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Study of a virtual reality intervention for pain and anxiety control in pediatric vaccination

Submission date
12/11/2023

Recruitment status
No longer recruiting

Registration date
19/12/2023

Overall study status
Completed

Last Edited
19/12/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Pediatric vaccination, a common needle-related experience, is often experienced with pain and anxiety, posing challenges to families and nurses. Unaddressed pain and distress during childhood medical procedures can harm future pain tolerance and responses. The efficacy of non-pharmacological techniques to control children's distress, adapted to age and context and mainly using distraction, is well documented. Virtual Reality (VR) involving multisensory stimulation is an innovative technology in the health context, generally well-accepted by children and adolescents. It is considered efficient in controlling children's pain and anxiety in needle-related procedures. However, most studies ot VR interventions have been conducted in well-controlled, experimental situations and replication in real-life contexts may be challenging. This study aims to evaluate the efficiency of a Virtual Reality distraction intervention to control vaccination-induced pain and anxiety in five-year-old children in primary care services.

Who can participate?
Five-year-old children registered in three Primary Health Care Units.

What does the study involve?
The study compares an experimental condition using VR as a distraction technique and a control condition with treatment as usual, in primary care settings. Five-year-old children are randomized into two groups: The experimental group is vaccinated while watching a movie through VR. Nurses synchronize their actions with the images from the film. The control group is vaccinated according to the usual procedures and comfort measures.
Anxiety is evaluated in both groups before and after the vaccination, and pain after the vaccination. The whole procedure will be vídeo recorded in both groups. To assess children's anxiety and pain, we will use two brief self-report scales and na observational scal to code the children´s behaviours registered on video. Parents fill out an informed consent form and sociodemographic questionnaire, and children give their assent before participating in the study.

What are the possible benefits and risks of participating?
Participants in the VR group may benefit from this distraction technique and feel less anxiety and pain. There are no expected benefits for the control group. There are no expected risks for participants in any group, as all will receive nurses' attention and support. The video used in the

VR group will be preliminarily tested to ensure it is well accepted by 5-year-old children. If any child in the VR group experiences discomfort from using the VR technique, it will immediately be interrupted.
The innovative aspect of developing the study in a natural context of primary care health units will inform about the specific conditions and obstacles to using the technique. It may reinforce the advantages of applying a simple and well-accepted methodology in this context to reduce children's and parents' distress during vaccination.

Where is the study run from?
Nursing School of Lisbon/ Lisbon University (Portugal)

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

Who is funding the study?
Investigator initiated and funded. Bene Farmacêutica finances the Virtual Reality materials and devices.

Who is the main contact?
Maria Leonor Rosa Roque (Nursing Ph.D. student)
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil Known

Protocol serial number
Nil Known

Study information

Scientific Title
VR4PV: superiority randomised controlled trial of a virtual reality intervention versus treatment as usual for pain and anxiety control in pediatric vaccination

Acronym
VR4PV

Study objectives
H1 - Children in the Experimental Group, using a VR distraction technique, report less self-reported anxiety following the vaccination procedure, than children in the Control Group.
H2 - Children in the Experimental Group, using a VR distraction technique, report less self-reported pain following the vaccination procedure, than children in the Control Group.
H3 - Children in the Experimental Group, using a VR distraction technique, will show indicators of less observed pain/distress following the vaccination procedure, than children in the Control Group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/11/2023, Comissão de Ética para a Saúde da Administração Regional da Saúde do Centro (Center Regional Health Administration Ethics Committee) (Alameda Júlio Henriques, Coimbra, 3000-457, Portugal; +351 239796800; ces@arscentro.min-saude.pt), ref: 12/2023

Study design
Multicentre interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Pain and anxiety associated with vaccination procedures

Interventions
Participants are five-year-old children, registered at two Personalized Health Care Units (UCSP) and one Family Health Unit (USF) in the center of Portugal.
Children eligible for vaccination will be identified through the institutional program Sclinico Enfermagem, under the responsibility of the Head Nurse of each Health Unit. All five-year-old children eligible for vaccination, according to the National Vaccination Program, and able to understand and speak Portuguese are eligible. Children with epilepsy, migraines, auditory, visual, and cognitive deficits, or other neurological conditions, and those who report any past symptoms associated with using headsets or Virtual Reality (VR) glasses will be excluded.
Parents/legal guardians will receive a phone call from the reference nurse in each health unit, informing them about the study and that they will receive a letter or email from the researcher with more details and the Consent Form.
Participating children will be randomly allocated to two groups: an Experimental Group (EG) using VR, and a Control Group (CG) using the usual routine practice, with the RANDOM.ORG

program. Each group (VR and Control) will function on different days. Parents who agree to their children´s participation will be informed of the scheduled day for the vaccination
On the vaccination day, parents/legal guardians will answer a brief sociodemographic questionnaire; parents and children will be informed of the camera´s presence and its purpose before the vaccination. Then children respond to the Children's Fear Scale (CFS) to assess anxiety before Immunization immediately after receiving the two vaccines; children will answer the Children's Fear Scale (CFS) and the Faces Pain Scale–Revised (FPS-R) to assess pain after the two vaccines.
The procedure will be videotaped and two trained researchers will fill out the Face, Legs, Activity, Cry, Consolability (FLACC) scale, based on observation of the taped images assessment.
On the vaccination day, children and parents/legal guardians will be welcomed by the nurse who will administer the vaccines, provide more information about the study, present the informed consent to parents/legal guardians and request the child's assent. Parents and children will be informed of the camera´s presence and purpose. Parents/legal guardians fill out the sociodemographic questionnaire.
EG – The Nurse will present the VR equipment, explaining its utilization. The child will watch an animation for approximately 3 minutes. During this time, the nurse, who is following the animation on a tablet, to guarantee synchronization of the procedure with the video, positions the child´s left arm, disinfects and administers the vaccine against Diphtheria, Tetanus, Acellular Whooping Cough and Poliomyelitis (DTPaVIP) in the deltoid region of the left arm. Afterwards, they will perform the same procedure, administering the Measles, Mumps and Rubella (VASPR) vaccine in the deltoid region of the right arm. Comfort measures will be applied if needed. After the two vaccines, the child will answer the FPS-R and CFS.
CG – The two vaccines will be administered following the usual procedure. Vaccination follows the same technical procedure. Assessment instruments are filled out by parents and children similarly to the EG. Comfort procedures will be applied if needed.
To minimize uncontrolled variables, children from both groups and their families will be welcomed and vaccinated in the same room at each health unit. The DTPaVIP and VASPR vaccines will be selected, taking care of the same laboratory and batch for all children. The syringes with 0.6x25 needles are included in the manufacturer´s kits.

Intervention Type
Other

Primary outcome(s)
1. Pain is self-assessed by the child, using Faces Pain Scale-Revised (FPS-R) at 2 min post-vaccination.
2. Anxiety is self-assessed by the child, using children´s Fears Scale (CFS) at 2 min post-vaccination.
3. Face, legs, Activity, Cry, Consolability (FLACC) will be used to code the children´s behaviour, recorded on video (by researchers) after the vaccination

Key secondary outcome(s))
1. Self-assessed anxiety pre-vaccination measured with FPS-R at 2 min before vaccination.
2. Demographics: Child's ethnicity, child´s sex, accompanying the child to the vaccine, children's previous experience with procedures measured by interview before the vaccination

Completion date
07/10/2025

Eligibility

Key inclusion criteria
Children without distinction of sex or ethnicity, accompanied by legal guardians, who agreed to participate in the study and suitable for vaccination according to the chronology of the 2020 National Vaccination Program, with a reasonable understanding of Portuguese

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Other

Lower age limit
5 years

Upper age limit
6 years

Sex
All

Key exclusion criteria
Children with epilepsy, migraine or other neurological diseases, reports of episodes of discomfort associated with the use of earphones and/or the use of VR glasses in a playful context and auditory, visual and cognitive deficits

Date of first enrolment
01/01/2024

Date of final enrolment
18/05/2024

Locations

Countries of recruitment
Portugal

Study participating centre
Health Units of the Cova da Beira Health Center Group (Agrupamentos de Centros de Saúde Cova da Beira (ACES Cova da Beira)
Avenida 25 de Abril
Covilhã
Portugal
6200-090 Covilhã

Sponsor information

Organisation
Nursing Research, Innovation and Development Centre of Lisbon (CIDNUR)/ Lisbon School of Nursing

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded with partial funding from Bene Farmacêutica.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. mcastelo@campus.esel.pt

-The type of data that will be shared (quantitative results for all measures)
When the data will become available (at the end of the study)
-For how long (one year)
-By what access criteria data will be shared including with whom, for what types of analyses, and by what mechanism (anonymized data will be shared upon request from other researchers interested in doing complementary analyses and reviewers of submitted articles)

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			27/11/2023	No	Yes