Result of music intervention on anxiety in critically ill patient.

No registrations found.

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

Summary

ID

NL-OMON28119

Source
Nationaal Trial Register

Brief title
RELACS

Health condition

Intensive Care Unit

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Anxiety: measured using the 6-item short version State -Trait Anxiety Inventory (STAI-6) questionnaire immediately after each music session during three consecutive days after inclusion.
- Agitation and sedation level: measured using the Richmond Agitations- Sedation Scale (RASS), assessed three times daily during every shift, as long as the patient is mechanically ventilated and/or sedated as part of the standard care procedure.
- Medication requirement (duration and dosages, corrected for body weight milligram/killogram), including remifenanyl, propofol, benzodiazepines, dexmedetomidine, clonidin, paracetamol, sufentanyl, fentanyl, morphine, ketamine, epidural analgesia, haloperidol, and other benzodiazepines, atypical anxiolytics and antipsychotics.
- Pain: measured using the Critical Pain Observation Tool (CPOT) in mechanically ventilated patients, or the NRS/VAS for pain in non-ventilated and alert/oriented as part of the standard care procedure.
- Sleep quality: assessed daily in the morning after awakening, starting before the music session at baseline, and during the intervention period. Sleep will be assessed using a visual numeric scale ranging from one to seven, in which one indicates “did not/barely sleep” and seven indicates: “slept very well”
- Delirium: measured with the Intensive Care Delirium Screening Checklist (ICDSC), which is routinely done in all ICU patients, three times daily, as part of the standard care procedure.
- ICU memory and experience: assessed by the ICU memory tool (ICU-MT) extended with self-made questions to assess ICU experience, once at the end of the study period.
- Complications related to agitation: defined as removal of lines and tube (auto-detubation) by the patient.
- Time spend on mechanical ventilation: measured in total amount of hours.
- ICU length of stay (LOS): measured in total amount of hours spend in the ICU after inclusion.
- Physical parameters: daily heart rate (HR), and arterial blood pressure (MAP) at the time when the primary outcome (anxiety) is assessed during the intervention period will be collected and analysed, in order to gain insight in proxy-measures for stress level.
- Patient memory and experience: assessed by the ICU memory tool (ICUMT) extended with self-made questions to assess ICU experience. We adapted and shortened the ICUMT to a seven-item questionnaire to avoid overlap, e.g. with assessment of anxiety or delirium, and with other tools, and to avoid invasive long questionnaires. For the patient experience assessment in the music group the questionnaire is extended with five items and for the control group with three items.

Study description

Background summary

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.

Study objective

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.

Study design

NA

Intervention

Recorded music

Contacts

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Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

- 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2020
Enrollment:	104
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
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.

Ethics review

Positive opinion

Date:	01-04-2020
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	NL8595
Other	METC Erasmus MC : MEC-2020-0212

Study results