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Can viewing a virtual reality video as part of preoperative information reduce anxiety before a caesarean section?

Submission date
05/11/2019

Recruitment status
No longer recruiting

Registration date
05/11/2019

Overall study status
Completed

Last Edited
19/12/2019

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to investigate whether adding a virtual reality video to standard preoperative information before a caesarean delivery reduces anxiety in patients and their partners.

Who can participate?
Women older than 18 with a term pregnancy, scheduled for a caesarean delivery

What does the study involve?
Participants are randomly allocated to either the virtual reality group or the control group. The latter only receives standard preoperative information. Patients in the VR group receive a short virtual reality video which shows all aspects of the caesarean delivery.

What are the possible benefits and risks of participating?
Women who are allocated to the VR group receive additional pre-operative information. There is a risk of motion sickness after watching the VR video, but this risk is minimal.

Where is the study run from?
Máxima Medical Centre Veldhoven (Netherlands)

When is the study starting and how long is it expected to run for?
November 2016 to January 2018

Who is funding the study?
Máxima Medical Centre Veldhoven (Netherlands)

Who is the main contact?
Lore Noben
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N17.017

Study information

Scientific Title
A virtual reality video to improve INFOrmation provision and to reduce anxiety before a Caesarean delivery: INFO-C trial

Acronym
INFO-C

Study objectives
Adding the virtual reality (VR) video to standard preoperative information causes a significant decrease in preoperative anxiety. Furthermore, we expected a positive effect of VR on levels of anxiety and patient satisfaction scores of both women and their partners. Third, this study was conducted to check whether VR would be feasible to implement without causing any harming side effects such as motion sickness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
On 15/06/2015 the researchers received a statement from their local institutional review board that no ethics approval was required (METC Máxima MC, PO Box 7777, 5500 MB Veldhoven, De Run 4600, 5504 DB Veldhoven; Tel: +31 (0)40 888 95 28; Email: metc@mmc.nl), N17.017

Study design

Single-centre randomized controlled trial.

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Preoperative anxiety

Interventions
The intervention comprised a 360° virtual reality video, in addition to standard preoperative information. The control group only received standard preoperative information. Randomization was performed using an online computer randomizer by means of stratified block randomization. Stratification was done based on history of emergency caesarean delivery (yes or no).

Intervention Type
Other

Primary outcome(s)
Anxiety measured using the Visual Analogue scale for anxiety (VAS-A) at the time of inclusion and at admittance on the ward

Key secondary outcome(s))
1. Patient satisfaction measured by means of questionnaires and filled in 1 to 2 weeks after the caesarean delivery
2. Motion sickness assessed using simulation sickness questionnaire filled in by participants from the VR group immediately after watching the VR video

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. Women over the age of 18
2. Planned for a primary caesarean delivery
3. No history of caesarean delivery or history of an emergency caesarean delivery
4. Gestational age above 37 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
97

Key exclusion criteria
1. A history of a primary caesarean delivery
2. Insufficient understanding of the Dutch language
3. Prematurity (gestational age below 37 weeks)
4. Placenta praevia
5. Pre-eclampsia
6. Suspected congenital anomaly

Date of first enrolment
11/11/2016

Date of final enrolment
28/12/2017

Locations

Countries of recruitment
Netherlands

Study participating centre
Máxima Medical Centre
P.O. box 7777
Veldhoven
Netherlands
5500MB

Sponsor information

Organisation
Máxima Medical Centre

ROR
https://ror.org/02x6rcb77

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Máxima Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Lore Noben (lore.noben@mmc.nl).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/12/2019	19/12/2019	Yes	No