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Virtual reality minimizes anxiety in children and adolescents with life-limiting conditions: a randomized control trial

Submission date
03/01/2025

Recruitment status
No longer recruiting

Registration date
08/01/2025

Overall study status
Completed

Last Edited
08/01/2025

Condition category
Mental and Behavioural Disorders

[ ] 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
Children and adolescents with life-limiting conditions (LLC) often face frequent hospital visits, unpleasant medical procedures, and treatment side effects. These experiences can cause high levels of anxiety and distress. To address this, there is an increasing focus on psychological interventions, including modern technologies and non-drug approaches.
One promising method is virtual reality (VR), which creates a computer-generated environment that makes users feel as though they are physically present in that space. While VR is a relatively new approach with limited research, early evidence shows it can reduce stress, anxiety, and pain in children. This study aims to evaluate how effective VR is and how it can help severely ill children in hospital settings.

Who can participate?
Children aged 10 to 17 years who have life-limiting conditions and are receiving treatment at University Hospital Motol in the Czech Republic

What does the study involve?
Children participating in the study are randomly placed into one of two groups while at University Hospital Motol's hemato-oncology or gastroenterology unit.
Group 1: Participants have two VR sessions, spaced 14 to 42 days apart.
Group 2: Participants have a video session first, followed by a VR session for the second session.
Before and after each session, participants answer questions about their anxiety, fear, and pain levels. After the VR session, they are also asked about symptoms of cybersickness, as well as their level of engagement, enjoyment, and immersion in the VR environment.

What are the possible benefits and risks of participating?
Participants may experience immediate reductions in anxiety and enjoy a fun and novel experience. In the long term, the study has the potential to improve the quality of life for severely ill children.

The main risk is potential cybersickness, which can cause symptoms like dizziness or nausea. To minimize this, a trained researcher will be present throughout the session to monitor the child's condition and provide support if needed.

Where is the study run from?
The study is managed by Charles University (1st, 2nd, and 3rd Faculty of Medicine), the National Institute of Mental Health, and University Hospital Motol, where the research takes place.

When is the study starting and how long is it expected to run for?
April 2022 to December 2023

Who is funding the study?
Vlček Family Foundation (NRV) (Czech Republic)

Who is the main contact?
Anna Zubkova, anna.zubkova1250@gmail.com, anna.zubkova@nudz.cz

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EK - 667/22

Study information

Scientific Title
The use of experiential virtual reality to minimize anxiety in children with life-limiting conditions: a randomized control trial

Study objectives
Experiential virtual reality is a feasible, acceptable, and effective method for alleviating anxiety in children with life-limiting conditions.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/06/2022, Ethics Committee for Multi-Centric Clinical Trials of the University Hospital Motol and 2nd Faculty of Medicine, Charles University in Prague (V úvalu 84, Prague, 150 06, Czech Republic; +420 (0)224 431 195; etickakomise@fnmotol.cz), ref: EK - 667/22

Study design
Single-centre interventional randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Efficacy

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
Anxiety in pediatric patients with life-limiting conditions (hematology-oncology and gastroenterology outpatient clinics)

Interventions
The study employs a randomized controlled trial design, integrating both between-subjects and within-subjects approaches to evaluate the feasibility and effectiveness of a virtual reality distraction intervention (VR-DT) in comparison to a video-based distraction method. Participants are randomized using simple randomization by drawing names from an envelope. The intervention is administered during chemotherapy or infusion sessions. Virtual reality is used for 10 to 15 minutes, with an additional 8 minutes allocated for pre-session questionnaires and 6 minutes for post-session questionnaires, resulting in a total session duration of 35 minutes. During the VR experience, the researcher assists with the VR equipment (Meta Quest 2 headset), addresses participant queries, and provides support in managing any stress or discomfort in emergency situations. In the control group, the same procedure is followed, but a video

intervention is used instead, delivered via an Apple iPad. A total of 18 children and adolescents are recruited through opportunity sampling and are randomly assigned to one of two groups. The experimental group (n = 10) receives two VR intervention sessions, spaced 14 to 42 days apart, according to their individual medical schedules, while the control group (n = 8) first participates in a video intervention, followed by a VR intervention in the second session. Measurements are taken before and after the interventions to assess anxiety, pain, fear, cyber sickness, and subjective feedback of the participants, using standardized scales and questionnaires.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Experiential Virtual Reality (using headset MetaQuest 2)

Primary outcome measure
Anxiety measured using the "Scale Measuring Anxiety in Children - Short Version" at pre-intervention and post-intervention stages for both VR and video groups. The same procedure was followed in both sessions.

Secondary outcome measures
1. Fear measured using the Children Fear Scale (CFS) and Child Medical Fear Scale (CMFS) at pre-intervention and post-intervention stages for both VR and video groups. The same procedure was followed in both sessions.
2. Pain measured using the Wong-Baker Faces Visual Analog Scale (VAS) at pre-intervention and post-intervention stages for both VR and video groups. The same procedure was followed in both sessions.
3. Cybersickness measured using the Simulation Sickness Questionnaire (SSQ) at the post-intervention stage exclusively for the VR group. The same procedure was followed in both sessions.
4. Engagement, enjoyment, and immersion measured using a structured 4-point scale (0: not at all – 3: significantly) at the post-intervention stage for both VR and video groups. The same procedure was followed in both sessions.
5. Desire for distraction and perceived efficacy measured using a 5-point Likert scale (1: strongly agree – 5: strongly disagree) at the post-intervention stage for both VR and video groups. The same procedure was followed in both sessions.

Overall study start date
30/04/2022

Completion date
11/12/2023

Eligibility

Key inclusion criteria
1. Sufficient level of contact with the environment and ability to cooperate
2. Fluency in Czech for both children and parents
3. Diagnosis of a life-threatening or life-limiting illness according to the internationally accepted list of palliative relevant diagnoses (Fraser et al., 2020)
4. Pediatric patients treated at University Hospital Motol

Participant type(s)
Patient

Age group
Child

Lower age limit
10 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
15

Total final enrolment
18

Key exclusion criteria
1. Age below 10 or above 18 years
2. Unstable health status
3. Inability to speak Czech
4. Absence of parental consent for participation in the study

Date of first enrolment
10/06/2023

Date of final enrolment
10/11/2023

Locations

Countries of recruitment
Czech Republic

Study participating centre
Motol University Hospital
V Úvalu 84/1

Prague
Czech Republic
15006

Sponsor information

Organisation
Vlček Family Foundation

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Sponsor type
Charity

Website
https://nrv.org/en/about-us/

Funder(s)

Funder type
Charity

Funder Name
Vlček Family Foundation

Results and Publications

Publication and dissemination plan
The study is planned for publication in a peer-reviewed journal, preferably BMC Palliative Care.

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The dataset generated and analyzed during the current study will be available upon request from Anna Zubkova (anna.zubkova1250@gmail.com)

IPD sharing plan summary

Available on request