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Virtual reality app for preparing children for an MRI scan

Submission date
11/03/2022

Recruitment status
No longer recruiting

Registration date
12/04/2022

Overall study status
Completed

Last Edited
25/01/2023

Condition category
Other

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

Plain English summary of protocol
Background and study aims
Magnetic Resonance Imaging (MRI) is an imaging technique for determining underlying disorders. However, MRI is a frightening experience for many children. They must lie in a narrow tube for some time and there are loud unpleasant noises during scanning. Many children panic, have claustrophobic feelings and are agitated. Virtual Reality offers an excellent opportunity to prepare children for an MRI in a child-friendly, realistic and interactive way in their home situation. Our aim is to develop a generic VR app that is applicable in different Dutch hospitals and that can be used at home by children and parents in preparation for an MRI. With this VR app we can increase the emotional wellbeing of many children and decrease health care costs by:
1. reducing feelings of anxiety, panic, agitation and claustrophobia of children
2. reducing the use of sedative medication and anesthesia
3. improve the quality of MRI scans, and
4. use MRI more efficiently.
Our hypotheses are: (1) smartphone VR app will be significantly more efficacious than care as usual (CAU) on both the primary outcome (the child's situational anxiety during MRI) and secondary outcomes, and (2) children with unfavorable predictor variables (e.g. more anxious) will benefit more from VR.

Who can participate?
Consecutive patients (aged 6-14 years) undergoing MRI, at the Sophia and Emma Children's hospital between March 2021 - December 2022.

What does the study involve?
Children will be randomly allocated to virtual reality preparation at home with an smartphone app or to care as usual. The advantages of smartphone VR are that the children are in control, and can explore the virtual MRI environment at their own initiative and pace. Moreover, the VR app is a largely nonverbal tool, so it has added value for non-Dutch speaking children and young children. Another added value is that children can do the preparation with the VR app as often as they want. Before, during and after the MRI questionnaires will be administered regarding anxiety and satisfaction.

What are the possible benefits and risks of participating?
The benefit of children allocated to the VR tool might be that they are less anxious before and during the MRI. There are no risks involved in participating to this study.

Where is the study run from?
The study is executed at the Erasmus MC- Sophia Children's Hospital in Rotterdam and the Amsterdam UMC - Emma Children's Hospital in Amsterdam, The Netherlands.

When is the study starting and how long it is expected to run for?
April 2020 to December 2022

Who is funding the study?
This study is funded by the Friends of Sophia Foundation (the Netherlands)

Who is the main contact?
Dr Bram Dierckx, b.dierckx@erasmusmc.nl
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NL68075.087.19

Study information

Scientific Title
Virtual reality smartphone app to prepare children for undergoing an MRI

Acronym
VRMRI

Study objectives
VR smartphone preparation is more effective than care as usual in children undergoing an MRI on pre- and peri- MRI child anxiety, use of sedation and anesthesia, child satisfaction as well as quality of the obtained MRI images and duration of MRI acquisition

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/04/2020, Erasmus MC Research Ethics Committee (Postbus 2040, 3000 CA Rotterdam, Netherlands; +31207034428; metc@erasmusmc.nl), ref: NL68075.087.19

Study design
Multicentre interventional single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Children with various somatic conditions who need to undergo an MRI at the Erasmus MC Rotterdam or Amsterdam UMC.

Interventions
Children are randomly assigned to one of two treatment arms: Virtual Reality preparation app or Care as Usual.

Virtual REALITY preparation encompasses a virtual, 3D environment that is creates a general MRI setting. The virtual 3D environment contains the waiting room, control room and MRI room. Children experience the virtual environment and procedures with a smartphone app and cardboard VR at home as often as they want. A great advantage of smartphone-based VR is that it is not static but dynamic and interactive, since children can look around and explore the virtual rooms and get accustomed to the setting and procedures at their own pace. Care as usual involves an information letter that is send to parents and children before MRI as part of standard clinical care. Computerized, blockwise randomization will be stratified by age group (6-10 or 10-14 years old), and type of MRI (upper body vs lower body).

Intervention Type
Other

Primary outcome measure
Anxiety is measured using a visual analogue scale before, during and after the MRI.

Secondary outcome measures
1. Sedation and anesthesia acquired from the patient dossier over the three measurement periods (i.e., pre-A, peri-B, post MRI-C)
2. Parental periproduceral anxiety using the STAI at each measurement
3. Quality of the obtained MRI images based on quantifying the blurring of the edge spread function at the border of the head that is associated with head movement during scanning. This algorithm provides a fine detailed measure with a Gaussian distribution of motion artifacts during scanning at time B
4. Duration of MRI acquisition (min)
5. Satisfaction measured using the visual analogue scale at time C
6. Child behavioral/emotional problems measured using the CBCL at time A

Overall study start date
07/04/2020

Completion date
31/12/2022

Eligibility

Key inclusion criteria

Consecutive pediatric patients (aged 6-14 years), undergoing an MRI at the Erasmus MC – Sophia or the Amsterdam UMC-Emma children's hospital, between May 2021 and December 2022

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
128

Key exclusion criteria
1. Mental retardation
2. Inability of parents to read or write Dutch
3. Epilepsy
4. Visual impairment

Date of first enrolment
01/05/2021

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC - Sophia Children's hospital
Wytemaweg 80, 3015 CN
Rotterdam
Netherlands
3015 CN

Study participating centre

Amsterdam UMC, Emma children's hospital
Meibergdreef 9
Amsterdam
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1105 AZ

Sponsor information

Organisation
Erasmus MC - Sophia Children’s Hospital

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Wytemaweg 80
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Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/sophia/

ROR
https://ror.org/047afsm11

Funder(s)

Funder type
Charity

Funder Name
Friends of Sophia foundation

Funder Name
Coolsingel Foundation

Results and Publications

Publication and dissemination plan
Planned publication in high-impact international journals.

Intention to publish date
01/03/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to privacy of the participants.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/01/2023	25/01/2023	Yes	No