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Virtual reality mediated deep breathing and relaxation training in pediatric and psychiatric care

Submission date
13/05/2025

Recruitment status
No longer recruiting

Registration date
23/05/2025

Overall study status
Completed

Last Edited
23/05/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Virtual reality techniques have been used for various purposes in healthcare to find novel ways to treat different medical conditions and to prepare patients for unpleasant procedures. The study aims to create virtual reality applications for children for learning deep breathing and relaxation, and to study their effectiveness, safety and usability in different child patient groups. The main goal is to learn if virtual reality-mediated deep breathing and relaxation training can reduce experiences of stress and anxiety via autonomic nervous system stimulation.

Who can participate?
The participants are child patients aged 8-17 years.

What does the study involve?
The participants perform either guided deep breathing or relaxation exercises using a virtual reality headset. The exercise is guided by a bot figure providing verbal instructions in a virtual nature environment.

What are the possible benefits and risks of participating?
The study patients receive the benefit of a learning experience of the guided deep breathing or relaxation exercise. The possible risk is having nausea or vertigo, which are occasionally reported during the use of a virtual reality headset.

Where is the study run from?
Tampere University Hospital (Finland)

When is the study starting and how long is it expected to run for?
May 2022 to June 2024

Who is funding the study?
1. Tampere University (Finland)
2. The Finnish Foundation for Pediatric Research (Finland)

3. Finnish Brain Foundation (Finland)
4. Päivikki and Sakari Sohlberg Foundation (Finland)

Who is the main contact?
MD, PhD Sauli Palmu, sauli.palmu@tuni.fi

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effect of virtual reality mediated deep breathing and relaxation training on stress and anxiety in child patients: a pilot trial

Acronym
VirNE

Study objectives
Deep breathing and relaxation training reduce stress and anxiety in child patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/06/2021, The Ethics Committee of the Wellbeing Services County of Pirkanmaa (PL 2000, Tampere, 33521, Finland; +358 50 347 0251, +358 50 329 5667; toimikunta.eettinen@pirha.fi), ref: RL21070L

Study design
Multicenter interventional randomized controlled pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Reduxing anxiety and stress in child patients

Interventions

The patients are allocated to either the intervention or the control group in numerical order. The intervention is virtual reality-mediated deep breathing or relaxation training. The study patients perform a 6-minute deep breathing or relaxation exercise with a virtual reality headset in the pediatric unit, observing a 360-degree virtual Finnish nature environment and a bot figure providing the patient with verbal guidance throughout the exercise. The study patients will perform the exercise once (in a distraction group) or four times (in a training group; one session per week in a 4-week period). During the exercise, heart rate variability is measured using a heart rate sensor belt (a chest strap). The control intervention is no treatment.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Oculus Quest 2 - virtual reality headset

Primary outcome measure
Heart rate variability measured using the virtual reality headset during the research situation

Secondary outcome measures
Heart rate and user feedback measured using the virtual reality headset during the research situation

Overall study start date
01/01/2021

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Child patients aged 8-17 years
2. Literate
3. Fluent in Finnish

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
220

Key exclusion criteria
1. Unstable heart condition
2. Anatomical facial features preventing the use of the headset
3. Hearing impairment or cochlear implant
4. Vision impairment
5. Tendency for vertigo
6. Clinically unevaluated seizures
7. Epilepsy
8. Migraine
9. Bulimia nervosa
10. Relative exclusion criteria: motion sickness, underweight

Date of first enrolment
04/05/2022

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
Finland

Study participating centre
Tampere University Hospital
Elämänaukio 2
Tampere
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33520

Study participating centre
Päijät-Häme Central Hospital
Keskussairaalankatu 7
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Sponsor information

Organisation
Tampere University

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Sponsor type
University/education

Website
https://www.tuni.fi/en

ROR
https://ror.org/033003e23

Funder(s)

Funder type
University/education

Funder Name
Tampere University

Funder Name
Finnish Foundation for Pediatric Research

Funder Name
Finnish Brain Foundation

Funder Name
Päivikki and Sakari Sohlberg Foundation

Results and Publications

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

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study are not publicly available due ethical and data privacy issues in healthcare, but are partly available from Elina Karppa (elina.karppa@tuni.fi) upon reasonable request. Consent from the participants was required and obtained; data is anonymised with ID codes.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3	14/05/2025	23/05/2025	No	No