Result of music intervention on anxiety in critically ill patient.

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We hypothesize that music intervention can have a positive effect on anxiety in critically ill patients and aim to study the effect of music intervention in these patients.

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

Samenvatting

ID

NL-OMON28119

Bron
Nationaal Trial Register

Verkorte titel
RELACS

Aandoening

Intensive Care Unit

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Anxiety measured using the Visual Analogue Scale for Anxiety (VAS-A) questionnaire immediately after each music session during three consecutive days after inclusion.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Anxiety is common in critically ill patients, and has likely become more prevalent in the recent decade due to the imperative of the recent PADIS guidelines to use low levels of sedation and strive for wakefulness. Administration of sedative and analgesic medication is often chosen to reduce anxiety, especially when associated with agitation, but especially sedatives are associated with prolonged mechanical ventilation, delirium and muscle wasting and are therefore preferably minimized. Previous studies have suggested positive effects of music interventions on anxiety in the critically ill, next to other physiological signs such as pain. However, management of anxiety has not been included in the PADIS guidelines, and there is lack of evidence to treat it in spite of its growing importance. Therefore, we aim to study the effect of music intervention on anxiety in adult critically ill patients.
Objective: The primary objective is to assess the effect of music intervention on the level of anxiety.
Study design: A randomized controlled trial.
Study population: Adult patients admitted to the intensive care unit, with whom communication is possible (Richmond Agitation Sedation Scale of -2 or higher).
Intervention (if applicable): The music group will be offered to listen to music two times per day for three days after inclusion, during 30-60 minutes per session. Chosen music will be based on the preference of the patient. The control group will receive standard of care during the entire study.
Main study parameters/endpoints: The primary outcome is the effect of music on the Visual Analogue Scale for anxiety (VAS-A). Secondary outcomes include effect of music on sedation and agitation level, medication requirement, pain, sleep, delirium, heart rate, mean arterial pressure, and ICU memory and experience.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Music is not associated with any known risks. Music volume will be limited to avoid hearing damage. Most of the outcome measures are already included in routine care of the ICU. We estimate a high potential for benefit with no potential for harm, given the previous literature on this topic.

Doel van het onderzoek

We hypothesize that music intervention can have a positive effect on anxiety in critically ill patients and aim to study the effect of music intervention in these patients.

Onderzoeksopzet

NA

Onderzoeksproduct en/of interventie

Recorded music

Contactpersonen

Publiek

Erasmus Medical Centre
Ellaha Kakar

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Wetenschappelijk

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Ellaha Kakar

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patient is hemodynamically stable and communicable (RASS of -2 or higher in the 24h before intended inclusion: meaning patient is at least briefly awakened with eye contact to voice).
- Expected ICU stay upon randomisation of at least another 48 hours.
- Written informed consent acquired from the patient or legal representative.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients with severe hearing impairment, defined as no verbal communication possible.
- Neurological condition (e.g. severe stroke), when deemed to interfere with processing of music (e.g. not applicable to patients with minor stroke in past medical history without significant residual neurological deficits; those patients could be included).
- Insufficient knowledge of the Dutch or English language for informed consent.
- Participation in another study that may possibly intervene with the primary outcome measure

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2020
Aantal proefpersonen:	104
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Data will be made available upon reasonable request after evaluation of the main researchers. This data will contain all the data generated during this trial as written in the study protocol. related documents regarding study protocol and statistical analyses are available and will be published, and are available also on www.clinicaltrials.gov and www.trialregister.nl. Data will be shared after the trial is finished and the results of the paper are published in a scientific journal. Possible availability of data is subject to European and Dutch privacy legislation. We propose to share data when possible and feasible, until ten years after data was collected.

Ethische beoordeling

Positief advies

Datum:	01-04-2020
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	NL8595
Ander register	METC Erasmus MC : MEC-2020-0212

Resultaten