

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	☐ Prospectively registered
Registration date 05/11/2019	Overall study status Completed	☐ Protocol
Last Edited 19/12/2019	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ 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

Contact name

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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

Primary study design

Interventional

Study design

Single-centre randomized controlled trial.

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