Implemenation of gainful music in surgery

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22524

Source
NTR

Brief title
IMAGINE

Health condition

Surgery, music, periopeative care

Sponsors and support

Primary sponsor: Máxima Medical Center
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The primary study outcome will be the adherence to protocol of perioperative music as part of standard surgical care. Adherence to the intervention will be calculated as the percentage of performed music interventions relative to the number of total possible interventions.

Secondary outcome

Barriers and facilitators to implementation of perioperative music, postoperative pain, postoperative analgesic medication requirement, intraoperative and postoperative complication rate, postoperative nausea and vomiting (PONV), length of hospital stay, patient reported experience measurements, using a custom-made survey, experiences of implementation of perioperative music by the surgical and anesthesia team and nursing staff, using a self-developed survey and interviews.

Study description

Background summary

Perioperative music can have a significant beneficial effect on postoperative pain and anxiety, reduce intraoperative sedative and postoperative opioid medication requirement, and attenuate the physiological stress response to surgery in patients undergoing surgery. Implementation research can assess contextual factors and barriers which can ultimately influence the outcome of an intervention in daily patient care. The aim of this study is to assess the feasibility and effect of implementing music as part of stand perioperative care.

This pilot study will be a single-center explorative, prospective, quasi-experimental pre-test / post-test implementation study performed at the operating department. This study will run from January 2020 till June 2020 and will take place at the Máxima Medical Center (MMC).

The study will consist of 4 different phases:
1. Assessment of current practice, identification of barriers and facilitators for implementation of perioperative music as part of standard surgical care;
2. Development of an effective implementation strategy and protocol;
3. Implementation of protocol and measurement of effect through a prospective, quasi-experimental pre-test / post-test study;
4. Process evaluation through qualitative (effect outcomes) and quantitative (survey, interviews) data

Study objective

We hypothesize that the implementation of music in perioperative care is feasible and will improve patient outcomes (reduce postoperative pain, reduce opioid analgesic medication requirement, reduce postoperative complications and length of hospital stay and increase satisfaction).

Study design

Time during hospital admission

Intervention

Participating patients will receive music before, during and after surgery, following a predefined implementation protocol by the implementation team. The music intervention starts when the patient has checked in the surgery ward, using a music player and headphone. Patients will receive music during surgery, independent of the type of anesthesia used. The music intervention will be continued during the surgical route to the recovery room and will be discontinued after discharge to the surgical ward or whenever the participant chooses to stop the music intervention. The music intervention will be a preselected list of playlists and patients will be able to choose from this list.

Contacts

Public
Máxima Medisch Centrum
Muriël Reudink

N/A
Scientific
Máxima Medisch Centrum
Muriël Reudink

N/A

Eligibility criteria

Inclusion criteria

For the patients to be eligible to participate in this study, a subject must meet all the following criteria:

• Aged ≥ 18 years
• Scheduled for elective surgery
• Signed informed consent form
• Will be operated in MMC location Veldhoven or Eindhoven

Exclusion criteria

Patients will be excluded during the study if he/she:

• Has severe hearing impairment, defined as no verbal communication possible
• Has insufficient knowledge of the Dutch or English language to understand the study

documents in the judgement of the attending physician or researcher
• Is unwilling or unable to comply with the intervention

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2020
Enrollment:	270
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-11-2019
Application type:	First submission

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
NTR-new	NL8213
Other	Máxima Medical Center : METC N19.102

Study results