



THE DEC:IDES TRIAL
Making decisions about treatment for psychosis



Information for Referrers

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

What is the research about?

Treatment decision-making capacity ('capacity') refers to a person's ability to make decisions about their treatment. It is an important issue for people diagnosed with a schizophrenia-spectrum disorder ('psychosis') because impaired capacity can mean a person does not understand what treatment options are available, or the implications of those options.

In 2018 the National Institute of Health & Care Excellence (NICE) called for clinical trials of interventions such as talking therapies to help people regain capacity. However, running these trials can take several years. One way of reducing this delay is to run several trials at the same time, as part of one bigger trial. This bigger type of trial is also called an 'Umbrella' trial. Although Umbrella trials have been used to accelerate the development of physical health interventions, they have yet to be used in mental health.

The main aims of this study are therefore to find out whether people with psychosis will take part in an Umbrella trial of talking therapies to improve their treatment decision-making capacity (the DEC:IDES trial), and to understand their experiences of participation.

Why is the research being carried out?

Before we can begin a larger version of the DEC:IDES trial, we need to find out whether people with psychosis will want to take part in it. In particular, we need to find out whether they will stay in the trial until it is finished, or whether they will leave early. We also need to understand *why* people might leave DEC:IDES early, so that we can improve it. For these reasons, we are running a smaller version first. This will involve 3 small clinical trials, each testing 1 of 3 different interventions. Each intervention has been designed to help participants resolve a problem which previous evidence suggests may reduce their decision-making ability. One intervention is designed to improve self-esteem, another is designed to reduce negative beliefs about psychosis ('self-stigma') and another is designed to help people with psychosis gather more information before making decisions.

We will record how many people participate in and complete our trial, and we will ask people for their views on what they liked and did not like about taking part. All this information will help us ensure the larger DEC:IDES trial is more acceptable to people with psychosis.

Who is being asked to take part?

In order to take part in the DEC:IDES pilot trial, potential participants need to be:

- a) aged between 18 and 65 years;
- b) able to be interviewed and complete the measures;
- c) diagnosed with a schizophrenia-spectrum disorder (schizophrenia, schizoaffective disorder, delusional disorder, psychosis not otherwise specified, brief psychotic disorder);
- d) presumed or already judged to have impaired treatment decision-making capacity.

They will be unable to take part if they:

- a) have a moderate to severe learning disability;
- b) have psychosis of a predominantly organic origin (e.g. brain injury, physical health condition, epilepsy) or have a primary diagnosis of substance or alcohol use disorder;
- c) cannot understand English sufficiently to engage in conversation without an interpreter.

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

Capacity to consent to medication or a hospital admission is distinct from capacity to consent to research or psychological therapy. This means people who lack capacity to consent to medication or hospital care may still retain capacity to consent to research or psychological therapy. However some people with psychosis will lack capacity to make all these decisions. We do not wish to exclude these people from our trial. Instead, we will follow a specialised consent process, in accordance with legal guidelines in Scotland and England (see 'How do I refer a patient for this research?' for further details).

What will happen to participants if they take part?

Participants will first be invited to meet with a fully trained and supervised research assistant, who will complete an assessment. This will involve interviews and questionnaires, and may take 3 meetings to complete. The results of this assessment will tell us whether a participant mainly has difficulties with self-esteem, self-stigma or information-gathering.

If a participant mainly has difficulties with self-esteem, they will be able to take part in the self-esteem trial. Half of these participants will be offered the self-esteem intervention, whereas the other half will be offered assessment and support. This will be decided randomly. This means the researchers cannot choose who will receive the intervention.

If a participant mainly has difficulties with self-stigma, they will be able to take part in the self-stigma trial. Half of these participants will be offered the self-stigma

intervention, whereas the other half will be offered assessment and support. Again, this will be decided randomly.

If a participant mainly has difficulties with information-gathering, they will be able to take part in information-gathering trial. Half of these participants will be offered the information-gathering intervention, whereas the other half will be offered assessment and support. As with the other trials, this will be decided randomly.

The self-esteem, self-stigma and information-gathering interventions each involve 6 weekly 1-hour therapy sessions, each of which will be provided by a fully trained and supervised psychological therapist. Each intervention will involve the following elements:

- Engagement and listening
- Positive regard and empathy
- Collaboration
- Development of a shared understanding of problem (a 'psychological formulation')
- Provision of written or audio-visual information relating to problem
- Between-session activity for participant
- Provision of structured self-help material relating to problem
- Testing of beliefs related to problems
- Practicing new strategies related to problem
- Development of a shared plan to maintain gains

'Assessment and support' will also involve 6 weekly 1-hour sessions with a psychological therapist. However, in these meetings, the therapist will work in collaboration with the person to complete a more detailed assessment of factors which help or hinder their decision-making capacity. They will provide engagement, listening, positive regard and empathy, but they will not develop a psychological formulation, nor will they provide the person with information relating to their problems. They will also not provide self-help material, or encourage the person to test their beliefs, practice new strategies or develop a shared plan for the future. Once the trial is over, however, the therapist will offer to meet with the person to share the results of the assessment and develop a psychological formulation. This may help them understand why they have difficulties in decision-making, and may help them identify ways of improving it. With the participant's consent, this information will also be shared with the clinical team.

Eight weeks after a participant enters the trial, they will be invited to attend a post-treatment assessment with our research assistant. This will involve the same interviews and questionnaires which the participant completed in the first assessment, and may again take 3 meetings to complete. To ensure the assessments are free from bias, the research assistant will not know which intervention the participant has received. They will ask the participant not to tell them.

Twenty-four weeks after a participant enters the trial, they will be invited to attend a follow-up assessment with our research assistant. This will again involve the same interviews and questionnaires which the participant completed in the first assessment, and may again take 3 meetings to complete. As before, the research assistant will not know which intervention the participant has received.

Some participants will also be invited to meet the research assistant to discuss their experiences of taking part in the DEC:IDES trial, and what they liked and did not like.

We will also invite some of our participants' clinicians to meet with the research assistant to discuss their experiences of the DEC:IDES trial, and what they liked and did not like.

Some participants may show an improvement in the extent to which they appreciate they have a mental health problem, for which they may need help. To fully understand the nature of this improvement, we will invite some of these participants to complete further interviews with the research assistant.

Who is doing this research?

Dr Paul Hutton (Associate Professor, Edinburgh Napier University) is the Chief Investigator and Principal Investigator for Scotland. Co-Investigators from Edinburgh Napier University are Professors Thanos Karatzias, Brian Williams and Jill Stavert, and Associate Professor Nadine Dougall. Dr Suzanne O'Rourke is a Co-investigator from the University of Edinburgh. Co-investigators from NHS Lothian are Dr Sean Harper and Dr Andrew Watson. Co-investigators in England are Dr Chris Taylor (Principal Investigator for Pennine Care NHS Foundation Trust), Dr James Kelly (Principal Investigator for 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).

Who is organising the research?

This study is being organised and sponsored by Edinburgh Napier University. Collaborating institutions and organisations are University of Edinburgh, University of Manchester, King's College London, NHS Lothian, Pennine Care NHS Foundation Trust and Lancashire Care NHS Foundation Trust.

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.

How do I refer a patient for this research?

We encourage referrers to contact us to discuss whether a patient may be eligible. We also encourage referrers to let us know at this stage whether they think their patient currently has capacity to consent to taking part in research.

If a potential participant has capacity to consent, then we will ask their key worker or care coordinator to approach them and provide them with an information leaflet describing the study and what will be asked of them should they wish to participate. Their key worker or care coordinator will be asked to assure them that participation in the study is voluntary and they can change their mind at any time. If the potential participant agrees, then we will contact them directly to arrange to discuss the study further. Please note we will need to consult with the referrer to conduct a risk assessment before meeting any potential participants in person. Potential participants will be given as long as they like to decide to take part, with a minimum period of 48

hours. If the potential participant consents to take part, then we will contact the referrer to complete a referral form.

If a potential participant living in Scotland does not have capacity to consent, then we will ask their key worker to contact their legal representative (i.e., their Guardian or welfare attorney, or their nearest relative). This representative will be asked to give consent on behalf of the person to take part in the study. They will be advised that they are free to decide whether they wish to make this decision or not, and that they are being asked to consider what the person would want, and to set aside their own personal views when making this decision. We will not contact a potential participant or their legal representative until they or their legal representative has informed their key worker that we have permission to do so. If we are given permission to make contact with them, then we will send them and their legal representative information about the study, and offer to discuss it further.

If a potential participant living in England does not have capacity to consent, then we will ask their care coordinator to contact their Nominated or Personal Consultee. This Consultee will be asked for their advice as to whether the person would wish to participate. They will be advised that the researchers will act in accordance with their advice, that they are free to decide whether they wish to offer this advice or not, and that they are being asked to consider what the person would want, and to set aside their own personal views when providing their advice. We will not contact a potential participant or their Consultee until they or their Consultee has informed their care coordinator that we have permission to do so. If we are given permission to make contact with them, then we will send them and their Consultee information about the study, and offer to discuss it further.

If a potential participant living in England or Scotland objects to taking part, or shows distress related to taking part, then we will not include them in the study. If they object or show distress related to participation after they have started taking part, then we will withdraw them from the study.

We 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