VIrtual Reality;
The effect on pain reduction during an External Version, a randomised controlled trial.

Published: 21-07-2020
Last updated: 10-04-2024

The primary objective of this study is to explore the effect of VR on pain during ECV. Secondary objectives are the rate of succesful ECV procedures and tot explore tolerability, faesibility and patient satisfaction of VR use.

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

Summary

ID

NL-OMON54693

Source
ToetsingOnline

Brief title
VIREV

Condition

- Other condition
- Maternal complications of pregnancy

Synonym
anxiety, Pain

Health condition

Pijn

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: persoonlijk budget hoofdonderzoeker

Intervention

Keyword: Obstetrics, Pain, Virtual Reality

Outcome measures

Primary outcome

The primairy outcome is pain measured on a numeric rating scale (NRS). A total

of 40 patiënts have to be included in each group. This means that a total of 80

women will have to be included in the study.

Secondary outcome

Secondary outcome measures:

Rate of successful ECV procedures

Patient tolerability, feasibility and satisfaction of VR use (questionnaire)

Study description

Background summary

The use of an externale cephalic version (ECV) to rotate the fetus from a non-cephalic to cephalic presentation reduces the rate of caesarean section by approximately two-thirds in term pregnancies with breech presentation. Reducing pain during external cephalic version can contribute to an increase in succes rate and consequently reduce the number of cesarean sections. Literature about the effectivity of virtual reality (VR) on acute pain reduction seems promising.

Study objective

The primary objective of this study is to explore the effect of VR on pain during ECV. Secondary objectives are the rate of succesful ECV procedures and tot explore tolerability, faesibility and patient satisfaction of VR use.

Study design

The study concerns a non-blinded, single centre, randomised controlled trial.

Intervention

The study population will be randomly divided into the intervention group (VR group) or the standard care group. The intervention group gets an immersive guided relaxation VR experience during the external version additional to the usual standard carde. The participants randomised to the standard care group receive the usual standard care given during external version.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: each participating woman is asked to complete a questionnaire after using VR and the degree of pain perception is questioned on the basis of a 0-10 score (NRS). The study population experiences a very small medical risk when participating to this study. They can experience side-effects of VR for example dizziness or nausea in rare cases epileptic insults.

Contacts

Public
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL
Scientific
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

Written and orally given informed consent
18 years and older
Native Dutch speaker
Singleton pregnancy in breech position
Scheduled ECV

Exclusion criteria

Contra-indication external version
Chronic pain patients defined as persistent or recurrent pain lasting longer than 3 months, The pain is no due to an obstetrical problem.
Chronic use of pain medication (opioids)
Alcohol or drug abuse
Known car sickness
Epileptic insults in previous history
Psychotically seizures in previous history
claustophobic
blindness
history of mental illness
patients in strict isolation (MRSA)
Age<18 years
Twin pregnancy
No native Dutch speaker

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-11-2020
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO Date:	21-07-2020
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	29-12-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	11-08-2021
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	06-02-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL71484.096.19