# FeelGood: Increasing perioperative positive emotions by Cognitive Bias Modification

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To study the efficacy of preoperative CBM in patients with increased anxiety levels undergoing knee- or spine surgery with expected postoperative moderate to severe pain.

Ethical review Approved WMO

**Status** Pending

**Health condition type** Bone and joint therapeutic procedures

Study type Interventional

## **Summary**

#### ID

NL-OMON56930

Source

ToetsingOnline

**Brief title** FeelGood

#### **Condition**

Bone and joint therapeutic procedures

#### Synonym

anxiety for operation, pain after operation

#### Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

#### Intervention

**Keyword:** anxiety, Cognitive Bias Modification, mood, operation, pain

#### **Outcome measures**

#### **Primary outcome**

Trial: Difference in Anxiety and depression (HADS) between baseline and post-training/preoperative.

#### **Secondary outcome**

Bias change as measured at the start of the first and end of the last CBM session (this is not measured in the no-intervention condition) \*

Surgery related anxiety (APAIS) between baseline and post-training/preoperative

Change in Anxiety and depression (HADS) between baseline and POD 7, 28 and month 3

Difference in PAIN OUT-patient outcome on POD 1

Change in neuropathic pain symptoms (DN2) between baseline and POD 7, 28 and month 3

Change in pain and impact on functioning (BPI) between baseline and POD 7, 28 and month 3

Change in catastrophizing (PCS) between baseline and POD 7, 28 and month 3
Use of opioids (Oral Morphine Equivalent) at baseline, preoperative, POD 1, 7,
28 and month 3.

# **Study description**

#### **Background summary**

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A large group of patients experiences moderate to severe pain after surgery impacting recovery and quality of life, despite optimizing (intrahospital) perioperative pain management. Female gender, preoperative pain, opioid use, emotional distress and type of surgery are known risk factors for developing pain after surgery. There is growing interest in improving pain management by implementing interventions in patients at risk during the entire perioperative period. Cognitive bias modification (CBM) is a promising fast acting non-intrusive computerized cognitive intervention aiming at enhancing a healthy positive information processing style, which could play a role in reducing preoperative emotional symptoms and thereby reducing postoperative pain.

#### Study objective

To study the efficacy of preoperative CBM in patients with increased anxiety levels undergoing knee- or spine surgery with expected postoperative moderate to severe pain.

#### Study design

The study will be a prospective single centre randomized controlled trial. Patients will be randomized to receive preoperatively a CBM intervention (group I), a sham intervention (group II) or no intervention (group III) and will be followed till 3 months after surgery.

#### Intervention

In the active CBM condition, patients receive treatment as usual (TAU) and perform 2 weekly sessions of the active CBM training for 4 weeks. In the control CBM training patients will receive sham training concurrent to TAU. The brief (app. 20 minute) CBM sessions of cognitive training will be done on a computer. The sessions are planned so that they do not interfere with medical treatment patients might receive. The non-intervention group will receive no CBM training but changes in distress and other outcomes will be assessed to document natural changes.

#### Study burden and risks

Patients will receive a 4-week training before surgery and will be followed until 3 months after surgery. At 6 moments during this period, it will be asked to fill in questionnaires, which we will try to confine with regular follow up. In addition to normal care, time investment for patients in the (CBM or sham) intervention group will be 4.5 hours and 1.5 hours in the no intervention group.

We expect no additional risk for patients in the CBM or sham intervention group.

## **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

Receiving knee- or spine surgery with expected postoperative moderate to severe pain, scheduled >= 4 weeks after TPS.
>=11 on the APAIS
Signed informed consent form
>=18 years

#### **Exclusion criteria**

Impossibility to obtain a valid informed consent
Insufficient comprehension of the Dutch language
Acuteness of symptoms (somatic or psychiatric) that prevent patient from

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# Study design

## **Design**

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Control: Placebo

Primary purpose: Prevention

#### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-09-2024

Enrollment: 120

Type: Anticipated

## **Ethics review**

Approved WMO

Date: 24-07-2024

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

# **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

Other https://osf.io/8PQHJ CCMO NL85252.091.23