

Virtual reality app for preparing children for an MRI scan

Submission date 11/03/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/04/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/01/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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(s)

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

Key secondary outcome(s)

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 periproducer 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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

14 years

Sex

All

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

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Study participating centre**Amsterdam UMC, Emma children's hospital**

Meibergdreef 9

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1105 AZ

Sponsor information**Organisation**

Erasmus MC - Sophia Children's Hospital

ROR

https://ror.org/047afsm11

Funder(s)

Funder type

Charity

Funder Name

Friends of Sophia foundation

Funder Name

Coolsingel Foundation

Results and Publications

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