Letter of Information to Participants

Project Title: Cognitive Remediation & Social Recovery in Early Psychosis (CReSt-R)

About this information leaflet:

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. This Participant Information Sheet will tell you about the purpose of the research, along with its potential risks and benefits.

There will be a screening process to ensure that you are eligible and that it is safe for you to take part in the study. If eligible, and you agree to take part, we will ask you to sign a consent form. Only the minimum amount of data necessary for the study is being sought. If there is anything that you are not clear about, we will be happy to explain it to you. Please take as much time as you need to read it. You will also be given a copy of this participant information sheet and the consent form to keep. You should only consent to participate in this research study when you feel that you understand what is being asked of you, and you have had enough time to think about your decision.

Description of the study:

This study is researching social cognition and social and occupational functioning in young people aged 16 to 35 living with psychosis. What does that mean?

The word **psychosis** is used to describe symptoms that affect a person's beliefs, thoughts, feelings and behaviours. Psychosis can cause someone to misinterpret or confuse what is going on around them. For example, a person who is experiencing psychosis may hear voices when alone but the voice is heard internally and so is very real to him/her. When someone becomes unwell in this way it is called a psychotic episode. An episode is a period of time when someone is having symptoms of psychosis that interferes with normal day to day life. Psychosis is most likely to occur in late adolescence or in the early adult years.

Social Cognition refers to how we think in social situations i.e. how we interpret, process, store and apply information we are receiving when interacting with other people in social situations.

Social & Occupational functioning refers to how we function in our day to day lives. There is evidence that a person living with psychosis has challenges interacting in their social environment including contact with family, friends and their wider social group. This can make it difficult to participate in everyday activities like going to school, attending work or simply leaving the house to meet a friend or attend an appointment.

What is involved in taking part in the study?

If you decide to take part in the study you will:

1) Complete a **clinical assessment** where you will be asked questions about your mental health. There will also be some neuropsychological tests which will test things like your memory. This session will last for approximately 2 hours.

2) You will have a **one-hour session** with a therapist once a week for 10-12 weeks. Depending on which arm of the study you are in, these sessions will focus on supporting you in coping with daily life in a variety of ways.

3) After **10-12 weeks** of meeting with the therapist you will repeat the clinical assessment and neuropsychological tests.

4) After **3 months** we will invite you to complete a final session where again we repeat the neuropsychological tests. By repeating these tests, we will have the opportunity to measure your activity over time.

Each participant will be reimbursed €20.00 per assessment session (3 sessions in total).

Risks

There are no risks associated with participating in this study. Your usual treatment team will recommend you to participate in the study. If at any time during the study you become unwell you can withdraw and we will let your treatment team know.

Benefits

We cannot predict improvements in individual participants. You will have the opportunity to provide feedback on your experience of the intervention to assist with developing future interventions.

General Data Protection Regulation

This study is guided by the EU General Data Protection Regulation (GDPR) which came into force in May, 2018. Your identity will remain confidential throughout and after the study. The signed consent form will be stored on site by the principal's investigator and only members of the research team will be granted access to the form. A reference number will be assigned to the participant's name upon participation in the study as part of ensuring confidentiality. This number will be used to identify all material collected from you. Only the research team will have access to the anonymised data from the experiment. These members are bound by a contractual code of secrecy that means that members would face disciplinary action who disclose or facilitate unauthorised access to identifiable data. All other data from the study visits (i.e. the clinical assessment visit, the neuropsychological assessment visit) will be safely stored with Prof. Gary Donohoe, who leads the study, and Emma Frawley at NUI Galway. This data will be analysed at a group level and this will be used in academic publications and presentations. Data will not be analysed at an individual level and it will not be possible to identify individual participants. At the end of this study (After 4 years) the data will be destroyed. If you have any further questions in relation to GDPR please contact the research team (Contact details below).

Conditions and withdrawal

It is entirely up to you if you would like to participate in this study. As a participant of this study, you may voluntarily decide to withdraw at any time without any consequences. In the event that you need to withdraw you only need to contact the research team via email or by phone. A decision not to take part or to withdraw from the study at any time, will not affect your rights in any way and will not impact on your current medical care.

Research Ethics Committee

This study has been approved by the Research Ethics Committee at Galway University Hospital. No persons, who are carrying out this research have a link to the Committee.

Lawful basis for the research

This health research is carried out based on the General Data Protection Regulation (Article 6 and Article 9).

Re-Contact

It is optional for you to be contacted by the same research team for future studies. If you agree the research team will contact you according to your preference via phone or email. If you agree to be contacted for future studies, you do not give consent to future studies. This option does not impact on the participation of this study or any future study.

For further information, please contact: CRESTR@nuigalway.ie or telephone 086 852 7199

The CReSt-R Team:

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