Contact: David Sher (DPhil student)
Email: david.sher@psych.ox.ac.uk,
Telephone number: +44 (0) 7874129928

PARTICIPANT INFORMATION SHEET

Study Title: The experience of taking antipsychotic medication for paranoia

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve. If you choose to take part there will be a 60 minute audio recorded interview. Talk to other people about taking part in the study if you wish, such as friends or family. Please feel free to ask us, the researchers listed at the end of this information sheet, if anything is unclear or you would like more information.

What is the purpose of this study?

Many people experience mistrustful or suspicious thoughts, including worries that others are deliberately trying to harm them. The technical term for these worries is paranoia. People who experience mistrustful thoughts are often offered medication. We want to understand people's experiences of being offered, taking, or trying antipsychotic medication for mistrustful thoughts, including peoples' thoughts and views about how people's experiences of taking antipsychotic medication can be improved. Although it is known that antipsychotic medication is the main treatment offered to people experiencing mistrustful thoughts, there has been little research on peoples' experience of taking the medication. Therefore, this study will involve interviewing people for around one hour on experiences of being offered, taking, or trying antipsychotic medication. We hope to use this information to identify ways in which such experiences of medication can be improved. This is an educational project being undertaken by David Sher as part of his doctorate.

Why have I been invited to take part?

We want to learn from people who were prescribed antipsychotic medication at a time when they were having strong mistrustful thoughts. Should you wish to take part, we will check with you whether you ever had or currently have mistrustful thoughts and are willing to talk about your experiences of being offered, taking, or trying antipsychotic medication. If you are, you can choose to take part in this research. This study will hopefully include the views of sixteen people. If you have any queries, would like further information about the research study, or would like to participate, you can contact the researcher directly, using the details at the end of this information sheet. If you prefer, and have been referred through your care team, you can speak to your care co-ordinator who will pass on your contact details to the researcher.

Do I have to take part?

No. If the research is suitable for you, it is up to you to decide whether to take part. You will have the opportunity to read through this information sheet and discuss any questions you might have with a member of the research team. It can also be helpful to talk to someone else about whether you would like to participate. If you agree to take part and the meeting is held via video call, telephone, or face-to-face, we will read the consent form to you.. The consent form will be completed by the researcher based on your answers to the consent questions, and it will then be emailed to you. If the meeting takes place face-to-face, you will be given a consent form to complete and sign. A copy of the signed consent form will be given or emailed to you.

You are free to withdraw at any time before or during the interview and up to two weeks after the meeting, without giving a reason and this will not affect your clinical care in any way. If you wish to withdraw from the study, your personal data will be deleted. However, it is not possible to remove the anonymised data you give more than two weeks after your meeting with the researcher, as after this time your anonymised data will be included in the study.

What will happen if I choose to take part?

Before you decide to take part we will check if the study is suitable for you. We will ask a little about your experiences of mistrust and medication and answer any questions. This will take no longer than 5-10 minutes. If you are eligible and choose to take part, then the researcher will arrange a convenient date and time to meet with you to talk about your thoughts and feelings about being offered, taking, or trying antipsychotic medication. We will also ask you for some basic information, such as your age, ethnicity and employment status. During our meeting, we will ask you some questions, for example 'When you took the medication, did you notice any changes in mistrustful thoughts?' and 'When did you first start taking medication?'

The interviews will be conducted remotely, using a video call, or via telephone if you prefer. Should you prefer to meet face-to-face, interviews can be arranged individually and in a private space, either at your local mental health service or at your home. The meeting will last approximately 45 - 60 minutes and will be audio-recorded. We will type up the audio recording. This written version of your interview will be pseudonymised by use of a unique participant identification number. This means we will remove information that can directly identify you, to ensure the information you give does not reveal your identity when it is written up. Occasionally, after your meeting with the researcher, you may be contacted by telephone to check that we have understood you correctly. Your usual treatment will not change at all because of this research.

What are the possible benefits of taking part?

There are no direct intended benefits of taking part in this study. However, we hope that this study will give people an opportunity to discuss their views on medication. Some people may find it helpful to talk about experiences that are important to them. This research will help clinicians and researchers to develop a better understanding of people's experiences of being offered, taking, or trying antipsychotic

medication whilst having mistrustful thoughts. We hope this will reveal ways in which people's experiences of taking antipsychotic medication can be improved.

If you choose to take part in the interview, you will be given £15 to thank you for your participation. We will also reimburse any reasonable travel expenses that you might incur, should a face-to-face meeting take place. In order to make payment we will need bank account data so that we can reimburse you for your participation in the study. Your bank details will be stored securely for 7 years in line with University financial policy. If you prefer, you may receive reimbursement through a voucher.

What are the possible risks of taking part?

We do not anticipate that there are any risks in taking part. However, sometimes people may become upset or uncomfortable when talking about their experiences. You will be able to stop or pause the interview at any time, and you do not have to answer a question if you do not want to. If you become distressed and need access to support during the interview, the researcher will offer to discuss this with you. If you continue to feel upset following your participation, and self-referred to take part in this study, then you would be welcome to speak with a clinical psychologist from the study team (see contact details below).

If you were referred to this study through your care team, a member of your care team will be aware that you are participating in this study and can discuss with you anything from the interview that you may have found upsetting. We can provide contact details for a member of your care team. If you continue to feel upset, you would be welcome to speak with a clinical psychologist from the study team (see contact details below).

What will happen to my information?

The meeting, usually referred to as an 'interview', will be audio-taped and then typed up. Audio recordings of interviews, with no identifying information, may be sent to a professional transcription company. The transcriber will sign a confidentiality agreement and delete their copy of the recording following transcription. The audio file of the interview will be deleted after analysis. The typed version of your interview will be stored securely and pseudonymised. This means we will remove information that can directly identify you and instead use a unique participant identification number.

The researcher will include quotes from the interview to illustrate the opinions of those who have participated when the results of the study are written up. It will not be possible to identify who said what, as each quote will be anonymous. If there are any quotes that you do not want to be used in the study then you can let the researcher know during the meeting. Alternatively, you can let us know by contacting a member of the team at a later time, using the contact information listed at the end of this information sheet. If you lose capacity to consent during the study, any identifiable data will be retained and used.

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly. We will be using

information from you and your interview and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 3 months after the study has finished.

We will store the de-identified research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for five years after the end of the study.

If your clinical care team referred you to this study, the local NHS trust will use your name, NHS number, and contact details to contact you about the research study, and to oversee the quality of the study. They will keep identifiable information about you from this study for in keeping with local policy for retention of medical records.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

Will my taking part in the study be kept confidential?

All information from the interview will be kept confidential. The exceptions to this are where there are significant concerns about a risk to you or other people. In this case, such concerns would be shared with a member of your clinical team. This would be done collaboratively in discussion with you, in line with standard clinical practice. Any disclosures of self-harm will be reported. Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations. These are the only individuals authorised to access the data, besides the study team and transcription company. If you were referred to the study through your care team, then your clinical team and General Practitioner (GP) will be told you are taking part in the study.

What will happen to the results of the research study?

The results will be written up, included in a DPhil dissertation, submitted for publication in a scientific journal and will be presented at academic and clinical conferences. Direct anonymised quotes may be used in future publications. At the end of the interview you will be asked if you would like to receive a summary of the findings and a copy of the final report when this is ready. If you do, we will ask what your preferred contact method and details are; these will be deleted as soon as the findings have been sent to you. The findings of this study will be used to create a basis for future research into exploring potential ways that people's experiences of taking antipsychotic medication can be improved.

Who is funding and reviewing this study?

The study has been self-funded by the lead researcher. Small grants have been received from the Department of Psychiatry at the University of Oxford. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by the North of Scotland (2) Research Ethics Committee (Ref: 22/NS/0145).

What if I have a complaint?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact David Sher (contact details below) or you may contact the University of Oxford Research Governance, Ethics and Assurance (RGEA) office on 01865 616480 or the director of RGEA via email, at ctrg@admin.ox.ac.uk. The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this specific research study. If you wish to contact the PALS team please call 0300 013 4799 or email feedback.cnwl@nhs.net (https://www.cnwl.nhs.uk/have-your-say/feedback-compliments-complaints/patient-support-service/).

Many thanks for taking the time to read this participant information sheet

Please do not hesitate to speak to us if you have any questions or would like to take part.

How can I contact you?

David A Sher
Department of Psychiatry, Warneford Hospital, Headington, Oxford, OX3 7JX
Email: david.sher@psych.ox.ac.uk
Telephone: +44 (0) 7874129928

Professor Daniel Freeman (clinical psychologist)
Department of Psychiatry, Warneford Hospital, Headington, Oxford, OX3 7JX
Oxford Health NHS Foundation Trust
Email: daniel.freeman@psych.ox.ac.uk
Telephone number: +44 (0) 1865 613109

Dr Felicity Waite (clinical psychologist)
Department of Psychiatry, Warneford Hospital, Headington, Oxford, OX3 7JX
Email: felicity.waite@oxfordhealth.nhs.uk
Telephone: +44 (0) 1865 618192