Greater Manchester West NHS
Mental Health NHS Foundation Trust

Individual & Family
Cognitive Behavioural Therapy

Individual & Family Cognitive Behavioural Therapy for Psychosis

INFORMATION FOR PARTICIPANTS

You are being invited to take part in a research study. It is important for you to understand why this research is being done and what it will involve. Please take time to read the information below and discuss it with others, particularly your family members, carers or loved ones. The research assistant who gave you this sheet will be happy to answer any questions that you might have about the information set out below. Feel free to ask if there is anything that is not clear, or if you would like more information. You may wish to read the information sheet more than once, and you should take the time to decide whether or not you wish to take part.

1. What is the purpose of the study?

The National Institute for Health and Care Excellence (NICE) have published guidelines recommending a talking treatment called Cognitive Behavioural Therapy (CBT) with or without family intervention for people who are experiencing difficulties related to unusual experiences and/or beliefs. Currently the evidence suggests that one-to-one Cognitive Behavioural Therapy can be helpful for people with these experiences. Further research is needed to find out whether additional Cognitive Behavioural Therapy (CBT) with key family members or family support members is also beneficial.

2. Why have I been given this information?

We are inviting people to take part if they are experiencing changes in their thoughts, feelings and behaviour, and currently living with (or regularly has contact with) a family member or family support member one. These experiences might include feeling suspicious, hearing things that other people cannot or having unusual beliefs. If you are interested in taking part in the study, we will ask you some questions to make sure the study is right for you.

3. Do I have to take part?

No. As entry to the study is completely voluntary, **it is up to you to decide** whether or not to take part. You should not feel under any pressure to make the decision. If you do decide to take part, you will be asked to sign a consent form. Even after signing you are still free to withdraw at any time and without giving a reason. This will not affect any care you may receive now or in the future.

4. What will happen to me if I take part?

You will be invited to meet one of our researchers at a location that is convenient for you to discuss the study in more detail and answer any questions you may have. If you decide that you wish to participate in the study, you'll be asked to sign a consent form. Following this you'll be asked to meet with a research assistant to talk about your current experiences, mood and your interactions with others. This appointment will take between 1-1.5 hours and you will be able to take breaks or complete the assessment over two visits if preferred.

Following this, we'll arrange to see participants again for two follow-up appointments. These will be planned for 6 months and 12 months after your initial appointment and will be very similar to your initial assessment.

In addition to these appointments you and a family member/carer may also be asked to take part in an intervention called Cognitive Behavioural Therapy (please see below).

5. Will this study involve treatment?

Sometimes, because we do not know which way of treating individuals is best, we need to make comparisons. Therefore, people who take part in this study will be allocated to receive **either** combined individual and family Cognitive Behavioural Therapy plus their usual treatment **or** treatment as usual alone. This allocation is decided at random by a secure telephone randomisation service so each study participant has an equal chance of receiving individual and family CBT or treatment as usual. We will compare those who receive combined individual and family Cognitive Behavioural Therapy from the trial to those who receive only treatment as usual.

We have found that individual Cognitive Behavioural Therapy can be helpful for people who have experienced changes in their thoughts, feelings and the way they see the world. We would like to find out if adding family therapy alongside individual therapy is helpful. A maximum of 25 individual therapy sessions will be available (usually one per week) lasting up to an hour, over a 6 month period. Therapy sessions will give you a chance to focus on whatever is of most concern to you at the time. Alongside this, 4-6 sessions of Cognitive Behavioural Therapy with key family members or family support members will be available. These sessions will focus on making sense of experiences, communication styles, problem solving and goal setting.

We would like to make audio recordings of the therapy sessions so that we can check the quality and content of the sessions. You may have copies of these recordings to listen to between sessions and in the future should you find this useful. The research assistant or therapist will seek your consent to do this before making any audio recordings. These audio recordings will be available for you to listen to if you wish. Any such recordings will be stored electronically on a secure NHS health record and will therefore only be kept for 5 years following completion of the study. .

6. What are the advantages and disadvantages of taking part?

We hope that combined individual and family Cognitive Behavioural Therapy will be helpful to those who are offered it but we can't guarantee this, and not everyone will be offered the therapy as part of the trial. The information we find out from this research may help us to provide better help for people in the future.

If you are allocated to Cognitive Behavioural Therapy, it is possible that talking about some of these issues may be upsetting. You will have opportunities to discuss any concerns you have with the researchers and you are free to withdraw from the study at any point without giving a reason. If you later decide you would like to withdraw from the researchthe data already collected will remain anonymised and be retained for the study, unless you state otherwise. No more data would be collected and this decision will not affect any care you may receive now or in the future.

7. Will taking part in the study cost me anything?

No. The study will only involve your time. We aim to make any appointments as convenient as possible, for example we may see you at your home, at a GP surgery or community venue. In order to compensate you for this and any expenses incurred you will be reimbursed £20 at the initial assessment and also at the 6 month and 12 month follow up assessments (£60 in total).

You will also have the opportunity to be involved in a qualitative study, which uses interviews to better understand an individual's own experience. Even if you take part in the main study you don't have to take part in the qualitative study. The interview will last up to an hour and you will be compensated £10 for the interview if you decide to take part.

8. Who will know I'm participating in the study?

All participant records are confidential and as such are stored electronically on a secure NHS computer systems and will therefore only be kept for 5 years following completion of the study Your records will be identifiable only by a unique personal code. Other people involved in your care such as your GP will be informed of your participation in the study. We will ask for your consent to inform these people.

If you are offered combined individual and family Cognitive Behavioural Therapy the therapist's written notes will also form part of your NHS record. This confidential information cannot be removed even if you choose to withdraw from the study. Like all information on your health record, this is retained for up to 30 years and may be accessed by other people involved in your care. The therapist will also write to your GP to inform them of treatment progress. We will ask for your consent to do this, unless we are concerned about any harm directed to yourself or other people. Even in these circumstances we would always try to inform you that we are planning to write to your GP. These letter(s) will generally include information about the nature of your experiences and about the understanding that you and the therapist have developed

of them. Information on the therapy you have received and your progress will also be included. These letters will form part of your NHS health record and in most circumstances you can receive copies of them if you wish.

Audio recordings will not form part of your NHS health record and will therefore only be kept for 5 years following completion of the study. Apart from the researchers, no one will have access to these recordings.

9. Who will have access to information collected about me during the study?

Your records from the study will be confidential just as your medical records are confidential. Personally identifying information (such as your name and address) will be stored in paper and electronic format and will be stored separately from research data (the questionnaires or interviews you complete). All personally identifiable information will be kept confidentially and securely; information that is in paper format will be kept in a locked filing cabinet in a locked office on NHS premises. Personally identifiable information that is stored electronically will be in a secure database on an NHS computer and is only accessible to specific members of staff who have been granted the necessary privileges, such as individuals from the research team, regulatory authorities or from the Trust where it is relevant to your taking part in this research.

10. What will happen to the results of the research?

The results of the study will be written up for publication in health professional journals and will be presented at national and international conferences. All data will be anonymous and any identifying data will not be published. If you wish to know the outcome of our research, we will be happy to discuss this with you.

11. Who is organising the research?

The chief investigator is Professor Paul French, Associate Director of the Psychosis Research Unit at Greater Manchester West Mental Health NHS Foundation Trust (GMW) who sponsor this study.

12. Who is funding the research?

The IF-CBT study is funded by the National Institute for Health Research's Research for Patient Benefit Programme (RfPB).

NHS
National Institute for Health Research

13. What do I do if I wish to make a complaint?

If you have a concern about any aspect of this trial, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the trial, you can contact the Patient Advisory Liaison Services on 0800 587 4793.

Thank you for taking the time to read this information sheet. It will be helpful to keep this sheet in case you need it for future reference.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Greater Manchester West 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).

If you want to discuss the study further, please contact either:

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