Dr Harriet Martin (Principal Investigator in Camden & Islington)
Tel: 0203 317 7421
Email: harriet.martin@candi.nhs.uk

Dr Emma Černis (Chief Investigator in Oxford)
Tel: 01865 618283
Email: emma.cernis@psych.ox.ac.uk

PARTICIPANT INFORMATION SHEET

Exploring Unusual Feelings

You are being invited to take part in a research study. This information sheet explains why the research is being done and what it would involve for you. Please ask us if anything is unclear or you would like further information. It may also be helpful to talk to someone else about whether you would like to take part.

What is the purpose of the study?

The aim of the study is to learn more about experiences that are sometimes called 'depersonalisation' or 'dissociation'. These are strange feelings and experiences, which can make people feel numb, unreal, detached, or 'spaced out'.

We are interested in knowing if experiences like these are related to other experiences, like having worries about others trying to harm you, or hearing or seeing things that other people cannot see or hear. We are also interested to find out whether these experiences are related to the way people experience emotions, the way people think, and how capable and confident people feel.

Who can take part in the study?

You have been invited because your clinical team have been informed about this study and think that it might be relevant to you. We hope that a thousand patients across NHS England will take part in this study. Adults attending Early Intervention services, or community mental health teams, or on psychiatric wards are being approached to participate in this study. Patients taking part will have had a range of experiences, such as feeling others are against them, thinking that they have been watched or followed, heard voices, thought they had very unusual abilities, or had very muddled thinking.

Do I have to take part?

No: it is up to you to decide whether you would like to take part or not.

You are free not to take part or to withdraw at any time, without giving a reason. This will not affect your clinical care.

What will happen if I decide to take part?

Firstly, we will describe the study, answer any queries you may have and go through this information sheet with you, which is then given to you. If you wish to participate, we will then also give you a consent form to sign. You will be asked to complete 10 questionnaires, which will take about 30 minutes in total. You can complete the questionnaires during this research meeting or you may take them home and return them in the next fortnight via a stamped addressed envelope that we will provide. Please note that the researcher(s) may wish to contact you to remind you to return the questionnaires if you choose to take them home.

The questionnaires ask about: strange feelings and experiences (the experience of them, possible thoughts about them, and reactions to them); fears about other people; hearing or seeing things that other people do not; how capable you generally feel; how you typically think about problems; what you think about negative emotions; how easy you find it to describe emotions; and your levels of happiness. You do not need to have any of the problems listed above to complete the questionnaires, as we want a wide range of people to take part.

Are there any possible disadvantages or risks from taking part?

We do not anticipate that there are any risks involved in participating in the study. However, if you were to feel upset about your participation in this research study then you would be welcome to speak to Harriet Martin, the principal investigator (please see contact details below). If the questionnaires cause distress, please stop and you can discuss any issues with your clinical team. It may be that these questionnaires highlight problems that you have not spoken to your clinical team about before. You are welcome to speak to your clinical team about these, or request for the research assistant to do this on your behalf, if you would prefer.

What are the possible benefits of taking part?

We do not anticipate that there will be any direct benefits from taking part. However, some people find the questionnaires interesting and help them to see that other people have had similar experiences to you. We hope that the information learned through this study will help researchers and mental health staff to develop new talking therapies in future.

Will my taking part in the study be kept confidential?

Your clinical team will be told that you have taken part in the study. All other information will be kept confidential unless you would like your clinical team to know or would like to discuss the questionnaires with them yourself. Responsible members of The University of Oxford and the relevant NHS Trust involved in the research may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

What will happen to my data?

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.

The University of Oxford will be using information from you to undertake this study but will not receive any identifying information about you from Camden & Islington NHS Foundation Trust. Camden & Islington NHS Foundation Trust will collect information from you and your medical records for this research study in accordance with our instructions and will use the minimum personally-identifiable information possible.

Camden & Islington NHS Foundation Trust will keep your name and contact details confidential and will not pass this information to the University of Oxford. Camden & Islington NHS Foundation Trust will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. The University of Oxford will only receive research information without any identifying information. Your name will not appear on any of the questionnaires that you complete. The anonymous questionnaires will be scanned and sent to the University of Oxford by secure email. At the end of the study, the original anonymous paper copies of the questionnaires will be kept for approximately 5 years in the relevant Trust in a locked cabinet in a locked room. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Camden & Islington NHS Foundation Trust will keep identifiable information about you for this research study for 3 months after the study has finished. This excludes research documents with personal information, such as consent forms, which will be held securely at Camden & Islington NHS Foundation Trust for 5 years after the publication of the study results and in your medical notes in accordance with local policy.

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
http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

You can find out more about how we use your information by contacting Dr Emma Černis (see contact details below).

Will I be reimbursed for taking part?

You will be reimbursed £5 for filling in the questionnaires.

What will happen if I don't want to carry on with the study?

Participation is voluntary, and you may change your mind as you complete the questionnaires (or before). Withdrawal will not affect the care you receive from the NHS. Once the questionnaires have been completed, you will have a fortnight to tell us that they cannot be used in the research (since the anonymised data enters the main dataset at this point and can no longer be identified).

What will happen to the results of this study?

The data collected during the study will be written up looking at the total information across all patients, and no individual is identified. The results will be presented in a scientific paper and in conferences. Results from this study will also be included in the CI's doctoral thesis. We will make a summary of the results available for participants at the conclusion of the study. If you wish to receive them, you may request them from your local team.

What if there is a problem?

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, or how your information is handled during the course of this study, you should contact Dr Emma Černis (contact details below) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email 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 research study. If you wish to contact the PALS team please contact Camden and Islington NHS Foundation Trust, Advice and Complaints Service, 1st Floor, East Wing, St Pancras Hospital, St Pancras Way, London, NW1 0PE

How have patients and the public been involved in this study?

In designing this study, we have taken into account patient and service user opinions on previous similar studies.

Who is organising and funding the study?

The study is organised by Dr Emma Černis at the University of Oxford. This study is funded by the Wellcome Trust which is a charity that funds scientific research. The study is sponsored by the University of Oxford.

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 favourable opinion by London - City & East Research Ethics Committee.

Study team contact details:

Dr Harriet Martin
Research Associate

Research Team, Camden & Islington NHS Foundation Trust, 1st Floor, Bloomsbury Building, St Pancras Hospital, 4 St Pancras Way, NW1 0PE
Tel: 0203 317 7421
Email: harriet.martin@candi.nhs.uk

Dr Emma Cernis – Study Lead
Wellcome Trust Clinical Doctoral Fellow and Clinical Psychologist

Department of Psychiatry, Oxford University, Warneford Hospital, Oxford, OX3 7JX.
Tel: 01865 618283
Email: emma.cernis@psych.ox.ac.uk

Professor Daniel Freeman
NIHR Research Professor and Consultant Clinical Psychologist

Department of Psychiatry, Oxford University, Warneford Hospital, Oxford, OX3 7JX.
Tel: 01865 226490
Email: daniel.freeman@psych.ox.ac.uk

Professor Anke Ehlers
Professor of Experimental Psychopathology and Wellcome Trust Principal Research Fellow

Oxford Centre for Anxiety Disorders and Trauma, Oxford University, The Old Rectory, Paradise Square, Oxford, OX1 1TW.
Email: anke.ehlers@psy.ox.ac.uk

Thank you for considering taking part.