North East London NHS
NHS Foundation Trust

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PARTICIPANT INFORMATION SHEET

Research Study on the experience of reviewing antipsychotic medication

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Background

We are carrying out this research to develop and evaluate a Medication Review Tool which aims to help people review their antipsychotic medication more effectively with their psychiatrist. "Antipsychotic" drugs (these are sometimes known as neuroleptics or major tranquilisers) including chlorpromazine (Largactil), trifluoperazine (Stelezine), haloperidol (Haldol or Serenace), sulpiride (Dolmatil), zuclopenthixol (Clopixol), olanzapine (Zyprexa), risperidone (Risperdal), quetiapine (Seroquel), amisulpiride (Solian), ariprirazole (Abilify), clozapine (Clozaril) and depot injections.

In the first part of the study we talked to a number of service users, carers and professionals to help us develop a "Medication Review Tool". In this part of the study, we will test out the Medication Review Tool to see how well it works. Participants will be randomly be allocated to either:

1. Use the Medication Review Tool in their consultations with the psychiatrist or;

2. Continue to receive their usual treatment (and **not** use the Medication Review Tool).

We will then compare the two groups to see if using the Medication Review Tool helped individuals' to highlight their concerns and make decisions about their antipsychotic medication. This is a pilot study which means that one aim of the study is to see if it is worthwhile conducting a larger study in the future.

What is the 'Medication Review Form' and how it will be used?

The Medication Review Tool is a **form** that is designed to help people communicate their views on their antipsychotic medication more effectively to their psychiatrist. The form includes sections on the good/bad effects of antipsychotics, as well as what you would like to change and keep the same about your antipsychotic medication. The form is available on a website which also has more information about different types of antipsychotic medication and side effects.

If you are allocated to use the form, you will be send out some information to you on schizophrenia and psychosis, as well as information about antipsychotic medication. An appointment will then be made where you will fill out the form with your care co-ordinator before your Care Programme Approach (CPA) meeting. The form will then be taken into your CPA meeting and will help highlight your concerns and preferences about your antipsychotic medication to the psychiatrist. Please note that people allocated to their usual treatment will **not** be using the Medication Review form.

The research interview, what will happen?

If you decide to take part in the study, you will be asked to participate in three research interviews. The first interview will take place before you are allocated to a group, the second interview will take place within two to four weeks after your meeting with your psychiatrist. During the interview the researcher will ask you about your experiences of discussing your antipsychotic medication with the professionals and how you found using the 'Medication Review Form'. Lastly, the third interview will take place two to three months after the meeting with your psychiatrist and will focus more on mental health symptoms and side effects of your antipsychotic medication.

All interviews will be conducted by an experienced research assistant and will last for a maximum of one hour, depending on how much you have to say. The interviews can be conducted either over the telephone (where possible), your home or your local mental health service clinic, depending on your preference.

The study will be co-ordinated by an experienced researcher based at NELFT, and other senior staff based in NELFT and in University College London.

Why have I been invited?

We are inviting people to take part if they are currently being treated with antipsychotic drugs.

Do I have to take part in the study?

It is **entirely up to you** whether you choose to participate in the study and you can take as much time as you like to decide whether you want to take part. Participating or not participating in the study **will not affect your medical care or legal rights in any way**.

What will happen if I decide to take part in the study?

If you decide you would like to take part, the project researcher will contact you to discuss any further questions you might have, and to arrange a time and place for an interview. When you meet the interviewer, they will ask you to sign a consent form to show you have agreed to take part. You will be given a copy of this information sheet and a copy of your signed consent form to keep.
The interviews will last for a maximum of an hour, although how long it lasts will depend on how much people would like to say. Part of the interview will be tape-recorded.

Unless you would prefer that we do not, we will let your General Practitioner and your consultant psychiatrist know that you are taking part in this interview study.

What if I change my mind about taking part in the study?

If there is any question you do not want to answer, **you can always decline to answer**. If at any time you decide you do not want to participate or do not want to continue with the interview, **you can always withdraw from the study at any time without giving a reason**. Participating or not participating in the study will not affect your medical care or legal rights in any way.

What's in it for me?

We hope the study will ultimately help to ensure that antipsychotic drugs are used more appropriately. You will also receive £20 towards reimbursing any expenses you may incur, such as travel expenses.

Is what I say confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence. However, if anyone mentions anything that suggests they might be a danger to themselves or to another person, then what they say may be passed on to their care team, in confidence. All research interviews will be coded with a number so that nothing you say will be traceable to you in the final report and if anything you say is quoted, it will be quoted anonymously so that nobody will know who said it. If you mention details which are traceable to you, they will be changed. The questionnaires will only be labelled with a participant number (not your name) and will be stored securely. Any tape recording of your responses will be transcribed into writing and will only be marked with your participant number. All participant data collected during the research will be destroyed within three years of the study.

What if there is a problem?

If you have a concern about any aspect of this study, you can speak to a member of the research team, who will do their best to answer your questions. You can call them on 0300 555 1201. You can also mention it to your care team if you would prefer to. Alternatively, if you are unhappy with the conduct of the researcher, or have any other concerns about any aspect of the way you have been approached or treated during the course of the this study, please contact Fiona Horton, Research and Development Administrator, using the following contact details:

Fiona Horton
Research and Development Administrator
NELFT R&D
1st Floor, Maggie Lilley Suite
Goodmayes Hospital
Barley Lane
Goodmayes
IG3 8XJ

Phone: 0300 555 1200 (dial extension 4485)
Email: Fiona.Horton@nelft.nhs.uk

If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure; details of which are contained within the NELFT complaints procedure which can be located on the Trust website.

What will happen to the results of the study?

The data from the trial will be analysed and written up into a paper for an academic journal about how people found using the Medication Review Tool and whether it was helpful or not. We will also present the results at the NELFT research conference. We will send you copies of the research papers from the study, if you wish to receive them.

We will develop a website were the Medication Review Tool will be available online for the service users to use in their consultations about their antipsychotic medication. The website will also provide more information on different types of antipsychotic medication and their side effects.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the **NRES Committee London – Camden & Islington**. The research has also been scrutinised by the **National Institute for Health Research** who are funding the research. The **North East London Foundation Trust's Research and Development** department have also inspected the research, and will continue to ensure that it is properly conducted.

How do I find out more or register my interest to take part?

Let your care coordinator know that you would like to take part, and he or she can contact the research team on your behalf. Alternatively **you can contact the research assistant, Kiran Azam, on 0300 555 1201 ext. 4485.**

Lastly, I would like to take this opportunity to thank you for considering this study and reading the information sheet.