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

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

attentively doing the task 20 min per day

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