



OLLSCOIL NA GAILLIMHE
UNIVERSITY OF GALWAY



University Hospital Galway
Ospidéal na h-Ollscoile, Gaillimh
GALWAY UNIVERSITY HOSPITALS

PARENT INFORMATION SHEET

Title of Project

Virtual Reality Distraction for Needle-Related Pain in Children and Adolescents with Autism Spectrum Disorder (ASD) with or without a Co-Occurring Intellectual Disability (ID): A Feasibility Study

Invitation

You and your child are invited to take part in a research study exploring the use of Virtual Reality (VR) as a method of distracting children and adolescent's attention from pain during blood draw procedures. This study is being conducted by Conor O'Neill, a student on the Masters in Applied Behaviour Analysis programme at the University of Galway, under the supervision of Prof. Brian McGuire and Dr. Helena Lydon.

Before you decide, it is important that you understand why the research is being done and what it will involve. This *Participant Information Sheet* tells you about the purpose, risks and benefits of this research study. If you agree to take part, we will ask you to sign a *Consent Form*. 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 this information. You should only consent to participate in this research study when you feel you understand what is being asked of you and you have had enough time to think about your decision. Thank you for reading this.

Purpose of the Study

This study will look at how effective virtual reality is at helping to distract children/ adolescents with autism spectrum disorder (ASD) with or without a co-occurring Intellectual

Disability (ID) during a needle-related procedure (i.e., a blood draw). We are interested to find out if virtual reality distraction in children/adolescents with ASD/ASD-ID is feasible and more effective in reducing needle-related pain during a blood draw procedure than treatment as usual.

Taking Part - What it Involves

Do I have to take part?

Participation in this research is voluntary and it is up to you to decide if you and your child would like to take part. If you do decide that you and your child would like to take part, you will be given this *Information Sheet* to keep and be asked to sign a *Consent Form*. *Assent* will also be sought from your child and will involve an on-going process regarding their acceptance and willingness to engage with the Virtual Reality headset or have the researcher present during their blood draw. If you and your child decide to take part, you are both still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or decision not to take part, will not affect your rights or your access to your blood draw in any way.

What will happen to me if I take part?

Once you are satisfied with all the information and consent to participate, you and your child will randomly be allocated into one of two groups in order to receive their blood draw. These groups include: (1) the use of a virtual reality headset, or (2) treatment as usual. If your child is randomly allocated to the virtual reality condition, they will be asked to wear an Oculus Quest 2 Virtual Reality Head-Mounted Display (VR-HMD). The VR-HMD provides per person wearing it with an immersive experience where they feel like they are in a new

environment. While wearing the VR-HMD your child will be shown the game Ocean Rift.

Ocean Rift is a game which shows your child an aquatic safari park to explore by looking around while their blood draw takes place. The Appendices on the last two pages show you images of the Oculus Quest 2 VR-HMD and Ocean Rift the aquatic safari park that your child will see when they wear the VR-HMD.

If your child is randomly allocated to treatment as usual, a researcher will be present during the blood draw. There will be no other difference to how your child's blood draw would normally take place.

After the blood draw procedure, you will be asked to complete some questionnaires in relation to your child's experience of pain during the procedure. Normal treatment and care from clinical staff will not be influenced in any way by participation in this study. Should you or your child become distressed at any stage during this process, please make this known. You and your child have the right to withdraw from the research at any point. You and your child's personal information will be coded and kept confidential. The data from the questionnaires will be analysed at the University of Galway and reported in a Master's level thesis and may also be published in a scientific journal.

How long will my part in the study last?

Taking part in this study is likely to add an extra 15-20 minutes to you and your child's visit to the hospital. This is inclusive of time spent before the blood draw procedure to ensure you have all the information about taking part, along with possible equipment preparation and familiarization and allocated time after the blood draw procedure for you to complete

some questionnaires. You and your child's participation in this research will be completed during their scheduled blood draw procedure.

What are the possible benefits in taking part?

We cannot predict if there will be any benefits for your child in participating in this study.

However, by taking part you will be contributing to emerging research on virtual reality distraction from pain during needle-related procedures in children with ASD/ASD-ID.

What are the possible disadvantages and risks of taking part?

This study includes a questionnaire that requires both you and your child to reflect on your child's experience of pain during the blood draw procedure. If your child is non-verbal or has limited verbal ability this will be accommodated and will not affect their participation in the research. If at any time you or your child become distressed or feel uncomfortable, you and your child can withdraw from the research at any point without any penalty.

What happens at the end of the study?

When all participants have taken part (this should be within 6 months of your participation), you will receive a summary of one or two pages of the main findings. While it could be up to 2 years before final results are published, we would be pleased to include you on an address list to receive publications arising from the study. Only general findings will be reported, without reference to identifiable individual results.

What happens if I change my mind during the study?

You and your child are entitled to change your mind about participating in this study at any time without disadvantage or penalty.

Who do I contact for more information or if I have further concerns?

If you would like more information or have any concerns about this study, please do not hesitate to contact the primary researcher Conor O'Neill at C.ONeill53@nuigalway.ie

Alternatively, the following research supervisors can also be contacted

Professor Brian McGuire at brian.mcguire@universityofgalway.ie Tel. 091 493266

Dr. Helena Lydon at Helena.lydon@universityofgalway.ie

This research study has received full ethical approval from the University of Galway's School of Psychology Research Ethics Committee and Galway University Hospital Clinical Research Ethics Committee.

If you have any queries in relation to the study you may contact: **Chair of the School of Psychology Research Ethics Committee (Professor Gary Donohoe), School of Psychology, University of Galway at gary.donohue@nuigalway.ie or the Chair of the Clinical Research Ethics Committee (Professor Peter McCarthy), Consultant Radiologist, Bon Secours Hospital Galway University Hospital at Colette.Collins@hse.ie or (091) 731990.**

If you have any concerns about this study and wish to contact someone in confidence, you may contact: **The Head of School (Dr. Padraig MacNeela), School of Psychology, University of Galway at padraig.macneela@nuigalway.ie or (091) 493266.**

Thank you

Appendices

Appendix A

Please see below images depicting the Oculus Quest 2 Virtual Reality Head-Mounted Display (VR-HMD) that will be worn by participants in the Virtual Reality group during the course of this study.



Head-Mounted Display



Controller A



Controller B



Appendix B

Please see below images depicting Ocean Rift a Virtual Reality aquatic safari park which is the Virtual Environment observed by participants wearing the Oculus Quest 2 Virtual Reality Head-Mounted Display (VR-HMD).

