

the anxiety reducing effect of preoperative music and the role of (emotion focused) coping

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The positive side-effects of preoperative anxiety reduction are less pain, need for medication, and postoperative woundinfections. Less anxiety also leads to a shorter stay at the hospital and less medical consumption. An increasing amount of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38434

Source

ToetsingOnline

Brief title

Anxiety and music at the OR:music-trial

Condition

- Other condition

Synonym

anxiety before undergoing surgery, preoperative anxiety

Health condition

habituele angst/spanning voor een medische behandeling

Research involving

Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis

Source(s) of monetary or material Support: onderzoeker zelf

Intervention

Keyword: COPING, MUSIC INTERVENTION, PREOPERATIVE ANXIETY

Outcome measures

Primary outcome

Three main questions of this study:

1. Is there a mediating effect of coping on the relation between preoperative stress and perioperative anxiety?
2. In comparison to no music, is there a reinforcing influence of self-chosen music on the relation between (emotion-focused) coping and anxiety?
3. To what extent do the background variables (sex, age, former operations and trait-anxiety) influence coping and anxiety?

Measurement instruments:

1. Coping Inventory of Stressful Situations (CISS-NL) 48 items to measure emotion, problem of avoidance coping.
2. STAI-trait: State-Trait Anxiety Inventory 21 items version to measure trait-anxiety
3. STAI- state dutch short version: 6 item version to measure state-anxiety
4. Visual Analogue Scale- anxiety
5. Amsterdam Preoperative Anxiety and Information Scale (APAIS)
6. Visual Analogue Scale pain

7. RR (bloodpressure mmHg), HR (heartrate) ,skintemperature

T0= Preoperative screening

T1= holding OR

T2=OR: after musicintervention, before general anaesthetics

T3= postoperative at daycare centre

Secondary outcome

To measure the subjective experiences of the music, the musictherapist will send a questionnaire postoperative to all participants of the music-condition.

Study description

Background summary

Preoperative anxiety is a well-known phenomenon. This form of anxiety can cause negative treatment-outcomes. Yet, because of negative side-effects, less premedication regimes are proscribed.

Some knowledge shows that music has anxiety reducing effects on preoperative anxiety. Small projects at the OR of St. Elisabeth hospital Tilburg show positive effects of music on preoperative anxiety, yet coping style of the patient needs to be considered. Eventually more tailored music interventions probably will lead to a greater anxiety reducing effect.

Study objective

The positive side-effects of preoperative anxiety reduction are less pain, need for medication, and postoperative wound infections. Less anxiety also leads to a shorter stay at the hospital and less medical consumption. An increasing amount of daycare patient sets for another approach of preoperative anxiety. Premedication causing a variety of side-effects, is less desirable for daycare patient.

When the patient is transported to the holding OR, premedication (

benzodiazepine) is given orally. Only within an hour the patient will benefit from the benzodiazepine. In most cases the patient will be transported to the OR, before they benefit from the premedication. Also the transport to the holding of the OR will arouse anxiety. Therefore music will be a good alternative for premedication. Musicintervention that meets the patients copingstyle will account for more anxiety reduction.

Study design

200 participants allocated at-random to one of the 2 groups: 1. Self-chosen music, 2.no music

Intervention

Musicintervention: at arrival of the OR holding, 1 group of patients receives self-chosen music, by headphone. They listen music until they receive anaesthetics.

Study burden and risks

This intervention is of minor burden to the participants. Filling out the questionnaire takes a small time-investment. The physiological measurements are all routine measurements. It is not necessary to visit the hospital an extra time.

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

minimal age 18 years old, daycare surgery patients, general anaesthetic, ASA 1

Exclusion criteria

mental diseases, heartdiseases, using medication that influence HR and RR, visual and/or hearing impairment, oncology-surgery

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2014
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date: 12-12-2013

Application type: First submission

Review commission: METC Brabant (Tilburg)

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	NL46208.008.13