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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24456

Source
NTR

Brief title
ViRA-PORT

Health condition

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

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: N.A.

Intervention

Outcome measures

Primary outcome

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 .

Secondary outcome

The secondary endpoints of this study are to evaluate the effect of VR on anxiety scores, Pain Catastrophizing Scale (PCS), analgesic use (peri- and post-operative, daily use of paracetamol, NSAIDs, opioids), length of hospital stay. In addition, we will assess tolerability, feasibility and satisfaction of VR use.

Study description

Background summary

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.

Study objective

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

Study design

Pre-operative: 1 hour before OR

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

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

• Incapacity to follow the protocol.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	14-07-2021
Application type:	First submission

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
NTR-new	NL9602
Other	METC ZUYD : METCZ20200018

Study results