Smartphone virtual reality exposure before MRI: effects on pre- and periprocedural anxiety. A multicenter RCT

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This study aims(1) To investigate the effectiveness of smartphone VRE preparation, compared with the regular care (information letter), on reducing anxiety for an MRI (primary outcome measure), anxiety in the child and the parent before and after…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52443

Source
ToetsingOnline

Brief title
Virtual Reality before MRI

Condition

- Other condition

Synonym
and abdomen, MRI for head, thorax

Health condition

angstbeleving bij diagnostisch onderzoek

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: stichting Coolsingel en stichting Vrienden van Sophia

Intervention

Keyword: Anxiety, MRI, Smartphone, Virtual Reality

Outcome measures

Primary outcome

The primary outcome measure is anxiety immediately prior to MRI (T2). This is measured with a VAS scale assessed by children, the researcher observes child anxiety by means of a VAS and a short questionnaire for children aged 8 years and older wil be filled out by children about their anxiety level (State trait anxiety inventory-children).

Secondary outcome

Secondary outcomes are:

- Anxietyof the child and parents at home (T1) and after the MRI (T2)

- Use of sedation and anesthesia

- Quality of the MRI images

- Duration of the MRI

Study description

Background summary

Every year about 5000 children undergo an MRI in the Erasmus MC - Sophia Children*s Hospital and the Amsterdam UMC - Emma Children*s Hospital. An MRI scan often is a frightening experience for a child. Children must lie in a narrow tube for an extended period of time, scanning is accompanied by very loud, unpleasant noises and often an infusion must be inserted to administer contrast fluid. Many children panic, have claustrophobic feelings and are agitated. As a result, scanning sequences need to be aborted, and/or the quality of the obtained MRI images is insufficient. Research shows that about 1 in 4 children need to be sedated or given anesthesia prior to and during an MRI procedure. Anesthesia carries inherent risks, such as gastrointestinal complaints, emergence delirium leading to prolonged hospitalization and in exceptional cases(<1 / 10,000), death.
It is well established that gradual exposure to feared situations is a very effective way to reduce anxiety. However, gradually exposing all children to the aspects of an MRI is not feasible, because this would interfere significantly with daily clinical practice. Virtual Reality Exposure (VRE) provides a unique opportunity to prepare children for MRI in a very realistic, child friendly and interactive way. This study will be the first, worldwide, to develop and test the efficacy of smartphone VRE preparation for children undergoing MRI.

Study objective

This study aims

(1) To investigate the effectiveness of smartphone VRE preparation, compared with the regular care (information letter), on reducing anxiety for an MRI (primary outcome measure), anxiety in the child and the parent before and after MRI, use of sedation and narcosis, quality of MRI images and duration of MRI examination (secondary outcome measures).

(2) To investigate the predictor variables for the effectiveness of VRE: socioeconomic status, age, gender, type
MRI, number of previous MRIs, anxiety of the child and the parent and psychopathology of the child in the last six
months.

Study design

Single-blind randomized study with psychosocial intervention and control group (RCT).

There will be three measurement moments:

T1 = measurement at home prior to smartphone VR intervention

T2 = measurement prior to MRI in the hospital
T3 = measurement after the MRI in the hospital

Intervention

One group receives the smartphone Virtual Reality Exposure (VRE) preparation. The VRE intervention consists of a virtual preparation
by interactively viewing the MRI environment and procedures by means of a cardboard that is attached to a smartphone. This intervention takes place in the home situation and children can see the VR preparation as often as desired.

The other group receives regular care (information letter that is sent to parents).

Study burden and risks

The risks associated with participation are negligible and burden is minimal.

Risks: The goal is to use smartphone Virtual Reality Exposure (VRE) to reduce anxiety. However, it can not be excluded that
some children become tense or scared during the VRE. We will inform parents that children may become anxious about the
VR intervention. In that case we advise them to terminate the VRE procedure and to reassure the child. In a current study of VR in preparation for children on an operation, it turned out to be hardly the case that children became anxious about the VRE intervention. Risks related to participation are therefore negligible.

Burden: Patients and their parents do not have to come to the hospital extra. All measurements take place on the day of
the MRI itself or at home. The tax for children is minimal because they only have to indicate their anxiety level on a Visual Analogue Scale (VAS). The tax for parents is also minimal because they only have to fill out a number of questionnaires.
Parents and their children will spend a total of approximately 45 minutes on the research, namely on undergoing the
VR preparation (15 min) and the different questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Children (2-11 years)

Inclusion criteria

Consecutive pediatric patients (aged 6-14 years), undergoing MRI at the Sophia Children*s Hospital and the Amsterdam UMC-Emma Children's Hospital between April 2020 and December 2022.

Exclusion criteria

Mental retardation (due to a specified syndrome), inability of parents to read or write Dutch, epilepsy, or visual impairment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2020
Enrollment:	128
Type:	Anticipated

Ethics review

Approved WMO Date:	07-04-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-03-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL68075.078.19