



Participant Information Sheet

DEcision-making Capacity: Intervention Development & Evaluation in Schizophrenia-spectrum disorder: The DEC:IDES Trial

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact 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.

Do I have to take part?

No, 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. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What is the purpose of the study?

Some people hear or see things that others do not, or believe things that others do not. They may be worried that others want to harm them. Sometimes, these experiences and beliefs can lead to a person being diagnosed with a mental health problem such as schizophrenia or psychosis. Sometimes, psychosis can also affect a person's ability to make their own decisions about treatment – such as taking medication or going into hospital. This means other people, including doctors, may make these decisions instead.

Over the last few years we have been developing new approaches to help people with psychosis make their own decisions about treatment. However, to find out if these approaches are helpful, we need to carry out 'clinical trials'. Trials are a kind of research study that can compare how helpful different treatment approaches are. However, to produce reliable findings, trials often need to include a lot of people and they need to be very carefully designed.

To ensure these larger trials are well-designed, it is common to run several small trials first. These are known as 'feasibility' or 'pilot' trials. Although these small trials cannot tell us whether a new approach is effective, they do provide essential information for designing the larger trials.

The aim of our study is therefore to complete several small trials of new approaches to help people with psychosis make their own decisions about treatment. This will help

us design larger trials of these new approaches, which will help to ensure they produce reliable results.

Why have I been asked to take part?

You have been invited to take part because:

- your doctor has given you a diagnosis of schizophrenia or a related psychotic illness.
- you may benefit from having support to make decisions about your treatment
- you are in contact with mental health services in NHS Lothian.

Please note further assessment is required to confirm whether you are eligible to take part in the study. The researchers will only know this once they have met with you and asked you some additional questions about your mental health and treatment. We will let you know the outcome of this assessment as soon as possible.

What will happen if I take part?

- A staff member from your NHS mental health team will give you this form to read. If you are interested in taking part, then this staff member will ask you for your permission to share your name, contact details and some information about your condition and care with the researcher. This will allow the researcher to begin to assess whether you are able to take part, and to contact you directly.
- With your agreement, the researcher will arrange to meet with you, either on the phone or in person. This will allow you to ask the researcher any questions you like about the study. If you decide you don't want to take part, then the researcher will not contact you again.
- If you remain interested in taking part, then the researcher will contact you no sooner than 2 days after this first meeting, to give you time to think about it before deciding. You can have a longer time if you prefer. The researcher will then invite you to meeting in person, where they will assess in more detail whether you are eligible to take part. They will ask you some questions about your mental health and the treatment you receive. If this assessment confirms you are eligible to take part then the researcher will ask you to sign a consent form. The researcher will check you understand everything on the form before you sign it.
- Sometimes, a person may lose the ability to decide whether or not to continue taking part in a study. This can happen if they become unwell. If this happens to you and you live in Scotland, we will ask your nearest relative, welfare attorney or guardian if they would like to give consent on your behalf to continue with the study. At all times we will follow the legal requirements of the Adults with Incapacity (Scotland) Act 2000. This means you would still be free to withdraw from the study at any time and without giving a reason.
- If you live in England and lose the ability to decide whether or not to continue taking part, we will seek and follow the opinion of your 'Consultee' as to whether you would wish to continue. Your Consultee will be someone who you know and trust. At all times we will follow the legal requirements of the Mental Capacity (England and Wales) Act 2005. This means you would still be free to withdraw from the study at any time and without giving a reason.

- If you decide to take part, then a researcher will meet with you several times over a 24-week period. In each meeting, they will ask you questions about your mental health and the treatment you receive. With your permission, these meetings will be audio-recorded.
- During this 24-week period, you will be invited to enter 1 of 3 clinical trials, based on the type of difficulties you have.
- In each trial, you will have a 50% chance of receiving either 6 weekly 1-hour sessions of therapy to help you with decision-making, or 6 weekly 1-hour sessions of more in-depth assessment of what helps or hinders your decision-making. This will be decided randomly. This means neither the researchers, the therapist or the participant can choose what they will receive. This is important for finding out which approach is most helpful and safe.
- The therapy sessions are designed to help you with one of the following type of difficulty:
 - Low self-esteem
 - Fears about your diagnosis
 - Gathering information before making decisions
- The assessment sessions are designed to gather more information about what helps or hinders your decision-making ability. If you are offered this, then the therapist will offer to meet with you after the study is over to discuss the results of this assessment. They will help you understand why you might have difficulties in decision-making, and what could help you with these. With your permission, we will share this information with your clinical team.
- We will also invite some participants to tell the researcher more about their experiences of taking part in the study. Some participants will be invited to tell us more about any improvements they had in their decision-making. These extra meetings should last around 1 hour and will also be audio-recorded. We may quote some of the things you tell us in any reports we produce, however we will not reveal your name or other information which could identify you.

What are the possible benefits of taking part?

- If you receive help for self-esteem, fears about your diagnosis or using more information before making decisions, then you may experience improvements in these areas.
- Taking part in this study may also help you understand the factors that help or hinder your ability to make decisions about your treatment. This may help your clinical team work out how best to support you in the future.
- The results of this study may also contribute to better mental health care and treatment for people experiencing similar difficulties.

Who is doing this study?

Dr Paul Hutton (Associate Professor, Edinburgh Napier University) is leading the overall study. The research team in Scotland includes Professors Thanos Karatzias, Brian Williams and Jill Stavert, and Associate Professor Nadine Dougall, from

Edinburgh Napier University, Dr Suzanne O'Rourke from University of Edinburgh, Dr Sean Harper and Dr Andrew Watson from NHS Lothian.

The research team in England includes Dr Chris Taylor (Pennine Care NHS Foundation Trust), Dr James Kelly (Lancashire Care NHS Foundation Trust), Dr Peter Taylor (University of Manchester) and Professor Richard Emsley (King's College London).

The study is funded by the Chief Scientist Office (Health Improvement, Protection and Services Research Committee – Response Mode Funding Scheme).

What are the possible disadvantages and risks of taking part?

- The number of assessments you might be asked to take part in ranges from 2 to 3. However some participants will also be invited to 1 or 2 additional meetings. These assessments and meetings can vary in length. This depends on lots of things, including how you are feeling at the time.
- We will offer breaks every 30 minutes and we will work flexibly according to your needs. Efforts will be made to make the meetings as comfortable as possible for you. We will reimburse you for your travel expenses and time, with a £10 Tesco voucher per each of the 2 or 3 assessments. At no point should you feel under pressure to complete the assessments.
- If any aspect of the study causes you distress or you become upset or anxious, this will be communicated to your mental health team so that they can follow up with you.
- If it appears that you present a serious risk to yourself or to other people, this will also be communicated and standard NHS procedures would be followed.

What if there is a problem?

If you live in Scotland and have a concern about any aspect of this study please contact Dr Paul Hutton by phoning 07514 054545 or emailing p.hutton@napier.ac.uk

If you live in England and are receiving care from Pennine Care NHS Foundation Trust, you can contact Dr Chris Taylor by emailing chrisdjtaylor@nhs.net or 0161 2537661.

If you live in England and are receiving care from Lancashire Care NHS Foundation Trust, you can contact Dr James Kelly by emailing j.a.kelly@lancaster.ac.uk or 01772 773498

They will do their best to answer your questions.

If you would like to speak to someone independent from the study, please contact Dr David Carmichael (NHS Lothian) at david.carmichael1@nhs.net or 01506 523748

In the unlikely event that something goes wrong and 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 against your NHS organisation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What happens when the study is finished?

For most participants, their involvement in the main part of the study will end around 24 weeks after they joined it. For some participants (those who joined the study later on), their involvement will last around 8 weeks only. Some participants will also be invited to attend additional meetings with the research team.

At the end of the research we will analyse the data from all the participants and write a report. Your data will be made anonymous as soon as possible and less than three months after your last session. The anonymous data will be kept for 10 years. We may quote some of the things you tell us in any reports we produce, however we will not reveal your name or other information which could identify you.

You can choose to have a summary of the results and outcome of the study sent to you once the research has been completed. This information will also be available on our study website www.decides-trial.com.

Will my taking part in the study be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. With your consent we will inform your GP that you are taking part.

To ensure that the study is being run correctly, we will ask your consent for responsible representatives from the Sponsor (Edinburgh Napier University) and NHS Lothian to access your medical records and data collected during the study, where it is relevant to you taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

Should information come to light from disclosure during the study suggesting that you, another adult or a child is at risk of harm, standard NHS procedures would be followed to address this risk which may limit confidentiality. Any such disclosure would be handled within NHS policy and would protect confidentiality as best possible.

All identifiable information used at the beginning of the study will be destroyed as soon as possible and replaced with anonymous identifiers. All identifiable information will be kept in NHS sites, before being destroyed.

What will happen to the results of the study?

The study will be written up as a scientific journal article. The results will also be presented at conferences. You will not be identifiable in any published results. You can choose to have a summary of the results and outcome of the study sent to you once the research has been completed.

Who is organising the research?

This study is being organised and sponsored by Edinburgh Napier University.

Who has reviewed the study?

The study proposal has been reviewed by the Health Improvement, Protection and Services Research Committee of the Chief Scientist Office, Scotland. A favourable ethical opinion has been obtained from the Scotland A Research Ethics Committee. Edinburgh Napier University and the Research & Development departments of NHS Lothian, Pennine Care NHS Foundation Trust and Lancashire Care NHS Foundation Trust have also reviewed and approved the study.

If you have any further questions about the study, the research team can be contacted using the details below:

Amanda Woodrow (Research Assistant for Scotland) at amanda.woodrow@napier.ac.uk or 07425 900165.

Dr Paul Hutton (Chief Investigator for DEC:IDES) at p.hutton@napier.ac.uk or 07514 054545.

Dr Chris Taylor (Co-Investigator and Principal Investigator for Pennine Care NHS Foundation Trust) at chrisdtaylor@nhs.net or 0161 2537661.

Dr James Kelly (Co-Investigator and Principal Investigator for Lancashire Care NHS Foundation Trust) at j.a.kelly@lancaster.ac.uk or 01772 773498.

If you wish to discuss this study with someone who is not involved in the research, please contact:

Dr David Carmichael (NHS Lothian) at david.carmichael1@nhs.net or 01506 523748.

If you wish to make a complaint about the study please contact NHS Lothian:

Patient Experience Team
NHS Lothian
2nd Floor
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 536 3370
Email: feedback@nhslothian.scot.nhs.uk

Thank you for taking the time to read this information sheet.