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Beneficial effects of music therapy on stress reduction

Submission date
04/10/2020

Recruitment status
No longer recruiting

Registration date
11/10/2020

Overall study status
Completed

Last Edited
12/10/2023

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Music therapy or sound interventions have been shown to benefit patients in terms of pain or fear relief and improvement of other patient-reported outcomes. The effect of stress on the heart, particularly the variation in heart rate, is known to indicate that more serious problems can occur later. The aim of this study is to investigate the effects of a sound intervention on heart rate.

Who can participate?
Patients who are exposed to increased stress levels due to their illness, as well as formally healthy people, can participate in the study.

What does the study involve?
The planned study project will investigate the effects of music therapy in patients and healthy individuals with an increased stress level, in particular with regard to a possible positive effect on the autonomic nervous system in terms of stress reduction. In order to take into account a possible positive effect of music intervention, a music intervention will therefore be compared to rest. Participants will have their heart rate measured before and after a 12-minute period of listening to music with either conventional headphones (CH; “MEZE 99 Classic”) or with the same – but internally modified – headphone (called “Lautsaenger”).

What are the possible benefits and risks of participating?
There are no known disadvantages for the participants in the study. There are no known harmful effects of music therapy. As music therapy is a recognised, established procedure whose effectiveness has already been proven in meta-analyses, the researchers hope to achieve a positive effect from which every participant in the study will benefit directly.

Where is the study run from?
University Medical Centre Mannheim (Germany)

When is the study starting and how long is it expected to run for?
May 2019 to September 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Anna Hohneck
annalena.hohneck@umm.de

Contact information

Type(s)
Scientific

Contact name
Dr Anna Hohneck

ORCID ID
https://orcid.org/0000-0002-7629-2770

Contact details
First Department of Medicine – Cardiology
University Medical Center Mannheim, Heidelberg University
Theodor-Kutzer-Ufer 1-3
Mannheim
Germany
68167
+49 (0)17670738117
annalena.hohneck@umm.de

Additional identifiers

Study information

Scientific Title
Beneficial effects of a sound intervention in the form of music therapy on stress reduction

Study objectives
Music therapy is a recognised medical procedure that uses music to address physical, emotional, cognitive and social disorders. The interventions used include playing instruments, vocal and instrumental improvisation, singing, composition/songwriting, music guided imagination techniques and listening to music.
Music therapy is said to have a positive effect on well-being, stress management, pain relief, emotional expression, memory, communication skills and physical rehabilitation.
There is some evidence that music therapy can be a useful supportive measure in the treatment of chronically ill patients. Results of recent systematic reviews suggest that music interventions have moderate to strong treatment effects on the parameters of anxiety, depression, fatigue, pain and quality of life in chronically ill patients. In addition, a slight improvement in vital parameters such as heart rate, blood pressure and respiratory rate has been described, which indicate a reduction in stress. This study will therefore examine the effects of music therapy in patients exposed to higher stress levels, especially with regard to a possible positive effect on the autonomic nervous system in terms of stress reduction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/11/2019, Local ethical committee, Medical Ethics Commission II, Faculty of Medicine Mannheim (University of Heidelberg, Theodor-Kutzer-Ufer 1-3, 68167 Mannheim, Germany; +49 (0)621 383 71770; ethikkommission-II@medma-uni-heidelberg.de), ref: 2019-736N

Study design
Interventional randomized parallel trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Increased stress level

Interventions
Current interventions as of 15/05/2023:

Participants are randomized to a 12-minute sound intervention (classical music) with either conventional headphones (CH; “MEZE 99 Classic”) or with the same – but internally modified – headphone (called “Lautsaenger”).

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Previous interventions:

All participants receive both a 15-minute sound intervention and a 15-minute rest intervention on separate days as part of a cross-over design.

The order of interventions is randomly decided using sealed envelopes.

The sound intervention was performed with an instrument called "Heaven and Earth" (http://klangkoerper.de/himmel-und-erde.html). This instrument consists of a semi-open resonance body with 29 strings (24 of those in C1sharp, two in C2sharp, two C3sharp, and one in G3sharp). The monochord is placed on the chest during the intervention to ensure optimal transmission of the vibrations.

The rest intervention is done in a lying position for 15 minutes after the 10-minute resting phase.

The gap between the two intervention days is a maximum of 4 weeks.

Intervention Type
Other

Primary outcome(s)

Cardiovascular parameters (heart rate, blood pressure, heart rate variability and pulse wave velocity) assessed non-invasively using the VascAssist 2 device at baseline and after the rest and sound interventions

Key secondary outcome(s))
Current secondary outcome measures as of 15/05/2023:

1. Numeric rating scale (NRS) for emotions and stress before and after sound intervention (emotional well-being, pain, anger, anxiety, sadness, stress, music for coping stress).
2. The modified Maslach Burnout Inventory (MBI) to assess the burnout risk before and after sound intervention.
3. NRS for subjective sound perception and to what extent listening stimulated the imagination was fulfilled after sound intervention. In addition, dichotomous questions were used to evaluate the headphone systems in particular.

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Previous secondary outcome measures:

Quality of life assessed using the health-related quality of life (HRQOL) questionnaire at baseline and after the rest and sound interventions

Completion date
01/09/2022

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Written informed consent

Participant type(s)
Healthy volunteer, Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
100

Key exclusion criteria

1. Acute myocardial infarction or stroke (within the past 30 days)
2. Cardiogenic shock
3. Indication for an aortocoronary bypass operation
4. Known minimal heart rate at rest below 50 bpm
5. Need for pacemaker stimulation
6. Hypotension with systolic blood pressure <80 mmHg or uncontrolled hypertension with systolic blood pressure ≥180 mmHg, bilateral axilla dissection
7. Parkinson’s disease or tremor of other origin
8. Atrial fibrillation

Date of first enrolment
01/07/2020

Date of final enrolment
01/09/2020

Locations

Countries of recruitment
Germany

Study participating centre
Heidelberg University
Third Department of Medicine (Hematology and Oncology)
Interdisciplinary Tumor Center Mannheim (ITM)
Medical Faculty Mannheim
Theodor-Kutzer-Ufer 1-3
Mannheim
Germany
68167

Sponsor information

Organisation
University Medical Centre Mannheim

ROR
https://ror.org/05sxbyd35

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the corresponding author Dr Anna Hohneck (annalenahohneck@umm.de). The data will be provided as anonymized data (Excel file), upon request from scientific stuff (after verification). The data transfer will take place via secure transfer services to guarantee security. The transmission of raw data will only take place after prior consultation with the participants and their corresponding consent. The data is provided only for transparency purposes only and not for further analysis.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2021	13/08/2021	Yes	No
Results article		11/10/2023	12/10/2023	Yes	No
Participant information sheet	version v1.1	30/09/2019	05/11/2020	No	Yes
Protocol file			05/11/2020	No	No