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

Published: 31-08-2020 Last updated: 08-04-2024

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

2 - The effect of Virtual Reality on Anxiety and Pain in patients undergoing Orthope ... 15-06-2025

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**

#### **Public**

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#### **Scientific**

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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

4 - The effect of Virtual Reality on Anxiety and Pain in patients undergoing Orthope ... 15-06-2025

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