

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 No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 12/07/2023	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 27/06/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Efficacy

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 years

Upper age limit

18 years

Sex

All

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

ROR

<https://ror.org/03bea9k73>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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