team has control over the allocation of participants.

Sixteen weeks later you will be invited to meet with the research assistant to complete a third assessment. This assessment will require you to repeat the completion of the questionnaires.

A further twelve weeks later you will be invited to meet the research assistant for a fourth and final assessment. This assessment will require you to repeat the completion of the questionnaires.

To compensate you for your time, you will be paid £20 for each assessment that you complete. The cost of travelling to the assessments can be repaid. All participants can potentially receive up to £80 over the course of the study.

Stage of study	**Compensation**
First assessment	£20 + travel expenses
Second assessment	£20 + travel expenses
Third assessment	£20 + travel expenses
Fourth assessment	£20 + travel expenses

What would happen if I was allocated to receive CBT?

If you are allocated to receive CBT, a therapist will contact you to arrange the therapy sessions. The therapy will involve 10 weekly sessions with a therapist, and each session will last for up to an hour. You will still be able to continue with your usual care in addition to receiving the therapy.

If you are allocated to the group who will be receiving CBT, this therapy will help you to explore different ways of thinking about yourself and your voices, as well as your relationships. The therapy will also help you to learn about different ways to respond to, and manage, distressing voices.

We will ask your permission to audio-record all of the therapy sessions. The recordings of the sessions will be securely stored and used by the therapists and other members of the research team to ensure that the therapy is being delivered as planned.

What would happen if I was not allocated to receive CBT?

If you are allocated to the group who will not be receiving CBT, you will continue to receive your usual care from your care team. Taking part in this study will have no effect on the care you receive from your care team.

Where would I have to go?

The meetings with a research assistant will take place in a convenient location for you. This may be your GP surgery, the place where your care team is based or your home. If you are allocated to receive CBT, the therapy sessions would take place at the base used by your local mental health service. If it is not possible for you to travel to this base, therapy may be offered at your home.

What are the possible risks of taking part?

The CBT being evaluated within this study is being delivered in a novel way, i.e., in a shorter version delivered by briefly trained therapists. For this reason, we do not know whether it will be helpful to participants, and we do not know if it will be helpful for you. By taking part in the study, you will be helping us to learn if CBT is helpful when delivered in this way, and this will help mental health services when they are planning what therapies to offer.

Your care team, including your Care Co-ordinator, would know that you were taking part in the study. If you are offered CBT, you would receive your usual care as well.

Talking about experiences of hearing voices 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 therapists will be supervised by experienced Clinical Psychologists. You would also be free to access help from your care team, should you wish, and to drop out of the therapy if you wished.

If you disclose information that suggests your safety or the safety of others may be compromised, the Assistant Psychologist or Research Assistant will be obliged to pass on this information to your Care Co-ordinator and clinical team.

What are the possible benefits of taking part?

We hope that the CBT will be helpful, but we can't guarantee this. The information we find out from this research will help provide helpful information about whether CBT delivered by briefly trained therapists is helpful for people who hear distressing voices. This will help mental health services to make decisions about what therapies should be provided for people who hear voices.

What happens when the research stops?

When the research study is finished, you will continue to receive your usual care from your care team.

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, 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 3040088
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 speak to your local PALS (Patient Advice and Liaison Service).

[Local PALS contact details]

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 information you gave us and from your medical records 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. All personal information will be destroyed when it is no longer needed.

After the results are published, an anonymised version of the demographics and questionnaire information you gave us, will be made available for reuse and sharing with other researchers outside the research team. This anonymised dataset will be stored on the University of Sussex Research Data Repository.

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 national 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 being paid for by the Department of Health's National Institute of Health Research (NIHR) and is sponsored by Sussex Partnership NHS Foundation Trust. The research is being carried out by researchers from Sussex Partnership NHS Foundation Trust, Pennine Care NHS Foundation Trust, Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust, University of Sussex, University of Surrey and University of Manchester.

Who has approved the research?

This study had been considered and approved by [insert name of Research Ethics Committee]. This committee has checked that patients have been given enough information to make an informed choice about whether or not to take part.

Where can I get more information?

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

[Local R&D contact details]

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:

[Local team email address]

If you would prefer to contact the research team by phone, the name and telephone number of the research assistant is given below. They can be reached during office hours, Monday to Friday:

Research Assistant	[insert name and contact details for RA at this site]

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.

If you would like to take part in the study, or to find out further information please call

Research Assistant	[insert name and contact details for RA at this site]

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