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A study on stress reduction effects of combined vibration and music stimulation

Submission date
30/07/2025

Recruitment status
No longer recruiting

Registration date
08/08/2025

Overall study status
Completed

Last Edited
03/10/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Stress is a growing health concern. This study aims to explore whether a simple form of vibration stimulation, synchronized with music and the participant's heart rate, can help people recover from acute stress more effectively.

Who can participate?
Healthy male adults aged between 25 and 49 years.

What does the study involve?
The study consists of two parts.
In the first part, participants receive one of three conditions: (1) vibration that gradually slows down, (2) fixed-rate vibration, or (3) no vibration.
In the second part, each participant experiences all three conditions in random order: (1) vibration plus synchronized music, (2) music only, and (3) no stimulation.
Stress levels are measured before and after each condition.

What are the possible benefits and risks of participating?
There is no direct benefit to the participants. Risks are minimal, as the vibration and music are non-invasive and commonly used in relaxation settings.

Where is the study run from?
The study is conducted at the Frontier Research Center of POLA Chemical Industries Inc. in Yokohama, Japan.

When is the study starting and how long is it expected to run for?
June 2020 to April 2021

Who is funding the study?
POLA Chemical Industries Inc. (Japan)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
UMIN000058197

Study information

Scientific Title
A confirmatory randomized crossover trial to evaluate the effects of gradually slowing tempo vibration and music stimulation on acute stress recovery in healthy male adults

Study objectives
1. To evaluate whether gradually slowing tempo synchronized vibration and music stimulation reduce acute stress in healthy adults.
2. To compare the stress-relieving effects of combined vibration and music stimulation, music only, and no intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 29/10/2020, Committee for the Protection of Human Subjects, POLA Chemical Industries Inc. (560 Kashio-cho, Totsuka-ku, Yokohama, 244-0812, Japan; +81 (0)45 826 7134; y-miyasaka@pola.co.jp), ref: 2020-F-132

2. approved 07/04/2021, Committee for the Protection of Human Subjects, POLA Chemical Industries Inc. (560 Kashio-cho, Totsuka-ku, Yokohama, 244-0812, Japan; +81 (0)45 826 7134; y-miyasaka@pola.co.jp), ref: 2021-F-022

Study design
Randomized crossover open-label placebo-controlled single-centre interventional study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Psychological stress, mental fatigue

Interventions
This study included two phases:

Phase 1 (Parallel design, n = 42):
Participants were randomly allocated to one of the following three arms:
1. Variable vibration: Participants held a handheld vibration device for 2 minutes. Vibration tempo was synchronized with their resting heart rate and gradually decreased to 50 bpm.
2. Fixed vibration: Participants received 2 minutes of vibration at a fixed tempo (50 bpm or half the heart rate).
3. Control: Participants held the same device without vibration.

Phase 2 (Crossover design, n = 36):
Each participant experienced all three conditions in a randomized order:
1. Vibration + music: Participants received synchronized vibration and music with tempo gradually slowing from 75 to 50 bpm over 3.5 minutes.
2. Music only: Participants listened to the same music without vibration.
3. Control: No music or vibration; participants held the device and wore headphones.

In both phases of the study, participants were randomly assigned to each condition using a computer-generated randomisation list prepared in advance.

Intervention Type
Device

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Custom-designed handheld vibration device and original synchronized ambient music

Primary outcome(s)
Subjective stress level measured using the Visual Analogue Scale (VAS) at three timepoints: baseline (before mental load), immediately after mental load (stressed), and after intervention (post-intervention)

Key secondary outcome(s))
1. Salivary cortisol levels measured using enzyme immunoassay at baseline, after mental load, and post-intervention
2. Emotional state and mood measured using the Emotion and Mood Inventory (EMI) at baseline and post-intervention
3. Subjective fatigue level measured using the Jikaku-sho Shirabe fatigue questionnaire at baseline and post-intervention
4. Tense Arousal (TA) and Energetic Arousal (EA) derived from an 8-item subjective stress scale assessed at baseline and post-intervention

Completion date
25/04/2021

Eligibility

Key inclusion criteria
1. Healthy males
2. Aged between 25 and 49 years
3. Provided written informed consent after receiving sufficient explanation of the study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
49 years

Sex

Male

Total final enrolment
78

Key exclusion criteria
1. History of cardiovascular or severe physical illness
2. Use of medications that affect the autonomic nervous system
3. Hearing difficulties or discomfort with headphones
4. Inability to maintain regular lifestyle during study period
5. Use of cardiac pacemaker
6. Determined unsuitable for participation by the principal investigator

Date of first enrolment
31/10/2020

Date of final enrolment
17/04/2021

Locations

Countries of recruitment
Japan

Study participating centre
POLA Chemical Industries, Inc. Frontier Research Center
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Sponsor information

Organisation
POLA Chemical Industries, Inc.

Funder(s)

Funder type
Industry

Funder Name
POLA Chemical Industries, Inc.

Results and Publications

Individual participant data (IPD) sharing plan
Individual participant data will not be shared publicly due to privacy protection and informed consent limitations.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/10/2025	03/10/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes