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Virtual reality distraction for needle-related pain and distress in children and adolescents with autism spectrum disorder (ASD)

Submission date
11/07/2023

Recruitment status
Recruiting

Registration date
12/07/2023

Overall study status
Ongoing

Last Edited
27/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to investigate the use of virtual reality (VR) as a distraction for pain management during blood draw procedures in children and adolescents with Autism Spectrum Disorder (ASD), with or without Intellectual Disability (ID). VR has shown promise in managing needle-related pain in typically developing children, but its use in children with ASD/ASD-ID is underexplored. VR technology can provide immersive images and block out real-world stimuli, potentially helping to distract individuals with ASD/ASD-ID during blood draw procedures. This research could have significant clinical benefits for healthcare practitioners working with this population, as it may provide an alternative to sedation, which can be high-risk and complicate routine medical care.

Who can participate?
Children and adolescents aged 5-18 years with a diagnosis of Autism Spectrum Disorder (ASD) with or without a co-occurring Intellectual Disability (ID), and their parents/legal caregivers.

What does the study involve?
Participants will be randomly assigned to the VR condition or the control condition (treatment as usual) during the venipuncture procedure.

What are the possible benefits and risks of participating?
We cannot predict if there will be any benefits from participating in this study. However, by taking part, participants will be contributing to emerging research on virtual reality distraction from pain during needle-related procedures in children with ASD/ASD-ID. This study includes a questionnaire that requires parents and children to reflect on the child's experience of pain during the blood draw procedure. If participants become distressed or feel uncomfortable, they will be provided with support by the medical team providing treatment.

Where is the study run from?
University Hospital Galway (Ireland)

When is the study starting and how long is it expected to run for?
September 2022 to September 2026

Who is funding the study?
Investigator-initiated and -funded

Who is the main contact?
Dr Helena Lydon, helena.lydon@universityofgalway.ie
Prof Brian McGuire, brian.mcguire@universityofgalway.ie
Conor O'Neill, C.ONeill53@nuigalway.ie

Contact information

Type(s)
Principal Investigator

Contact name
Dr Helena Lydon

ORCID ID
https://orcid.org/0000-0002-8202-0843

Contact details
School of Psychology
University of Galway
University Road
Galway
Ireland
H91 EV56
+353 91494457
helena.lydon@universityofgalway.ie

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A comparison of virtual reality distraction and treatment as usual for needle-related pain and distress in children and adolescents with autism spectrum disorder (ASD): a feasibility study

Study objectives
Is Virtual Reality based distraction a feasible and more effective method than treatment as usual in reducing needle-related pain in a sample of children and adolescents with ASD with or without a co-occurring ID during a blood draw procedure?

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 11/05/2023, Clinical Research Ethics Committee, Galway University Hospital (Room 2, 2nd Floor, HR Building, Merlin Park Hospital, Galway, -, Ireland; +353 91775022; colette.collins@hse.ie), ref: C.A. 2998

2. Approved 22/01/2025, Clinical Research Ethics Committee, Galway University Hospital (Room 2, 2nd Floor, HR Building, Merlin Park Hospital, Galway, H91 N973, Ireland; +353 91775022; colette.collins@hse.ie), ref: C.A. 2998/Amendment

3. Approved 03/03/2025, Children's Health Ireland Research Ethics Committee (Children's Health Ireland, Dublin, D12 N512, Ireland; -; ethics.committee2@childrenshealthireland.ie), ref: REC-539-24

Study design
Interventional randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Children and adolescents with a diagnosis of Autism Spectrum Disorder (ASD) with or without a co-occurring Intellectual Disability (ID).

Interventions
Intervention Condition: Participants in the intervention condition will receive access to Virtual Reality (an Oculus Rift 2 and the VR app Ocean Rift) for the duration of their venipuncture procedure.
Control Condition: Participants in the control condition will receive treatment as usual during their venipuncture procedure.
Randomisation: The control/intervention groups will be selected using random assignment. This

will be achieved using a computerised number generator (https://www.randomizer.org). One researcher who will not be involved in the data collection will conceal participant allocations in numbered envelopes. Each participant will have a unique ID number and the ID numbers will be applied in sequence as participants enrol in the study. The condition to which the individual has been allocated will be revealed by opening the relevant numbered envelope and noting the group allocation (1 = VR intervention group, 2 = Treatment as usual).

Intervention Type
Behavioural

Primary outcome measure
1. A task analysis of the venipuncture is gathered during the procedure
2. Pain is measured using a visual analogue scale (VAS) after the procedure
3. Feasibility data related to wearing the VR headset will be gathered after the procedure

Secondary outcome measures
Parent and Nurse/Phlebotomist Measures:
1. Behaviour measured by Behaviour Observation Checklist during the venipuncture.
2. Pain measured by visual analogue scale (VAS) during the procedure
3. Satisfaction with VR and venipuncture measured using Likert rating scales after the procedure

Overall study start date
01/09/2022

Completion date
01/09/2026

Eligibility

Key inclusion criteria
1. Children and adolescents with a diagnosis of Autism Spectrum Disorder (ASD) with or without a co-occurring Intellectual Disability (ID), and their parents/legal caregivers
2. Have a venipuncture scheduled or attend the day ward and require a venipuncture.

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
18 Years

Sex
Both

Target number of participants

Key exclusion criteria
1. Children under the age of 5 years and over the age of 18 years
2. Have not been clinically diagnosed as having ASD/ASD-ID
3. Children/adolescents with medical conditions that preclude virtual reality use such as epileptic seizures and vision problems
4. The inability to obtain consent from a parent/legal caregiver, and assent from a child

Date of first enrolment
13/07/2023

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Ireland

Study participating centre
University Hospital Galway
Saolta University Health Care Group
Newcastle Road
Galway
Ireland
H91 YR71

Study participating centre
Mayo University Hospital
Westport Road
Knocknaphunta
Castlebar
Ireland
F23 H529

Study participating centre
Child and Adolescent Mental Health Services (CAMHS) Community Healthcare West
Merlin Park Hospital
Merlin Park
Galway
Ireland
H91 N973

Study participating centre
Children's Health Ireland
Connolly Hospital
Mill Road
Blanchardstown
Dublin
Ireland
D15 RRN1

Sponsor information

Organisation
Ollscoil na Gaillimhe – University of Galway

Sponsor details
University Road
Galway
Ireland
H91 TK33
+353 91 524411
painresearch@nuigalway.ie

Sponsor type
University/education

Website
https://www.universityofgalway.ie

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/09/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Helena Lydon Helena.lydon@universityofgalway.ie
The data will be available following the publication of the research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2		12/07/2023	No	Yes