MusiC to prevent deliriUm during neuroSurgerY

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22786

Bron
Nationaal Trial Register

Verkorte titel
MUSYC

Aandoening

Delirium.

Ondersteuning

Primaire sponsor: Erasmus MC Doelmatigheid 2019
Overige ondersteuning: Mrace Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is presence or absence of postoperative delirium within the first 5 days after surgery.

All participating patients on the ward will be screened using the Delirium Observation Screening (DOS) scale. Additional to the DOS, in case of raised suspicion of delirium, a psychiatrist is consulted to confirm or reject clinical diagnosis of delirium based on the DSM-V criteria.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Delirium is a common and severe complication after neurosurgical procedures. Music before, during and after surgical procedures has proven its effectiveness in reducing pain, anxiety, stress and opioid medication in surgical patients. These symptoms belong to the main eliciting factors for developing delirium. Effective preventive therapy for delirium is not available. We hypothesize that music listening, being a sustainable intervention with negligible risk of side effects, can lower delirium incidence among neurosurgical patients, resulting in reduction of in-hospital stays, healthcare costs and post-operative morbidity and mortality.

Objective:
To assess the effect of peri-operative music on post-operative delirium in patients undergoing a craniotomy.

Study design:
Single-centre prospective randomized controlled trial.

Study population:
Adult patients undergoing a craniotomy at the Erasmus MC in Rotterdam.

Intervention:
Recorded music, with headphones or earbuds, before, during and after surgery.

Main study parameters/endpoints:
Diagnosis of post-operative delirium screened by the DOS score confirmed by the consultant psychiatrist following the DSM-V criteria.

Doel van het onderzoek

We expect an incidence of delirium in our control group of 30%. This is based on literature documenting incidence of delirium in neurosurgical patients in a northern European population of 29-33%.

The expected effect cannot be based on previous literature since no adequate trials exist on the effect of music on delirium. Other non-pharmacological interventions mention a relative reduction of 36-77%. We will consider the intervention clinical relevant if a relative reduction

of 60% with an absolute reduction of 18% is achieved.

Onderzoeksopzet

T0: inclusion, T1: intervention during admission, T2: 6 weeks follow-up, T3: 3 months follow-up, T4: 6 months follow-up

Onderzoeksproduct en/of interventie

Patients will be randomly allocated to either the intervention (music) or control (standard care) group.

Participants in the music group will receive headphones with music 30 minutes before surgery. Patients will be able to choose music from a preselected list composed by a team consisting of researchers and dedicated music therapists. The headphones will be removed just before entering the operating room. Once in the operating room they will receive earbuds after intubation, compatible with the Mayfield and site of operation. The intraoperative music intervention will be continued during the surgical procedure and discontinued just before detubation. The duration of the intraoperative music intervention depends on the duration of
surgery and will be documented. After surgery, during recovery at the post-operative care unit (PACU) another 30 minutes of music through headphones will be given. The following 3 days at the neurosurgical ward they will receive music twice a day for 30 minutes.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients undergoing a craniotomy.
2. Adult patients (cq age ≥18 years)
3. Sufficient knowledge of the Dutch language to understand the study documents in the judgement of the attending physician or researcher.
4. Provision of written informed consent by patient or legal representative.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Impaired awareness before surgery (i.e. GCS < M6).
2. Planned post-operative ICU admission.
3. Suspected delirium (defined as fluctuating awareness).
4. Current antipsychotic treatment.
5. Patients undergoing interventions impeding supply of music (e.g. surgical translabyrinthine approach, awake surgery).
6. Severe bilateral hearing impairment, defined as no verbal communication possible.
7. Current participation in other clinical trials interfering with results.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	09-07-2020
Aantal proefpersonen:	189
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Data Sharing statements according to ICMJE Guidelines. Individual participant data will be available. This includes data that underlie the results reported in this article, after de-identification (text, tables, figures and appendices). Other documents such as Study Protocol, Statistical Analysis plan, Informed Consent form, Clinical Study Report and Analytical Code will be made available. This will be made available to researchers, which need it to approve their proposal or for meta-analysis, which request data after providing a methodologically sound proposal beginning 3 months until 5 years after article publication. Proposals should be directed to p.kappen@erasmusmc.nl. To gain access, data requestors will need to sign a data access agreement.

Ethische beoordeling

Positief advies

Datum:	04-04-2020
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	NL8503
Ander register	METC EMC : MEC-2020-0064

Resultaten

Samenvatting resultaten
N/A