Greater Manchester West NHS
Mental Health NHS Foundation Trust

Individual & Family
Cognitive Behavioural Therapy

Individual & Family Cognitive Behavioural Therapy for Psychosis

FAMILY MEMBERS or Supported Family Members

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 loved ones is also beneficial.

2. Why have I been given this information?

We are inviting family members or supported family membersof people who are experiencing changes in their thoughts, feelings and behaviour to take part in the clinical research trial.

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 asked to sign a consent form and meet with a researcher to complete some questions about their daily activities, mood and use of health and social care services. This will take between 30-40 minutes.

Following this, we'll arrange to see you 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 your family member or loved one 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 providing individual therapy is helpful. The individual will receive a maximum of 25 therapy sessions will be available (usually one per week) over a 6 month period. These therapy sessions will give them a chance to focus on whatever is of most concern for them at the time.

6. What will my involvement be?

Key family members or supported family members such as yourself will be invited to attend Family Cognitive Behavioural Therapy over 4-6 sessions, lasting up to an hour each. These sessions will focus on making sense of the individual's 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.

7. 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 your loved one is 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

8. 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 £10 at the initial assessment and also at the 6 month and 12 month follow up assessments (£30 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.

9. 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. You may wish to inform other people of your participation in the study, such as your GP.

10. 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.

11. 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.

12. 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.

13. 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

14. 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:

Heather Law
(Trial Manager)
0161 358 1402
Heather.law@gmw.nhs.uk

Emma Izon
Research Assistant
0161 358 2140
07584 217 270
Emma.izon@gmw.nhs.uk

Paul French
(Chief Investigator)
0161 358 1395
Paul.french@gmw.nhs.uk