

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

<b>Submission date</b> 11/07/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/07/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/06/2025	<b>Condition category</b> 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](mailto:helena.lydon@universityofgalway.ie)  
Prof Brian McGuire, [brian.mcguire@universityofgalway.ie](mailto:brian.mcguire@universityofgalway.ie)  
Conor O'Neill, [C.ONeill53@nuigalway.ie](mailto:C.ONeill53@nuigalway.ie)

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Helena Lydon

### ORCID ID

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### Contact details

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## Additional identifiers

## 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](mailto: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?
<a href="#">Participant information sheet</a>	version 2		12/07/2023	No	Yes