The Effects of Guided Imagery on Pain Management, Pre-operative Anxiety, and Recovery in Burn Wound Patients scheduled for Corrective or Reconstructive Surgery: a Randomized Controlled Pilot Study.

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Goals:1.To estimate the effect size for our primary and secondary outcome measures, allowing us to perform a more reliable power estimate for the actual trial.The primary objective of this pilot study is to determine whether a non-pharmacological...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON34532

Source
ToetsingOnline

Brief title
The Guided Imagery intervention Study for Burn Injuries: The GISBI study.

Condition

- Skin and subcutaneous tissue disorders NEC

Synonym
burn injury, burn wound patients in need of Corrective or Reconstructive Surgery

Research involving

Human

Sponsors and support

Primary sponsor: Rode Kruis Ziekenhuis
Source(s) of monetary or material Support: Nederlandse Brandwonden Stichting

Intervention

Keyword: Anxiety, Burns, Guided imagery, Pain

Outcome measures

Primary outcome

•Amount of used morphine via the PCA-system during the first 3 days after surgery:

Amount of morphine via the Patient Controlled Analgesia (PCA) system will be documented in the anesthesia report, medication lists from the recovery room and nursery department.

Secondary outcome

•Use of all post-operative pain medication:

Type and amount of used pain medication and medication for anxiety symptoms will be documented daily during the two weeks of the study in the patient diary.

•Pre-operative anxiety state:

will be measured 7 days before intervention (T0) and at the day of the surgery (T1) using the 6-item APAIS

•Self-rated pain:

will be noted daily in the patient diary using a 10-cm visual analogue scale (VAS) for pain (ranging from "no pain" to "pain as bad as could possibly be"), from 7 days before to 7 days after surgery. The first 24 hours after surgery

VAS scores will be noted every 6 hours according to standard care.

•Self-rated recovery:

will be noted daily in the patient diary using a 10-cm visual analogue scale

(VAS) for self-assessed surgical recovery (ranging from "poor" to "excellent"),

during 7 days after surgery.

•Feasibility (compliance to intervention).

Patients will be asked to record their daily experiences with guided imagery

and standard care in the patient diary. A compliance questionnaire is part of

the patient diary. Patients will be called by the pain nurse in the

intervention period prior to the surgery to monitor compliance. . Involved

nurses and medical doctors will be asked to complete an evaluation form about

their opinion of practical use of *guided imagery*

Study description

Background summary

In previous prospective studies, psychological stress has been shown to impair surgical wound healing and increase postoperative pain medication. We aim to investigate whether guided imagery can reduce pre-operative anxiety, reduce post-operative pain and use of post-operative pain medication, so it could improve surgical recovery.

The working hypothesis is that patients who receive a psychological stress reduction intervention prior to surgery will report lower stress and higher perceived control, use less pain medication and a better self-reported recovery than patients who receive standard care alone.

Study objective

Goals:

1.To estimate the effect size for our primary and secondary outcome measures,

allowing us to perform a more reliable power estimate for the actual trial.
The primary objective of this pilot study is to determine whether a non-pharmacological intervention, i.e. relaxation with guided imagery, added to the standard perioperative analgesic and anxiolytic pharmacotherapy program, can reduce post-operative pain medication, post-operative pain, pre-operative anxiety and induce post-operative recovery, compared to standard care.

2.To gain experience with the feasibility of the peroperative use of guided imagery as a self-management tool in patients with burn wounds scheduled for corrective or reconstructive surgery, and to refine it if needed

Study design

A mono-centre randomized controlled pilot study with two parallel groups

Duration 2 weeks

Contact 1 (intake: 6 months-1 week before surgery)
•Information and informed consent
•Screening
•Demographic and anthropometric data
•Classification initial burn / type of surgery
•Prestatification/ randomisation
•Instruction for timelines and patient diary (pain nurse)

Before surgery, 1 week (day -7 till day 0, at home)
•Start guided imagery daily pre-operative exercise 3 (intervention group)
•Start daily patient diary (7 days daily before surgery)

Contents pre-operative patient diary (day -7 till day 0):
-Pain medication, self rated pain (VAS) rest/ exercise, experience, compliance, adverse events
-At day -7 (T0) and day 0 (T1): APAIS

Contact 2/3 (telephone interview: 7 and 3 days before surgery)
•Compliance CD (intervention group)
•Compliance patient diary
•Adverse events (intervention group)

The day of the surgery= day 0 (at the hospital, T1)

After surgery, 1 week (day 0 till day 7, at home or at the hospital)
•Continue guided imagery daily post-operative exercise 4 (intervention group)
•Continue patient diary (7 days daily after surgery)
•End of study: 7 days after surgery, T2

Contents post-operative patient diary (day 0 till day 7):

-Pain medication self rated pain (VAS) rest/ exercise, self-rated recovery (VAS) experience, compliance, adverse events

Intervention

Intervention group:
In addition to standard care: Patients are provided a CD of the guided imagery ("Gezonde Verbeelding", Elsevier publisher) to take home and practice once a day during a period of 7 days before surgery (exercise 3 on the CD) and 7 days after surgery (exercise 4 on the CD). The exercise will be about 20 minutes in length each day. The CD has been developed by the Van Praag Institute (VPI) specifically on the one hand to enhance relaxation and prepare patients for surgery, and on the other hand to enhance relaxation and recovery after surgery

Control group:
Patients in the control group will receive standard care and no additional intervention before and after surgery.

Study burden and risks

Patients won't have extra contacts in relation to this research. During the pre-operative consultancy by the anesthesiologist they receive the extra information and the research requisites (CD (if randomised), patient diary, extra patient information, and flow cart).

The intervention group will have a time investment of 20 minutes a day to practise the exersice from the CD.

Patients are called twice during the intervention period by a project member to monitor compliance (5 minutes per telephone call)

Patients will have to report daily in the patient diary during the 2 weeks of the study (pain medication, pain, anxiety, recovery, experiences, compliance and adverse events), about 5-10 minuts per day.

It is expected there are minimal risks for the intervention group . There are no knowm adverse events of guided imagery.

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 informed consent
•Age >= 18 year
•Patients with previous burn injury with a need for reconstructive or corrective surgery
•Ability to understand and speak the Dutch language
•Accessible by phone
•Access to CD-player at home

Exclusion criteria

•Known contra-indication to medication used in the standard pain- and general anaesthesia protocol (Midazolam, Paracetamol, Diclofenac, Tramadol, Diprivan, Sufentanil, Morphine, Esmeron and Sevofluran)
•Actual psychosis

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:	Recruiting
Start date (anticipated):	01-03-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	24-12-2010
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL33985.094.10