the effect of a MUsic intervention on poStictal agitation in Electroconvulsive therapy patients

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The objective of the study is to assess the effect of music on postictal agitation when played peri-interventionally for patients undergoing electroconvulsive therapy for severe depression.

Ethical review	Approved WMO
Status	Pending
Health condition type	Deliria (incl confusion)
Study type	Interventional

Summary

ID

NL-OMON57276

Source
ToetsingOnline

Brief title
MUSE

Condition

- Deliria (incl confusion)

Synonym
agitation, Postictal agitation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Erasmus MC Foundation

Intervention

Keyword: Electroconvulsive therapy, Music, Postictal agitation

Outcome measures

Primary outcome

The primary outcome is presence of postictal agitation as determined by the Richmond Agitation-Sedation Scale (RASS).

Secondary outcome

The secondary outcomes are severity of PIA, duration of PIA, pretreatment anxiety, music listening behavior, duration of recovery (time spent in the recovery room), pre-, peri-, and post-treatment medication use, severity of depression, and cognitive impairment, measured by the Montreal Cognitive Assessment (MoCA) questionnaire.

Study description

Background summary

Postictal agitation (PIA) is a fairly common adverse effect after electroconvulsive therapy (ECT) treatment that when present, predicts other complications such as retrograde amnesia. Multiple studies have suggested that a music intervention in the context of surgery significantly reduces pre-operative anxiety, as well as the need for sedatives and analgesic medication. Pretreatment anxiety is common for ECT patients and is a known predictor of PIA. Currently there is no preventative treatment for PIA. Given the beneficial effects of music demonstrated in similar hospital settings combined with its easy implementation and lack of side effects, we hypothesize that music listening can lower the incidence and severity of PIA among patients undergoing ECT therapy, thereby also reducing post treatment cognitive impairment.

Study objective

The objective of the study is to assess the effect of music on postictal

agitation when played peri-interventionally for patients undergoing electroconvulsive therapy for severe depression.

Study design

Multi-center prospective randomized controlled trial.

Intervention

Recorded music, with headphones, for 30 minutes directly before ECT and 12 minutes directly after ECT.

Study burden and risks

Music as an intervention is not known to have a negative effect on subjects. The volume of the music will not exceed 80 decibels. The burden includes the electric stimuli. Negative consequences are minimized by taking safety precautions. The burden will be to fill in questionnaires and to listen to music. Participation in this study includes two extra outpatient visits of approximately 20 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients undergoing ECT treatment for depression
2. Hypnotic agent used is etomidate
3. Adult patients (>=18 years)
4. Sufficient understanding of the Dutch language
5. Written informed consent by patient or legal representative

Exclusion criteria

1. Significant impaired hearing
2. Severe neurological condition
3. Patients receiving ECT for treatment of schizophrenic disorders

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	92

Type:	Anticipated

Ethics review

Approved WMO Date:	28-01-2025
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL86074.078.24