

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

Submission date 30/07/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/08/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 03/10/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

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

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

560 Kashio-cho

Totsuka-ku

Yokohama

Japan

244-0812

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