Letter of Information

Project Title: Social Cognitive Interventions following Adverse early Life Experiences.

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.

Purpose of the study:

This study is researching ways to improve social thinking (known as social cognition) in people who have experienced early childhood adversity, in a way that is of benefit for social and occupational function.

Social thinking refers to our ability to take in and process information relevant to social situations, including recognizing emotions in another person, considering another person's perspective, and understanding social interaction.

Early life adversity means having the experience of events involving considerable difficulties or challenges for a child or young person before the age of 18. These often include the experience of neglect (e.g. physical or emotional neglect) or abuse (e.g. physical, emotional, or sexual abuse). These can also include other experiences such as the death of a parent or the experience of bullying.

Social & Occupational functioning refers to how we function in our day to day lives. There is evidence that a person who has experienced adversity in childhood can have 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 **assessments** that involve neuropsychological tests which will test things like your memory. In addition, you will be asked questions about your mental health and your day-to-day life. As part of this you will be asked about your own childhood experiences. This session will last for approximately 2 hours. You will complete these assessments at the **beginning of the study, 6 weeks later, 12 weeks later, and finally 18 weeks later.**

2) The **intervention** will consist of therapy sessions with a trained therapist that will be delivered in person and will incorporate the use of virtual reality (VR). These sessions will focus on supporting you in coping with daily life by seeking to improve your social cognition – your ability to process social information.

To do this we will seek to train an aspect of cognition known as *metacognition* – which means learning about how we figure things out. In simply terms metacognition involves learning to know when you know, knowing when you don't know, and knowing what to do when you don't know. A good example of metacognition is knowing that we need to make a shopping list before we go to the supermarket so that we remember what to buy. Applied to social cognition, this might mean knowing that you need to closely observe another person's face and tone of voice in order to understand what they are feeling. To train meta-cognition in social settings we will use virtual reality googles to provide a simulation of everyday settings in which to practice (e.g. a doctor's waiting room, a coffee shop).

If you agree to take part, you will have 8 sessions which will be delivered over eight weeks, one per week.

3) At the end of your participation in the study, you will be invited to take part in an interview to provide the research team with feedback on your experience of taking part in the study.

Risks

There are no risks associated with participating in this 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). 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. All other data from the study visits will be safely stored with Prof. Gary Donohoe. 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. If you have any further questions about GDPR, 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.

Research Ethics Committee

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

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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 the Principal Investigator:

Prof. Gary Donohoe

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