Greater Manchester West
Mental Health NHS Foundation Trust

Randomised Controlled Trial of Cognitive Therapy for Psychosis for people not taking medication

INFORMATION FOR PARTICIPANTS

You are being invited to take part in a research study. This study has been reviewed by the Northwest 6 Research Ethics Committee – Greater Manchester South. It is important for you to understand why the research is being done and what it will involve. Please take time to read the information carefully, and discuss it with others if you wish. Feel free to ask us 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 should take time to decide whether or not you wish to take part.

What is the purpose of the study?
Some people with psychosis continue to experience their difficulties despite taking medication. We know from research that cognitive therapy can improve such difficulties in some cases. Further research is needed to identify if cognitive therapy is helpful for people who are not taking medication. This study will help to address this question.

Why have I been given this information?
We are looking for people who have been offered anti-psychotic medication and have decided that they would not like to take it or have chosen to come off their anti-psychotic medication for whatever reason (e.g. because of side effects), and have not taken medication for the last 6-months or longer. This is because we want to know whether a psychological talking treatment (called 'cognitive therapy') on its own (i.e. without antipsychotic medication) is helpful to people who experience psychosis.

Volunteers should be experiencing psychosis (such as hearing distressing voices or holding unusual beliefs) and be experiencing persistent difficulties. If you fit these criteria, we would like to invite you to enter our study.

Do I have to take part?
No. As entry to the study is entirely 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 in the future. Additionally, if you decide to take part in the study and then later on also decide that you would like to take anti-psychotic medication then that will not be problematic. Furthermore, if you are in the group that receives cognitive therapy (see below for further details), therapy would not stop if you decide to take medication.

What will happen to me if I take part?

You will be invited and met by researchers at a convenient location for you to discuss the study in more detail. Here we will explain the exact nature of the research, explaining our reasons for conducting this study and answer any questions you may have. If you decide that you wish to continue, you will be met again by the researcher and asked to fill in 9 questionnaires and talk to someone for approximately 2½ hours (this can be split over 2 or more sessions if you wish), in order to check that you are suitable for the study.

Following this, if you are found to be suitable, you will be asked to sign a consent form and we will arrange to see you once every 3 months (i.e. 7 times) for a period of 18 months, to monitor how things are for you. These sessions will also take up to 2½ hours. You may also be asked to take part in a psychological talking treatment (called 'cognitive therapy'). In addition, you will be asked if you would like to take part in an interview about your preferences and treatment choices, both at the beginning and end of the study – this interview will be conducted by a service user researcher (someone who has previously used mental health services because of psychotic experiences).

Will this study involve treatment?

Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. Therefore, people will be put into groups and then compared. The groups are selected randomly – i.e. selected by chance. Patients in each group will have a different treatment and these are compared. Half of the people who agree to take part will be offered psychological treatment (cognitive therapy). This will give those people a chance to focus on whatever is of most concern to them at that moment. This treatment will consist of up to 26 sessions of cognitive therapy (usually about one hour each on a weekly basis). The sessions will take place at a convenient location for you such as your home or GP surgery. These appointments will all be within working hours.

Some sessions will be recorded so the quality and content of the therapy you receive can be assessed, to ensure all participants have a similar experience. These audiotapes/cds will be available for you to listen to if you wish (some people find this useful), and afterwards, any such tapes/cds will be kept in a locked cabinet and destroyed at the end of the study.

We hope that the treatment and monitoring will help you. However, this cannot be guaranteed. The information we get from this study may help us in the future treat people with psychosis better.

What are the advantages and disadvantages to taking part?

If you take part in the study, it is hoped that both the treatment and monitoring will be helpful to you. It is possible that they will improve any mental health difficulties that you are experiencing.

However, it is also possible that talking about some of these issues may be upsetting. You will have the opportunity to discuss any concerns you have with the researcher and you are free to withdraw from the study at any point.

What happens if I lose the capacity to consent to continue in the study?

For a variety of reasons people can sometimes lose the capacity to decide whether to continue to take part in a study. This could happen if you become unwell, for example. Although this is an unlikely event, we are obliged to take certain steps to ensure we respect your wishes if this happens.

We will ask you to appoint a Personal Consultee. This is a person who you trust and who knows you well enough to tell us whether you would wish to continue to participate (e.g., friend, family member, carer or someone with Lasting Power of Attorney). However this person cannot be professionally involved in your care.

If you cannot identify a Personal Consultee you can appoint a Nominated Consultee. A Nominated Consultee has the same role as a Personal Consultee although they can be professionally involved in your care (e.g., GP, solicitor). However Consultees must not be connected with the study in any way.

If you cannot appoint a Nominated Consultee we can help you with this. GMW NHS Trust has a Panel of Nominated Consultees who are trained in this role. Please ask the research assistant or your therapist for more information if you require this.

Consultees cannot consent on your behalf. However if you lose capacity they can advise us as to whether you would wish to continue to participate.

We will ask you to consent to us sharing enough information about the study (and your participation) with your Consultee in order to allow him or her to fulfil their role.

To avoid any uncertainty or confusion, we will also ask you to tell us in advance what your wishes are should you lose capacity. We will ask you whether (1) you would wish to continue to participate despite not having the capacity to consent to this, (2) you would wish to withdraw from the study or (3) you would wish to withdraw from the study until you regained your capacity to consent to participate.

If you wished to continue to participate despite not having capacity to consent to this, then we would only continue if (1) you and your Consultee agree to this at the time, (2) your therapist and medical practitioner (GP or psychiatrist) agree that no harm will be caused by doing so and (3) you have clearly stated in advance that you would like to continue (and you have not withdrawn this statement).

For a variety of reasons (e.g., concerns about confidentiality) you may decide you would rather not have a consultee. Although this will not stop you being able to take part, please note that for legal reasons we would therefore have to withdraw you from the study if you lose capacity to consent to continue. Unfortunately we would have to do this despite your expressed wishes now or at the time and despite the possibility that being withdrawn could cause you harm.

Will taking part in the study cost me anything?
No. The study will only involve your time. In order to compensate you for this, and any expenses incurred, you will received a payment of £10 at 5 out of 7 assessments, which will be at the following:- the end of the initial assessment, and at the 3, 6, 9, and 18 month assessments.

Who will know I am participating in the study?
Other people involved in your care such as your Consultant Psychiatrist, Care Coordinator and GP will be informed.

Who will have access to information collected about me during this study?
Your records (written and audio-taped) from the study will be as confidential as your medical records. We will hold some personal information on file at the University. Your personal

details will not be routinely available to the researchers because all forms will be completed using an anonymised personalised identification number and will be kept in a securely locked place. University staff who are not part of the investigation team will not have access to your details.

What will happen to the results of the research?
After the study is completed, we will analyse the results and submit them for publication in a scientific journal. Presentations may also be given at scientific conferences. You will not be identified in any publication or presentation. If you wish to know the outcome of our research, we will be happy to discuss them with you.

Who is organising the research?
The chief investigator is Professor Tony Morrison from the School of Psychological Sciences Department at the University of Manchester. This study has been approved by the Wrightington, Wigan and Leigh Research Ethics Committee.

Please keep this information sheet. Thank you for considering this proposal.

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

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