Duration Of Music Interventions aNd pAiN Tolerance in healthy individuals

Published: 19-04-2023
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The main objective is to investigate the effect of different durations of music interventions on pain endurance. Secondary objectives are to investigate the effects of music duration on heart rate variability and subjective measurements of emotions...

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

Summary

ID

NL-OMON53814

Source
ToetsingOnline

Brief title
DOMINANT

Condition

- Other condition

Synonym
Acute pain, pain

Health condition

Pijn

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Healthy individuals, Music, Pain tolerance

Outcome measures

Primary outcome

The main study endpoint is pain endurance (expressed in amperage).

Secondary outcome

Secundary endpoints are heart rate variability (expressed in milliseconds) and

subjective measurements of emotions, anxiety and pain.

Study description

Background summary

Music interventions reduce perioperative pain and anxiety. A recent study shows that healthy participants seem less susceptible to acute pain when listening to music. However, it is yet unclear how long music needs to be presented in order to have an effect. Therefore, we would like to propose a pilot randomized controlled trial in order to investigate the optimal duration of musical interventions.

Study objective

The main objective is to investigate the effect of different durations of music interventions on pain endurance. Secondary objectives are to investigate the effects of music duration on heart rate variability and subjective measurements of emotions, anxiety and pain.

Study design

This study will be performed as a pilot randomized controlled trial.

Intervention

Respectively 1, 20 and 40 minutes of patient preferred music presented through headphones.

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. Participation in this study includes one outpatient visit of approximately 60 minutes. There is no direct benefit for the subjects.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

>= 18 years of age
Sufficient knowledge of the Dutch language to understand the study documents (in the judgement of the attending physician or researcher)
Provision of written informed consent by subject

Exclusion criteria

Significant hearing impairment
Current complaints of tinnitus
Current use of analgesic medication
Presence of acute or chronic pain
History of cardiac disease or arrhythmia
Current treatment by a medical specialist or general practitioner
Active or professional musician or singer
Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	06-03-2024
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	19-04-2023

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-02-2024
Application type:	Amendment
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	NL82922.078.22