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Evaluating an automated virtual reality therapy for needle fears in adolescents

Submission date	Recruitment status	[X] Prospectively registered
01/08/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/08/2024	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/07/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The hypodermic needle may be the most important medical device invented. Billions of needles are used worldwide each year. However, a significant minority of the population are very fearful of needles. This can make medical procedures unpleasant. It can also lead to avoidance of vaccination, blood donation and tests, and uptake of treatments. Fear of needles is especially high in young people. Needle fear can be successfully treated using psychological therapy (graded exposure and applied tension) but because of a shortage of therapists very few people are able to access such help. Working with adolescents with needle fears, we have automated the delivery of evidence-based psychological therapy for needle fear within virtual reality (VR). We now wish to assess the effectiveness for young people of this automated VR therapy for needle fear.

Who can participate?
Adolescents aged 12 - 15 years old (inclusive) with a needle fear.

What are the possible benefits and risks of participating?
It is hoped that VR therapy will help people feel less fearful of needles. The study aims to find out whether this is the case. We do not anticipate any significant risks in taking part, however, on rare occasions people may experience motion sickness from using VR. Additionally, some people can feel faint or faint when exposed to needles and therefore participants are seated whilst using the VR.

Where is the study run from?
The University of Oxford (UK) is running the study. Oxford Health NHS Foundation Trust, Berkshire Healthcare NHS Foundation Trust, and Buckinghamshire Healthcare NHS Trust are involved in referring patients to the study.

When is the study starting and how long is it expected to run for?
January 2023 to December 2025

Who is funding the study?
The principal funding is from the Beryl Alexander Charity. Support is also received from the NIHR Oxford Health Biomedical Research Centre (UK)

Who is the main contact?
Prof. Daniel Freeman
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Contact information

Type(s)
Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

IRAS number
334022

ClinicalTrials.gov number

Secondary identifying numbers
IRAS 334022, PID17233

Study information

Scientific Title
Virtual reality (VR) for needle fears: a randomised controlled trial of an automated VR therapy for the treatment of needle fears (trypanophobia) in adolescents

Study objectives
Compared to no treatment, an automated VR therapy will reduce needle fear (end of treatment) for young people with needle fears.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/02/2024, South Central – Oxford B Research Ethics Committee (Health Research Authority, 2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 1048134; oxfordb.rec@hra.nhs.uk), ref: 23/SC/0420

Study design
Parallel-group randomized controlled trial with single-blind assessment

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community, Home, School, Other

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Needle fear

Interventions
Participants (adolescents with significant needle fears) will be randomised to receive the VR therapy or the control group (Treatment as usual, which is typically no treatment). Participants will be allocated to one of the trial arms using a 1:1 allocation ratio. Randomisation will use a permuted blocks algorithm, with randomly varying block size. Assessments will be conducted at 0, 3 (end of treatment), and 6 weeks by a research assistant blind to group allocation. The assessments involve the participant completing questionnaires relevant to assessing their needle fear. We will offer the VR therapy to participants in the control arm after completion of the 6-week follow-up assessment.

The treatment being tested is an automated VR therapy for needle fears. This software is intended to reduce needle fears. It is a cognitive-behavioural exposure and applied tension intervention. The programme takes approximately three hours to complete. The treatment content was designed by the Oxford Cognitive Approaches to Psychosis (O-CAP) research group at the University of Oxford, with young people with lived experience taking part in the design process. The treatment was programmed by the University of Oxford. The VR application has UKCA marking as a Class I Medical Device (Software as a Medical Device).

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
VR for Needle Fears

Primary outcome measure
The Injection Phobia Scale- Anxiety (Child Version) at 0, 3, and 6 weeks.

Secondary outcome measures
1. Needle-related disgust reactions measured by the Disgust Emotion Scale for Children – Injections and Blood Draws Subscale at 0, 3, and 6 weeks.
2. Needle-related fearful cognitions measured by the Needle Cognitions Questionnaire at 0, 3, and 6 weeks

Overall study start date
24/01/2023

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Aged 12 - 16 years old (up to 16th birthday)
2. Have significant needle fears that they would like treated (as determined by a screening tool)
3. Willing and able to give assent for participation in the study
4. A parent/guardian is willing and able to give informed consent for their child's participation in the study

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Photosensitive epilepsy or significant visual, auditory, or balance impairment that would make use of VR inappropriate
2. Current engagement in any other psychological treatment for needle fear
3. Command of English inadequate for engaging in the therapy or completing the assessments
4. A participant may also not enter the trial if there is another factor, which, in the judgement of the investigator, would preclude the provision of informed consent/assent or from safely engaging with the trial procedures. Reason for exclusion will be recorded

Date of first enrolment
04/10/2024

Date of final enrolment
15/07/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
University Offices
Oxford
United Kingdom
OX1 2JD

Study participating centre
Oxford Health NHS Foundation Trust
Warneford Hospital
Warneford Lane
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Study participating centre
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Study participating centre
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Organisation
University of Oxford

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Sponsor type
University/education

Website
https://researchsupport.admin.ox.ac.uk/contacts/rgea

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Beryl Alexander Charity

Funder Name
NIHR Oxford Health Biomedical Research Centre

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal and conference presentations.

Intention to publish date
31/03/2026

Individual participant data (IPD) sharing plan
Requests - accompanied by a study summary - for sharing of de-identified data will be considered by the Chief Investigator (daniel.freeman@psy.ox.ac.uk) and team. The intent is to share data for reasonable requests. Data will be made available to external researchers subject to the constraints of the consent under which data were collected, with an appropriate data sharing agreement, and after publication of the main study report.

IPD sharing plan summary

Available on request