The effect of Virtual Reality on Anxiety and Pain in patients undergoing Orthopedic surgery
A prospective Randomized controlled Trial

Published: 31-08-2020
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The aim of this study is to determine whether VR used in the postoperative period after elective orthopedic surgery will decrease pain scores.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON49532

Source
ToetsingOnline

Brief title
ViRA-PORT

Condition

- Joint disorders

Synonym
artificial hip, total hip arthroplasty. artificial knee, total knee arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Er zijn geen financieringen voor deze studie. Het is een investigator initiated studie;waarbij het ziekenhuis optreedt als sponsor

Intervention

Keyword: anxity, pain, Virtual Reality

Outcome measures

Primary outcome

The primary endpoint of this study is to evaluate the effect of VR on pain and

anxiety sensation pre- , peri- and postoperative compared to standard care

without VR in patient operated for TKA or THA.

Secondary outcome

The secondary endpoints of this study are to evaluate the effect of VR on

analgesic use (daily use of paracetamol, NSAIDs, opioids) and length of

hospital stay

Study description

Background summary

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.

Study objective

The aim of this study is to determine whether VR used in the postoperative period after elective orthopedic surgery will decrease pain scores.

Study design

A prospective randomized -controlled trial.

Intervention

n.a.

Study burden and risks

Directly following arthroplasty, the joint will be painful, but this effect normally disappears in the first weeks after TKA. The study population experience a negligible medical risk when participating to this study. They can experience side-effects of VR like for example dizziness or nausea

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

*Written and orally given informed consent
*18 years and older
*Native Dutch speaker
*Indication for elective total hip or total knee replacement surgery under spinal anesthesia

Exclusion criteria

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

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2021
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	31-08-2020
Application type:	First submission
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	NL72705.096.20

Study results

Date completed:	28-07-2022
Actual enrolment:	60