Effectiviteit van Virtual Reality op de pijn en angst beleving na een totale knie of heup prothese operatie

Gepubliceerd: 14-07-2021 Laatst bijgewerkt: 18-08-2022

Our hypothesis is that VR (intervention) will significantly improve the mean NRS for pain after surgery.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24456

Bron
NTR

Verkorte titel
ViRA-PORT

Aandoening

Patients who fulfill the inclusion criteria and receive elective orthopedic surgery (total hip OR total knee replacement)

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: N.A.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint of this study is to evaluate the effect of VR on pain sensation as measured with the NRS for pain after orthopeadic hip and knee arthroplasty compared to standard care .

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale
Lack of postoperative acute pain management is associated with increased morbidity, longer recovery time, more opioid use and subsequently increased health care costs. There is increasing evidence virtual reality (VR) is effective in the reduction of acute pain.
Objective
The aim of this study is to determine whether VR used during hospitalization period for elective orthopedic surgery will decrease pain scores after surgery and mobilization.
Study design
A prospective randomized -controlled trial.
Study population
Eligible patients receive elective orthopedic surgery under spinal anesthesia (total hip or total knee replacement) in the Zuyderland Medical Centre location Sittard-Geleen.
Intervention
The intervention group can choose for an immersive guided relaxation VR experience or an interactive VR experience during the pre- and postoperative period.
Comparison
The standard care- group will receive the usual standard care pre-and postoperatively.
Main study parameters/endpoints
The primary outcome is postoperative pain measured on a numeric rating scale (NRS). To improve the mean NRS for pain after surgery with 15 mm with a standard deviation of 20mm (alpha 0.05 and beta 0.20) and taken 10% lost to follow up into account, a total of 30 patients have to be included in each group. And a total of 60 patients will have to be included in the study.

Doel van het onderzoek

Our hypothesis is that VR (intervention) will significantly improve the mean NRS for pain after surgery.

Onderzoeksopzet

Pre-operative: 1 hour before OR

Post-operative (twice): ~2-4 hours post OR and 6 weeks post OR

Onderzoeksproduct en/of interventie

The intervention group can choose for an immersive guided relaxation VR experience or an interactive VR experience during the pre- and postoperative period.

Contactpersonen

Publiek

Zuyderland Medisch Centrum
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Wetenschappelijk

Zuyderland Medisch Centrum
Martijn Schotanus

06-52377871

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Written and orally given informed consent
- 18 years and older
- Proficient in Dutch
- Indication for elective total hip or total knee replacement surgery under spinal anesthesia
- Medically cleared for participation by the surgeon

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Chronical use of pain medication (opioids)
- Known motion sickness
- Epileptic insults in previous history
- Claustrophobic
- Blindness

• Incapacity to follow the protocol.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	14-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9602
Ander register	METC ZUYD : METCZ20200018

Resultaten