Implementation of music Intervention in the Perioperative standard care (IMRPOVE-study)

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23299

Bron
Nationaal Trial Register

Verkorte titel
IMPROVE

Aandoening

Colorectal cancer, inflammatory bowel disease (IBD, consisting of Crohn’s disease and ulcerative colitis)

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam Department of Surgery P.O. Box 2040, 3000 CA Rotterdam, The Netherlands
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the adherence (%) to the music intervention, by calculating the percentage of patients who consented in receiving the intervention and who truly received the intervention during the implementation phase, and assessing the initial impact of the implementation on pain of the first POD.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Preoperative, intraoperative and postoperative recorded music interventions have been proven effective in reduction of pain and anxiety. Also, recent reviews and meta-analyses provide significant evidence for lower postoperative stress response, lower intraoperative sedative use, and lower postoperative opioid use when music interventions are applied in the perioperative period. Considering the above, the highest level of evidence (level-1) exists for implementation of recorded music interventions before, during and after surgery. Unfortunately, a major gap exists between new evidence in health care and its introduction into the standard care of patients. Also, literature does not provide sufficient information on the implementation of perioperative recorded music interventions. Thus, this study will focus on implementing perioperative music intervention in the perioperative standard care.

Objective:
The main objectives of this study is the adherence to the music intervention, and the initial impact of the implementation on pain on the first postoperative day (POD). The implementation is conducted using the Consolidated Framework for Implementation Research (CFIR), in the perioperative care of adult patients undergoing an elective gastrointestinal (GI) surgical procedure including oncological and inflammatory bowel disease (IBD) resections. Secondary objectives are penetration of the intervention in the standard care, adherence to the implementation strategy, assessment of the determinants of an effective implementation of perioperative recorded music and to study the effects of the implementation of perioperative recorded music on pain during the entire hospitalization, intraoperative and postoperative medication use, hospital and intensive care unit (ICU) length of stay (LOS).

Study design:
This implementation study will be divided into three phases in which the five domains of the CFIR (characteristics if intervention, the outer setting, the inner setting, the individuals involved, and implementation process) will be processed:
Phase 1 Evaluation of the intervention characteristics, current practice regarding anxiety and pain, assessment of the barriers and facilitators for implementation of perioperative music

intervention in the standard care.
Phase 2 Development of a tailored implementation strategy
Phase 3 Implementation process

Study population:
Implementation study
Phase 1
Adult patients, 18 years and older, who underwent an elective gastrointestinal (GI) surgical procedure including oncological and inflammatory bowel disease (IBD) resections (IBD includes of Crohn's disease and ulcerative colitis (UC)) admitted to the GI nursing department will be asked for participation in the qualitative analysis and will be asked for informed consent on data collection from the patients' medical records.
Health care professionals involved in the perioperative period of the above mentioned patient population; surgeons, surgery residents and fellow's, anesthesiologists, nurse anesthetist, and ward nurses (at the surgical ward and intensive care unit) will be asked for participation in the qualitative analysis.

Music Intervention
Phase 3
Adult patients, 18 years and older, planned for undergoing an elective GI surgical procedure including oncological and inflammatory bowel disease (IBD) resections (IBD includes of Crohn's disease and ulcerative colitis (UC)) admitted to the GI nursing department will be approached for participation.

Intervention:
Implementation study
Phase 1 Prospectively, data will be collected on secondary outcome measures. Institutional surveys will be carried out in patients and health care professionals, consisting anesthesiologists, nurse anesthesiologists, surgeons, intensivists, and ward nurses, involved in the perioperative care of the target group in order to identify positive and negative influencing determinants of the practice, current practices, and characteristics of the intervention.
Phase 2 Based on the determinants assessed in phase 1 a tailored implementation strategy will be developed.
Phase 3 The tailored implementation strategy will be initiated at the GI surgical department. Reflection and evaluation of the implementation strategy will be assessed by performing surveys, personal and/or group interviews regularly during the implementation process and at the end of the implementation process. Patient data will be collected on outcome measures.

Music intervention
Phase 3 Patients who are willing to participate will be offered to listen to recorded music through a hearing device before, during, and after music intervention based on the applied custom designed implementation strategy.
The timing of the intervention before and after surgery will be decided during phase two. (assessment of a custom designed implementation strategy). Postoperatively participating patients will be advised to listen to music twice a day for at least 30 minutes per session

starting from the first postoperative day until the patient is discharged from the hospital.

Main study parameters/endpoints:
The primary outcome is the adherence (%) to the music intervention, by calculating the percentage of patients who consented in receiving the intervention and who truly received the intervention during the implementation phase, and assessing the initial impact of the implementation on pain of the first POD.

Secondary outcomes consist of adherence to the implementation strategy, penetration of the intervention in the standard care, assessment of the determinants of practice for implementation and the effect of music on postoperative pain scores during the entire hospitalization, NSAIDs, opioid and sedative medication used perioperatively, postoperative complication, hospital and ICU LOS.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Music has no negative effect on humans. Therefore, the risks and burden in this study are negligible. Music volume will be controlled by a lock on the device. Apart from the music intervention the patient does not have to undergo additional examinations.

Doel van het onderzoek

Preoperative, intraoperative and postoperative recorded music interventions have been proven effective in reduction of pain and anxiety. Also, recent reviews and meta-analyses provide significant evidence for lower postoperative stress response, lower intraoperative sedative use, and lower postoperative opioid use when music interventions are applied in the perioperative period. Considering the above, the highest level of evidence (level-1) exists for implementation of recorded music interventions before, during and after surgery. Unfortunately, a major gap exists between new evidence in health care and its introduction into the standard care of patients. Also, literature does not provide sufficient information on the implementation of perioperative recorded music interventions. Thus, this study will focus on implementing perioperative music intervention in the perioperative standard care.

Onderzoeksopzet

Preoperative, intraoperative and postoperative until the participant is discharged from the hospital.

Onderzoeksproduct en/of interventie

Music intervention provided using headphones

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Phase 1
Patients
Adult patients who have undergone or will undergo a surgical procedure at the surgical department. In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Age ≥ 18 years old
2. Patients who have undergone an elective gastrointestinal (GI) surgical procedure for oncology treatment or inflammatory bowel disease (IBD, consisting of Crohn’s disease and ulcerative colitis (UC)) admitted to the GI nursing department
3. Written informed consent provided by patient or a medical representative of the patient.

Health care professionals
Institutional health care professionals involved in the perioperative period, including;
1. Surgeons
2. Surgery residents/ fellow’s
3. Anaesthesiologists
4. Nurse anaesthetists
5. Nurses involved in the perioperative process of the patient

Phase 3
Music Intervention
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Age ≥ 18 years old
2. Patients planned for an elective gastrointestinal (GI) surgical procedure for oncology

treatment or inflammatory bowel disease (IBD, consisting of Crohn’s disease and ulcerative colitis (UC)) admitted to the GI nursing department
3. Written informed consent provided by patient or a medical representative of the patient.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Phase 3
Music Intervention
A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Severe hearing impairment causing problems with verbal communication.
2. Patients who are unable or unwilling to receive the music intervention.
3. Patients who do not adequately control the Dutch or English language.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2019
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
Not applicable

Ethische beoordeling

Positief advies

Datum:	08-10-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8071
Ander register	METC Erasmus MC : MEC-2019-0563

Resultaten

Samenvatting resultaten
Not applicable