The influence of music choice on pain tolerance in the context of social background in healthy volunteers.

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

Summary

ID

NL-OMON56178

Source
ToetsingOnline

Brief title
MOSART

Condition

- Other condition

Synonym
(electric) pain stimulus, acute pain reaction

Health condition

acute pijn

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Music, Pain, Socioeconomic background

Outcome measures

Primary outcome

Pain endurance expressed in amperage.

Secondary outcome

Heart Rate Variability

Anxiety (Stait-Trait-Anxiety-Inventory-6)

Emotions (Self-assessment manikin)

Pain intensity (11-likert numeric rating scale)

Music listening questionnaire

Music genres and characteristics

Study description

Background summary

Implementation of music in health care settings has shown to have many beneficiary effects in regard of stress, anxiety and pain related outcomes. Most clinical trials show high heterogeneity in regard of music selection and characteristics. Direct comparisons between different music interventions are limited. Some research suggests that self-selected or preferred music is more beneficiary. All in all, it remains unclear which music works best. Moreover, sociological research shows that music perception depends also on social background. Therefore, we propose a randomized controlled trial to investigate the effect of different music on pain tolerance in the context of social background.

Study objective

The primary objective of this study is the pain tolerance of linear increasing electric stimuli between music and control setting (podcast), especially looking at the social background. Moreover, comparison of the two music interventions, self-chosen and researcher-chosen music, will be performed. Secondary objects are the effects on anxiety (STAI), emotion (SAM), the sympathetic-adrenomedullary axis (HRV) and the participants music and pain perception.

Study design

This study has a randomized cross-over design. Thus, all subjects will receive the same three interventions in a randomized order.

Intervention

Subjects will receive two music interventions (self-chosen and researcher-chosen music) and control (podcast) for 20 minutes each. Music will be given by headphones. Each participant will receive every intervention in a randomized order. In between *wash-out* periods of 20 minutes will be established. At the end of each intervention increasing electric stimuli will be administrated by the participant itself pressing a button.

Study burden and risks

The use of music as intervention has no known deleterious effects on subjects. Safety precautions will be taken to limit the volume of the music on headphones (<= 80dB). Burden includes the electric stimulus, which is minimized by safety precautions and the completion of several safety questionnaires. Measurements of heart rate variability will be collected with a chest strap which has no known deleterious effects on subjects. Participation in this study includes one visit of approximately 2 hours. There is no direct benefit for subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Between 18 and 60 years of age
Female
Sufficient knowledge of the Dutch language to understand the study documents
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
Current treatment by a medical specialist or general practitioner
History of cardiac disease of arrhythmias
(Suspected) pregnancy
Diagnosed psychiatric or neurological impairments
Electric implants (e.g. pacemakers)

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	22-08-2023
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO Date:	31-07-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-10-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-09-2024
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	NL84165.078.23