ODDESSI: Phase 2 Participant Information Sheet

Open Dialogue: Development and Evaluation of a Social Network Intervention for Severe Mental Illness (ODDESSI)

Introduction

We feel your relative/friend or service user you have been consulted about is unable to decide for himself/herself whether to participate in this research.

To help decide if he/she should take part in this study, we would like to ask your opinion whether or not they would want to be involved. We ask you to consider what you know of their wishes and feelings, and to consider their interests when making this decision. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide that they would have no objection to taking part we will ask you to read and sign the Consultee Consent Form that will be given to you by a researcher from the ODDESSI team. We will then give you a copy of this consent form to keep. We will keep you fully informed during the study so that you can let us know if you have any concerns or you think your relative/friend should be withdrawn.

If you decide that they would not wish to take part in this study, it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of consultee you may seek independent advice.

We will understand if you do not want to take on this responsibility.

Please read the following Participant Information Sheet. It is the same as the information that would have been provided to your relative/friend or service user that you have been consulted about. Please feel free to ask any questions that you may have when reading this information. Contact details can be found out the end of the information sheet.

The ODDESSI study is funded by the National Institute for Health Research (NIHR) Programme Grant for Applied Research RP-PG-0615-20021

We would like to invite you to take part in a research study. A clinician from your mental health service will have contacted you initially and passed on your potential interest in the study to the research team.

Before you decide whether to participate, it is important that you understand why the research is being done and what it will involve. This sheet will give you some information about why we are running the study and what you would be asked to do if you decide to take part. You are very welcome to ask any further questions about the study, or if you find that any of the information provided is unclear.

What is the purpose of the study?

This study is part of a research programme called ODDESSI (Open Dialogue: Development and Evaluation of a Social Network Intervention for Severe Mental Illness). The ODDESSI programme is looking to assess if having an Open Dialogue model of care within the NHS will be more beneficial to you than the current care you receive from your mental health services. To do this, we need to find out if it is possible to run a large-scale research study of Open Dialogue.

Therefore, this phase of the research is looking to see if it is possible to conduct a larger scale study for the next stage of the research. In this phase, the research team is interested in finding out whether or not it is possible to recruit participants for the study and to carry out a range of assessments. We will then use this information to inform the larger trial.

What kind of care will I receive in this study?

All people in this study will receive standard mental health care. Currently, people who experience a mental health crisis may receive support from a Crisis Resolution Home Treatment Team and a Community Mental Health Team. In these services, you will be treated by a team of doctors and other health professionals who will support you in your recovery. Open Dialogue (OD) is an alternative way of supporting people in crisis. It offers the same drug and psychological treatments that a community service provides. In addition, OD has regular meetings with family members and others involved with your care, and provides both crisis and community mental health services within one team. Whether you receive support from a Crisis Resolution Home Treatment Team and Community Mental Health Team or from an Open Dialogue Team will depend on the GP practice you are registered with.

Why have I been invited to take part?

You have been invited to take part in this study because you have been referred to receive crisis care from either an Open Dialogue Team or Crisis Resolution Home Treatment Team. You have expressed interest in taking part in the study to a member of your clinical team.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. Participation is voluntary and you are free to withdraw at any time without explanation and without your care being affected. Data collected up until the

period you withdraw from the study may be used, but only if you are happy for this to be done. Otherwise you may request for your data to be destroyed and no further use is made of it.

What will taking part involve?

Once you have had some time to read this information sheet and decide whether taking part in this study is right for you, a researcher from the ODDESSI team will contact you by telephone to arrange an initial meeting in person. The researcher will go through this information again with you and answer any questions you may have. They will then go through a consent form with you to sign to show you have agreed to take part in the study. Following this, you will go through a series of questionnaires with the researcher, some of which may be recorded. This meeting will take around 1.5hours. Should you wish for your carer to not be contacted, they will not be approached.
Three months following this, you will be contacted by a researcher from the ODDESSI team again to take part in the follow-up interview of this study. The follow-up interview will be similar to the first interview, where you will be asked to sign a consent form and will then go through similar questionnaires with the researcher.

Who will access my medical records?

We will ask for your permission for the research team to access your medical records. This information will be used to understand how your mental health has been whist receiving care from the clinical team. Your information will be kept confidential and will not be passed on to anyone outside of the research team. You will be assigned an individual study ID code to ensure your anonymity in the research.

What are the possible benefits of taking part?

The information gained for this study will help to inform a larger scale trial of the ODDESSI programme. We hope that you will find it interesting to take part in research and talk with a researcher. Additionally, you will be compensated with a £15 shopping voucher for your time taken to participate in this study, once you have taken part in the interview. Another £15 voucher will also be received after completing the follow-up interview. Although it is unlikely for you to incur travel expenses, as the researcher will aim to conduct the interviews at your home, we will reimburse travel costs due to your participation in this research.

What are the possible disadvantages and risks of taking part?

There are minimal risks or disadvantages foreseen with participating in this study. There is a possibility that topics discussed may cause upset or distress. If you do find any topics in the interview upsetting, the researcher will stop the interview and you can continue if/ when you are ready to. You can also stop the interview at any point without this affecting your care. The ODDESSI researcher will be able to support you if you do become distressed in the interview.

What if something goes wrong?

If you are unhappy, or if there is a problem, please feel free to let us know by contacting Prof. Stephen Pilling (s.pilling@ucl.ac.uk)and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with then you should contact the Informal Enquiries Department (also known as Patient Advice & Liaison Service (PALS) at North East London NHS Foundation Trust (information.governance@nelft.nhs.uk). Please provide details of the name or description of the study (so that it can be identified), the researcher(s) involved, and the details of the complaint you wish to make. North East London NHS Foundation Trust provides cover for any negligent harm arising from the design of the research.

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How will my information be kept confidential?

All information provided by you will be kept confidential. All of the discussion information you provide will be anonymised, so that you cannot be identified. We will ensure your personal details will be kept separately from audio-recorded data and stored in a password protected document on a secure NHS computer at North East London NHS Foundation Trust.

Your Open Dialogue or Crisis Resolution Home Treatment Team may know that you are taking part in the ODDESSI study but the information you provide to us will not be shared with your clinical team. However, in the event that you share any information that raises concerns for your safety or the safety of others, or where you report any criminal disclosures, it will be necessary to break this confidentiality agreement. The research team will need to share the information you provided with relevant services or with the authorities

How will my information be managed?

North East London NHS Foundation Trust (NELFT) is the sponsor and research site for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NELFT will keep identifiable information about you.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Shaira Hassan, (shaira.hassan@nelft.nhs.uk), NELFT Research & Development department, Maggie Lilley Suite, Goodmayes Hospital, Ilford, IG3 8XJ. Or visit https://www.nelft.nhs.uk/research .

NELFT will use your name, NHS number and contact details 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. Individuals from NELFT and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in NELFT who will have access to information that identifies you will be people who need to collect and manage your study data and monitor the data collection process. 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.

NELFT will keep identifiable information about you from this study for 10 years.

What will happen to the results of this study?

We intend to use these results to inform the next phase of the ODDESSI study and aim to publish the results in reports and scientific journals. You will not be identified in any report or publication.

Who is organising and funding this study?

The ODDESSI study is led by Professor Stephen Pilling at University College London. This study forms part of a research programme funded by the UK Department of Health through the National Institute for Health Research Programme Grants for Applied Research (RP-PG-0615-20021).

Who has reviewed this study?

The study has been reviewed by the National Institute for Health Research (NIHR) who have funded the study. The study has been granted ethical approval by the [XXX].

Further information and contact details

If anything is not clear or you would like more information please contact the Chief Investigator or the Trial Manager.

Prof. Stephen Pilling (Chief Investigator)
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More information about the study is also available at: http://www.ucl.ac.uk/pals/research/cehp/oddessi

Thank you very much for taking the time to read this information sheet. Please ask if there is anything that is not clear or if you would like more information.
Please take time to decide whether or not you would wish to take part.

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