Recruitment materials

NHS
National Institute for Health Research

FOCUS
Focusing on Clozapine Unresponsive Symptoms (FOCUS): a randomised controlled trial

Greater Manchester West NHS
Mental Health NHS Foundation Trust

FOCUS Trial
(Focusing on Clozapine Unresponsive Symptoms)

INFORMATION FOR PARTICIPANTS

You are being invited to take part in a research study. 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 below carefully, and discuss it with others if you wish. 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 time to decide whether or not you wish to take part.

1. What is the purpose of the study?

The standard medication for psychosis called ‘antipsychotics’ is often helpful for people who experience things like hearing voices or having very strong beliefs that others do not seem to share or agree with. These experiences are sometimes referred to using the term ‘psychosis’. However, some people do not show much improvement with antipsychotic medication and may therefore be prescribed one particular type of antipsychotic medication called clozapine, which can be beneficial. For some people who cannot tolerate clozapine because of side effects or for those who continue to experience some difficulties in regards to psychosis, there is some evidence to suggest that a talking treatment called Cognitive Behavioural Therapy (CBT) can produce improvements. However, further research is needed to identify if CBT is helpful for people who either cannot take clozapine or who continue to experience difficulties when taking this medication. This study will help to address this question.

2. Why have I been given this information?

We are looking for people who have experience of psychosis or a schizophrenia type diagnosis and have either (1) been prescribed clozapine and, despite taking clozapine for at least 12 weeks, still experience mental health problems that negatively affect their way of life or (2) who have been prescribed clozapine but have stopped taking it over the past 2 years due to unpleasant side effects or because it no longer helps their mental health problems as well as it used to. 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. If you would like to bring a friend, a care co-ordinator or a community psychiatric nurse (CPN) with you when you meet with us to discuss the research you are very welcome to do so.

3. 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 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 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 participate in this study you will be asked to sign a consent form. Following this, you will be met again by the researcher and talk to them for about 1 to 1 ½ hours about your current experiences in order to check that you are suitable for this study. If you are suitable you will also be asked to fill in 13 questionnaires this would take approximately 1 hour (this can be split over 2 or more sessions if you wish).

Following this, we will arrange to see you two more times for a follow up appointment. These appointments will be planned 9 months following your initial appointment and then again at 21 months after your initial appointment. These sessions will also take up to 2½ hours. We would also like to contact you via telephone at four time points over the period you are involved in the trial to ask if you would complete a very short questionnaire over the telephone, this would take no more than ten minutes to complete. These telephone appointments would be scheduled at 3 months, 6 months, 13 months and 17 months. You may also be asked to take part in a psychological talking treatment (called ‘cognitive behavioural therapy’), please see section 5 for more information.

After your final (21 month) assessment, you will be asked if you would like to take part in an additional study. This study involves listening to a five minute recording twice while following some instructions about how to respond to the recording and filling in some questionnaire measures. You will also be asked to wear a small device on your finger to measure any physiological response to the task. This should take no more than 30 minutes to complete and you will receive a £10 payment for your time.

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 trial will either be allocated to receive cognitive behavioural therapy (CBT) plus their treatment as usual OR treatment as usual alone. The allocation to either CBT plus treatment as usual or treatment as usual alone is selected randomly – i.e. selected by chance. We will compare those who receive CBT from the trial in addition to their usual treatment with those who receive their usual treatment only (treatment as usual) This means that **half of the people who agree to take part will be offered psychological treatment**

(cognitive therapy) in addition to their usual treatment. This will give those people a chance to focus on whatever is of most concern to them at the time. This treatment will consist of up to 30 sessions of cognitive therapy (usually about one hour each on a weekly basis) over a 9 month period. 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, which is usually between the hours of 9am to 5pm. If you receive CBT, you may be asked at the end of therapy if you would like to talk to one of our researchers about your experiences of CBT. This is so we can learn from you about what it is like to have CBT. The interview will be quite informal, though the interviewer will have certain questions to ask about your experience of CBT, and also to allow you to highlight what's most important for you about the process. The interview can take at a time convenient for you, within general working hours, and can take place either at your home or another location convenient for you. We expect interviews to last for up to an hour, and they will be recorded so that your answers can be accurately typed up. Only specific members of the research team will have access to the recording. Once the interviews are typed up they will be anonymised, meaning no information will be included in the typed version that could identify you personally as the interviewee. If you are eligible for this part of the study you will be contacted by one of the research team and asked if you would like to hear more. If you take part in this additional interview you will receive a payment of £10 as a token of appreciation.

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 confidentially in a locked cabinet and destroyed at the end of the study in December 2016.

If you are receiving the CBT treatment we hope that the treatment and the follow up appointments will help you. However, this cannot be guaranteed. Regardless of whether or not you are allocated to receive CBT, all participants are equally valuable as the information we get from BOTH groups in this study may help us in the future to treat people who experience psychosis more effectively.

If you consent to the study we will access your medical records and we will enter details of the therapy that you may receive onto your medical records. Personally identifying information 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 or University premises. Personally identifiable information that is stored electronically will be in a database called OpenCDMS and is only accessible to specific members of staff who have been granted the necessary privileges. All transmission and storage of participant identifying data complies with current relevant NHS security standards

6. 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. You can also talk to your CPN, GP or psychiatrist about participation in this study and any concerns you may have.

7. **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 the initial appointment and at each of the monitoring appointments, £30 in total. In addition, we will also send you four non cash vouchers over the time you are involved in the trial; two will be sent to you between the baseline assessment and 9 month monitoring appointment and two will be sent to you between the 9 month monitoring and 21 month monitoring appointment. We will discuss with you options for where the vouchers can be redeemed.

Whilst we offer home visits for both the monitoring appointments and therapy, if you would prefer to have appointments somewhere else we can arrange this for you and if this requires you to travel for the appointment, we can compensate any travel expenses incurred.

8. **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.

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

Your information (written and audio-taped) from the study will be as confidential as your medical records. The information that you provide (research data such as questionnaires, interviews and audio recordings) will not be shared with other people i.e. medical staff or people involved in your care unless you say it is OK to do so. The only instance in which information you provide may be shared is if you provide us with information which indicates that either yourself or another person is at risk of danger, in which case we would need to share this information with another person involved in your care such as your care coordinator, psychiatrist or your GP. However, we would ALWAYS discuss this with you beforehand.

10. **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. Results will be used to improve services. You will not be identified in any publication or presentation. If you wish to know the outcome of our research please let us know.

11. **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 Lancaster NRES Committee Northwest.

12. **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 Service or the complaints manager on 0800 587 4793 / 0161 772 3642.

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

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

Professor Tony Morrison (Chief Investigator):
0161 772 4642

Dr Melissa Pyle (Trial Manager):
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Greater Manchester West **NHS**
Mental Health NHS Foundation Trust

CONSENT FORM

Client Identification Number for this study:

Title of Project: **Focusing on Clozapine Unresponsive Symptoms (FOCUS) Trial: a randomised controlled trial**

Chief Investigator: **Professor Tony Morrison**

Name of Researcher:

Please initial box

1. I confirm that I understand the nature of the study proposed, having read and understood the information sheet provided. I have had opportunity to ask questions, and am satisfied with the answers I received. ☐

2. I understand that my participation is voluntary, and that I am free to withdraw from the study at any time. Should I wish to with draw, I understand that I can do so without giving reason, and without my medical care or legal rights being affected. ☐

3. I agree to take part in the study. ☐

4. I agree that you may inform my general practitioner and care coordinator of my involvement in the study. ☐

5. I understand that my medical notes and data collected during the study may be looked at by individuals from the research team, regulatory authorities or from the Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to this information. ☐

6. I agree that you may audio tape sessions as required and understand that I may have a copy of any tapes made. ☐

Subject Name	Date	Signature
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Researcher	Date	Signature
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