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PARTICIPANT INFORMATION SHEET
Psychosis and the Therapeutic Relationship: A Vignette Study

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you need. If there is anything that is not clear, or if you would like more information, please ask. Contact information can be found further down this document. Unfortunately, we are not able to provide translations of the participant information sheet at this time.

WHAT IS THE PURPOSE OF THIS STUDY?

We know that therapy can be really helpful for people struggling with their mental health**. However, we also know that not all people have good experiences of therapy and that sometimes therapy does not help people get better.** Sometimes, therapy may even make things worse.

To understand why therapy is not always helpful, there has been lots of research on what matters in therapy. What is clear from this research is that the therapeutic relationship between professional and client is more important than anything else. This leads us to ask, "What makes a good relationship between therapists and their clients?", **so that we can do better for our clients in future**.

This study focuses on the therapeutic relationship between a hypothetical therapist and a hypothetical client (you!), presenting with psychosis. **Our goal is to understand how therapists can help people with psychosis feel supported and understood, so that they have better outcomes**.

This study is a doctoral project, being completed in partial fulfilment of the requirements of the Doctorate in Clinical Psychology (DClinPsych) at the University of Oxford.

WHY AM I BEING INVITED?

- You have been asked to participate in this study because you may have experience of psychosis.
- To make our results meaningful, we need to recruit 200-350 adults with experience of psychosis to take part in this study. We hope that these people will be from a wide range of backgrounds, so that the findings will apply to a wide range of people.
- Taking part in this research, or completing the screening questionnaire, should not be taken as evidence that you *do* or *do not* have psychosis. If you are worried about your mental health, you should always speak to a registered health professional.

DO I HAVE TO TAKE PART?

- No. **You do not have to take part in this study**. It is your choice if you want to be involved, and **there will be no consequences for your care or your legal rights, if you decide not to take part**.
- If you do decide to take part, you will be given the option to download a copy of this Information Sheet to keep and be asked to sign a consent form.
- You can stop taking part at any time, without giving a reason.

WHAT WILL HAPPEN TO ME IF I DECIDE TO TAKE PART?

This study takes part online. **It is estimated that it will take you 20-30 minutes to complete.** You can take a break if you need to, but you will not be able to return to your previous responses if you exit the survey, so you should keep the webpage open if you need to stop temporarily.

First, you will be asked to answer some brief questions to determine whether you are eligible to take part. If you are not eligible, you will not be asked for any further information.

If you are eligible for the study, you will then be asked to provide your consent to participate in the study by answering some questions and providing an electronic signature. These questions will check that you understand the purpose of the study, what is required of you, and what will be done with the data you provide.

Then, you will then be asked to provide some information about yourself (e.g. age group, gender, ethnicity). Some of this information will be used to make sure that there is an even spread of different types of people across the experimental groups. It will also tell us about what types of people have completed the study, so we know if our results apply to lots of people, or only a few. Allocation to group will be completed by a computer program that generates random numbers, to determine which condition you are placed in.

Next, you will be asked to read some short descriptions of therapy, describing an interaction between a therapist and a person with psychosis. You will be asked to imagine yourself as the client in this scenario.

After reading the descriptions, you will answer some brief questions about what you have read, how it made you feel and what you thought of the therapist.

At the end of the study, you will be given the option to download your responses and your consent form. You will also be able to provide contact information, if you wish, so that we can keep you updated with that we find. To learn more about how we use your data, please refer to the "WHAT WILL HAPPEN TO MY DATA?" section below.

WHAT SHOULD I CONSIDER BEFORE TAKING PART?

You can take part in this study, even if you are involved in other research studies.

You can take part in this study, whether or not you have ever been in therapy.

You can take part in this study, whether or not you take medication. You should continue taking any prescribed medication as normal.

You may not want to take part in this study, if imagining being in therapy or recalling your own therapy experiences is likely to trigger extreme distress.

You may want to review this Information Sheet by yourself, or with someone you trust, before proceeding with the survey. You can download this document to read offline before answering any questions, if you wish.

ARE THERE ANY POSSIBLE DISADVANTAGES OR RISKS TO TAKING PART?

It is expected that participating in this study will take approximately 20-30 minutes of your time.

There are no known or expected risks of taking part in this study. However, it may bring up difficult emotions for some people. In these cases, we recommend reaching out to people you trust to talk about how you are feeling. You may also wish to stop participating in the study: You can do this at any time. Finally, you may wish to talk to a support service (e.g. Samaritans, Hearing Voices Network). Information about sources of support are listed at the end of this document.

There is a possibility that some people participating in this study do not identify as having psychosis but meet the screening criteria. In these cases, we recommend that the participant seeks advice from a registered healthcare professional as soon as possible. Although the screening tool used in this study is not a diagnostic tool, people scoring 6 points or higher are considered to be at high risk of developing psychosis, if they do not already have psychosis. If you complete the screening questionnaire and are granted access to the study, this means that you will have scored at least 6 points and therefore fall into this category. **If you are worried about what this means for you, we recommend reaching out to your healthcare provider and/or one of the support agencies listed on the debrief form.**

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

It is hoped that the results of this study will help us better understand how people with psychosis experience therapy, so that we can make recommendations about how to improve the therapeutic

experience for this group. This may mean that people like you have a better experience and better outcomes in future. However, there are no, other, direct benefits to taking part.

WILL MY GENERAL PRACTITIONER (GP) BE INFORMED OF MY PARTICIPATION?

Your GP will not be notified about your participation in this study.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

No one will be told about your involvement in the study, unless you want them to know. It is up to you to keep people informed of your involvement if you think that it would be helpful. For example, you may want to tell your therapist about the study if it brings up strong emotions that it would be helpful to discuss in therapy.

You may wish to provide us with contact information, so that we can tell you what we find once the study is completed. This is **optional**. If you do decide to provide contact information, this will be kept separate from answers you provide during the study and stored **for a maximum of two years after study completion**.

All other data you provide will be anonymised, meaning that no-one (including the research team) will be able to tell what answers you have given.

Further information about how your personal data is used is provided in the section "WHAT WILL HAPPEN TO MY DATA?".

WILL I BE REIMBURSED FOR TAKING PART?

Unfortunately, we are not able to pay people for taking part in this study.

WHAT WILL HAPPEN TO MY DATA?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), 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 sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from you for this research project. We will share your information related to this research project with the following types of organisations: universities and relevant NHS Trusts for participants identified through NHS Trusts) .

We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision, survey provision, transcription services etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party

providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions.

This information will include your name, contact details, demographic information (e.g. age group, gender, ethnicity). People will use this information to do the research or to check your records to make sure that the research is being done properly. Responsible members of the University of Oxford, regulatory authorities and the relevant NHS Trusts may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

International Transfers

We may share data about you outside the UK for research related purposes to: (1) the collection and processing of research data via third-party service, Qualtrics. Qualtrics is an international, cloud-based, survey platform that helps researchers collect and analyse research data.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations: survey provision (i.e. Qualtrics).

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing

- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules https://ico.org.uk/for-organisations/report-a-breach.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

After the study ends, the retention period (this means the length of time we keep your data for) will begin and we will keep your data for a minimum of three years, in line with the University Policy on Management of Data. Once the retention period has finished, the study data will be kept in a way that does not identify you.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

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You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK by:

- asking one of the research team:
    - Chief Investigator: Dr Lorna Hogg (lorna.hogg@hmc.ox.ac.uk)
    - Principal Investigator: Miss Holly Dale (holly.dale@stcatz.ox.ac.uk)
- calling us on 07775 544 240
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: https://compliance.admin.ox.ac.uk/research-data.

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

You can change your mind at any time. If you withdraw from the study, we will destroy any contact information you may have provided, unless you state otherwise, but will continue to the use the data collected up to your withdrawal. It will not be possible to identify you from this information. To withdraw from the study after you have completed the survey, please use the contact information on the following page.

WHAT WILL HAPPEN TO THE RESULTS OF THIS STUDY?

Initial findings will be summarised in an informal report, which will be shared with participants who have opted in to receive this information by providing their contact information. We expect to share this report with participants by September 2027, at the latest.

A full report will then be published in a high-impact research journal. A copy of this report will also be submitted to the University of Oxford, on behalf of the Principal Investigator, in partial fulfilment of the requirements for the Doctorate in Clinical Psychology (DClinPsych). We also hope to present at conferences (e.g. British Psychological Society annual conference).

No participant will be identifiable from any report or publication placed in the public domain.

WHAT IF WE FIND SOMETHING UNEXPECTED?

Responses to this survey are deemed unlikely to produce findings of clinical significance for participants of this study.

WHAT IF THERE IS A PROBLEM?

> *If you have a concern about any aspect of this study, please speak with the research team. They will do their best to answer your questions.*

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact Dr Lorna Hogg (lorna.hogg@hmc.ox.ac.uk) or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, 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. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

HOW HAVE PATIENTS AND THE PUBLIC BEEN INVOLVED IN THIS STUDY?

People with lived experience of psychosis were involved in developing this study. In particular, people with lived experience were consulted on the study design – particularly the written descriptions participants will be asked to read – and all recruitment materials. These people will continue to be involved once we have collected data, reviewing anonymous quotes from participants, and offering their perspective on the results.

WHO IS ORGANISING AND FUNDING THE STUDY?

This study is organised by the Principal Investigator, Holly Dale, as part of her doctoral research, and supervised by the Chief Investigator, Dr Lorna Hogg. As a doctoral candidate, the Principal Investigator was allocated a budget to run this study. All costs incurred are covered by the Oxford Institute of Clinical Psychology Training and Research. The University of Oxford is sponsoring this study.

CONFLICTS OF INTEREST

There are no, known, conflicts of interest relating to this study.

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 participants' interests. This study has been reviewed and given a favourable opinion by London Central Research Ethics Committee.

FURTHER INFORMATION AND CONTACT DETAILS:

For further information please contact the Chief Investigator, Dr Lorna Hogg, via email (lorna.hogg@hmc.ox.ac.uk), phone (01865 223771) or letter (Oxford Institute of Clinical Psychology Training and Research, Isis Education Centre, Warneford Hospital, Headington, Oxford OX3 7JX).

Thank you for reading this information and considering taking part in this study.

SOURCES OF SUPPORT

Samaritans – For confidential support when you're struggling with any mental health problem, you can call **116 123** (24hours a day, every day)





Hearing Voices Network – Peer support for people who hear voices, email **info@hearing-voices.org** for information on your local support group

SHOUT - Text **SHOUT** to **85258**, for a free, confidential text service 24hours a day, every day

Switchboard - If you identify as gay, lesbian, bisexual, or transgender, you can call **0300 330 0630** (10AM -10PM)

Local Health Services – If you are concerned about your mental health or are worried about whether or not you have psychosis, we recommend **speaking to your local GP or primary care physician**. They will be able to help you get in touch with a qualified mental health professional for specialist advice and support.