# The effect of virtual reality on anxiety and pain in anterior cruciate ligament reconstruction: a prospective randomized controlled trial

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

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Tendon, ligament and cartilage disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON51859

**Source**
ToetsingOnline

**Brief title**
VR-ACLR

### Condition

- Tendon, ligament and cartilage disorders

**Synonym**
ACL-Rupture., Anterior Cruciate Ligament reconstruction

**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

## Intervention

**Keyword:** ACL rupture, anxity, pain, Virtual Reality

## Outcome measures

### Primary outcome

The primary endpoint of this study is to evaluate the effect of VR on pain sensation pre- and postoperative compared to standard care without VR in patient operated for an ACL-reconstruction

### Secondary outcome

The secondary endpoints of this study are to evaluate the effect of VR on anxiety, pain catastrophizing, analgesic use (daily use of paracetamol, NSAIDs, opioids), adverse events, patient satisfaction regarding the VR glasses 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.
However, this is still unknown in patients undergoing surgery for anterior cruciate ligament (ACL) reconstruction

### Study objective

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

### Study design

A prospective randomized -controlled trial.

### Intervention

One group will wear Virtual Reality glasses preoperative, 2h and 4h after the anterior cruciate ligament reconstruction.
The other group does not wear Virtual Reality glasses.

### Study burden and risks

Directly following ACL-reconstruction, the joint will be painful, but this effect normally disappears in the first weeks after ACL-reconstruction. 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)

## Inclusion criteria

-written an orally given informed consent
- 18 years and older
- Primary ACLR under spinal anaesthesia
- Oral and written informed consent
- Proficient in Dutch
- Medically cleared for participation by surgeon

## Exclusion criteria

- Posterolateral corner reconstruction
- General anaesthesia
- Femoral nerve block
- Chronical use of pain medication (opioids)
- Known motion sickness
- Epileptic insults in history
- Claustrophobia
- Blindness

# Study design

## Design

| | |
|---|---|
| Study phase: | 3 |
| 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): | 30-03-2022 |
| Enrollment: | 36 |
| Type: | Actual |

# Ethics review

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|---|---|
| Approved WMO Date: | 21-02-2022 |
| 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 | NL80151.096.21 |

# Study results

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|---|---|
| Date completed: | 29-06-2023 |
| Actual enrolment: | 36 |