Meaningful Music in Healthcare (MiMiC): Patient study

Published: 17-11-2021
Last updated: 04-04-2024

The primary objective is to see whether a live music intervention can significantly lower perceived postoperative pain compared to recorded music intervention and do-nothing control. The secondary objective is to explore neuroinflammatory...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50812

Source
ToetsingOnline

Brief title
PatMiMiC

Condition

- Other condition

Synonym
postoperative pain perception / subjective pain

Health condition

perceived postoperative pain

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Triade;Toukomst;Prins Bernhard Cultuurfonds

Intervention

Keyword: live music intervention, mechanism, neuroinflammation, postoperative pain

Outcome measures

Primary outcome

The main study parameter is the difference between subjective pain ratings

before and after music intervention and after 3- and 6-hour follow-up.

Secondary outcome

• objective pain metric (volume of administered pain medication)

• respiratory rate and tidal volume

• Heart rate (HR)

• Blood pressure

• neuroinflammation blood markers (IL6, NGAL, CRP, serum TPSO);

• behavioral indicators of neuroinflammation (delirium and post-operative

cognitive decline incidence);

• EEG markers of neuroinflammation (alpha-power, delta/alpha power ratio,

entropy).

Study description

Background summary

Postoperative patients who previously engaged in the live musical intervention Meaningful Music in Healthcare (MiMiC) reported significantly reduced

perception of pain than patients without the intervention (van der Wal- Huisman et al., 2020). This encouraging finding indicates a potential for postsurgical musical interventions to have a place in standard care as therapeutic pain relief. However, live music is logistically complex in hospital settings, and previous studies have reported the more cost-effective recorded music to serve a similar pain-reducing function in post-surgical patients (van der Wal-Huisman et al., 2018). Moreover, little is known about the potential underlying physiological mechanisms that may be responsible for the reduced pain perceived by patients after live music intervention.

Study objective

The primary objective is to see whether a live music intervention can significantly lower perceived postoperative pain compared to recorded music intervention and do-nothing control. The secondary objective is to explore neuroinflammatory underpinnings of postoperative pain, and the potential role of music intervention in mitigating neuroinflammation.

Study design

This intervention study will compare subjective postsurgical pain ratings among three groups: live music intervention, recorded music intervention, and standard care control. The design will take the form of an on-off non-randomized controlled trial (NCT, Mathe et al., 2015).

Intervention

Intervention is a daily music session of up to 30 minutes for a maximum of five days. The live music intervention group is visited by professional musicians once a day for 15 minutes and asked to interact. The recorded music, active control intervention group receives 15 minutes of pre-selected music over headphones. The do-nothing group receives typical post-surgical care that does not include music.

Study burden and risks

Participants will be in recovery after elective surgery in the UMCG. Participation requires approximately 12 minutes questionnaires before surgery. Daily data collection includes one blood sample (10ml), one hour total of EEG recording, four times daily HR, blood pressure, respiration rate, pain rating on a VAS, and (unless standard-care treatment) ~15 minutes of live or recorded music intervention. As blood samples and measurements of HR, blood pressure and respiration rate are routine measurements collected as part of standard postoperative care, they will be integrated with standard care insofar as possible. There are no known risks for participation. Based on past related research (UMCG research register 201600541), patients generally seem to enjoy

the music interventions.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1 1
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

over 18 years
elective surgery
post-surgery hospitalization
able to hear music
able to give informed consent
able to communicate

Exclusion criteria

under 18
outpatient surgery
acute surgery
severe hearing loss/unable to hear music
unable to communicate

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-06-2022
Enrollment:	360
Type:	Actual

Ethics review

Approved WMO

Date:	17-11-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL76900.042.21