ISRCTN11331226 https://doi.org/10.1186/ISRCTN11331226

Stress management programme with virtual reality-based biofeedback

Submission date
26/05/2023

Recruitment status
No longer recruiting

Registration date
26/05/2023

Overall study status
Completed

Last Edited
14/11/2023

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 common and has negative effects on mental and physical health. This study aims to use a stress management method called heart rate variability biofeedback to reduce levels of stress in healthy adults. During a heart rate variability biofeedback training participants learn to control the activity of their heart. In order to teach participants, virtual reality technology is used to visualize changes in the heart's activity in an engaging way. Practising this for a longer period of time can reduce stress levels and improve other stress-related symptoms such as anxiety or depression.

Who can participate?
Healthy volunteers aged 18-40 years

What does the study involve?
Participants are randomly allocated to one of two groups. Participants doing the heart rate variability biofeedback training will be compared to participants in a wait-list control group, which will receive the training only after the assessments. Both groups will be compared at three timepoints: before the training, 1 week after the training and 4 weeks after the training. During these assessments, the researchers measure the psychological and biological effects of the training.

What are the possible benefits and risks of participating?
Comparable studies show that several weeks of heart rate variability biofeedback training reduce stress significantly. This includes reducing perceived stress, anxiety, and depression, as well as improving quality of life and well-being. The training can also improve participants' heart activity. Even if randomly assigned to the waitlist, participants have the option to do the training after the study to benefit from its effects. There are no direct disadvantages to participating, and there are no serious health risks. During the training short-term hyperventilation may occur, leading to dizziness and lightheadedness. Additionally, the use of virtual reality technology may temporarily cause a condition known as cybersickness, which includes symptoms such as eye strain, headaches, paleness, sweating, dry mouth, fullness, disorientation, dizziness, impaired coordination, nausea, and vomiting. However, these potential side effects of the training and virtual reality technology are rare and harmless.

Where is the study run from?
The Swiss Federal Institute of Technology in Zurich (Switzerland)

When is the study starting and how long is it expected to run for?
August 2021 to October 2022

Who is funding the study?
The Swiss Federal Institute of Technology in Zurich (Switzerland)

Who are the main contacts?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2202-StressmanagmentVR

Study information

Scientific Title
Evaluating the psychobiological effectiveness and user experience of virtual reality heart rate variability biofeedback intervention programme for stress management in healthy individuals: a randomized wait-list control trial

Study objectives
The virtual reality-supported heart rate variability biofeedback intervention programme will improve primary and secondary outcomes (i.e., stress and stress-related measures) from pre-intervention to post-intervention and from pre-intervention to follow-up compared to the wait-list control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/03/2022, Ethics Commission of ETH Zurich (ETH Zürich, Stab Forschung, Weinbergstrasse 11, WEC E 15/17, 8092 Zürich, Switzerland; +41 (0)44 632 85 72; ethics@sl.ethz.ch), ref: 2022-N-35

Study design
Single-center interventional randomized wait-list controlled trial without blinding

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Reduction of stress and stress-related symptoms in healthy individuals

Interventions
The 4-week intervention programme investigated in this study includes four training sessions of heart rate variability biofeedback in virtual reality conducted weekly in the laboratory, which are supplemented by brief daily at-home exercises supported by a mobile application. The study also includes a wait-list control group. Participants (50% male and 50% female) will be randomly assigned to either the intervention group or the wait-list control group, which will both simultaneously undergo three assessments (pre-assessment during week 1 of the intervention, post-assessment in the week after the intervention and follow-up-assessment 4 weeks after the intervention). Randomisation takes place when participants sign up for their sessions. Experimenters have already pre-assigned groups to a specific day and time. Participants will only be informed about their group assignment after they have signed up.

Randomisation was achieved by hidden pre-assigned groups (intervention or wail-list control) for each session participants could sign up for. Specifically, participants were able to select one of ten possible first sessions (i.e. in the first week), without knowing the hidden pre-assigned group of each sessions. Only after signing up for the study were the participants informed about the assigned group.

Intervention Type
Behavioural

Primary outcome(s)
1. Levels of self-reported stress are measured using the Perceived Stress Scale (PSS) and the subscale Stress of the Depression, Anxiety and Depression Scales (DASS) before the intervention (PRE) and one (POST) and four (FOLLOW-UP) weeks after the intervention
2. Heart rate at rest measured using a wearable chest belt (Polar H10) before the intervention (PRE) and 1 (POST) and 4 (FOLLOW-UP) weeks after the intervention.
3. Systolic and diastolic blood pressure at rest measured using a blood pressure monitor (Omron HBP-1120) before the intervention (PRE) and 1 (POST) and 4 (FOLLOW-UP) weeks after the intervention
4. Heart rate variability features at rest measured using a wearable chest belt (Polar H10) before the intervention (PRE) and 1 (POST) and 4 (FOLLOW-UP) weeks after the intervention
5. Levels of self-reported psychological state using a Visual Analogue Scale (VAS) and the Multidimensional Mood Questionnaire (MDMQ) are measured before, during and after a psychosocial stress test one week after the intervention (POST)
6. Salivary cortisol and salivary alpha-amylase measured using IBL-Tecan SaliCaps® and heart rate and heart rate variability features measured using the wearable chest belt Polar H10 before, during and after a psychosocial stress test 1 week after the intervention (POST)

Key secondary outcome(s))
1. Levels of self-reported anxiety are measured using the DASS before the intervention (PRE) and 1 (POST) and 4 (FOLLOW-UP) weeks after the intervention
2. Levels of self-reported depression are measured using the DASS before the intervention (PRE) and 1 (POST) and 4 (FOLLOW-UP) weeks after the intervention

3. Levels of self-reported mindfulness are measured using the Mindfulness Attention and Awareness Scale (MAAS) before the intervention (PRE) and 1 (POST) and 4 (FOLLOW-UP) weeks after the intervention
4. Levels of self-reported psychological well-being are measured using the World Health Organisation-Five Well-Being Index (WHO-5) before the intervention (PRE) and 1 (POST) and 4 (FOLLOW-UP) weeks after the intervention
5. Levels of self-reported health-related quality of life are measured using the Short Form Health Survey (SF-36) before the intervention (PRE) and 1 (POST) and 4 (FOLLOW-UP) weeks after the intervention
6. Levels of self-reported fatigue are measured using the Multidimensional Fatigue Inventory (MFI-20) before the intervention (PRE) and 1 (POST) and 4 (FOLLOW-UP) weeks after the intervention
7. Levels of self-reported basic psychological needs satisfaction and frustration are measured using the Basic Psychological Need Satisfaction and Frustration Scale (BPNSFS) before the intervention (PRE) and 1 (POST) and 4 (FOLLOW-UP) weeks after the intervention

Completion date
25/10/2022

Eligibility

Key inclusion criteria
1. Fluent in German
2. Have normal or corrected-to-normal vision
3. Exhibit no disability of arms or hands
4. Have obtained at least a secondary school diploma
5. 18-40 years of age

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
All

Total final enrolment
99

Key exclusion criteria

1. Self-reported acute (including common cold) and chronic somatic diseases (including epilepsy, photo epilepsy or other pre-existing neurological conditions)
2. Psychiatric disorders
3. Regular medication or medication in the last 2 months to treat acute illnesses, or any cardioactive medication (e.g., antidepressant, antipsychotic, antihypertensive),
4. The consumption of psychoactive substances in the last 3 months
5. Heavy drinking (equal or greater to 15 and equal or greater to 8 drinks per week for men and women, respectively)
6. Consumption of tobacco (more than 5 cigarettes/week). If participants report to smoke more than 5 cigarettes/week but only on weekends (e.g., social events, parties) they are not excluded.
7. Women with irregular menstrual cycles
8. Woman who use hormonal contraception, are pregnant or lactating

Date of first enrolment
21/04/2022

Date of final enrolment
06/05/2022

Locations

Countries of recruitment
Switzerland

Study participating centre
Decision Science Laboratory ETH Zürich
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Sponsor information

Organisation
Eidgenössische Technische Hochschule Zürich

Funder(s)

Funder type
University/education

Funder Name

Eidgenössische Technische Hochschule Zürich

Alternative Name(s)
ETH Zurich, ETH Zürich, Federal Institute of Technology Zurich, ETH Zürich (Eidgenössische Technische Hochschule Zürich), Eidgenössische Technische Hochschule Zürich (Switzerland), Eidgenössische Technische Hochschule Zürich (ETH), ethzurich, ETH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/10/2023	14/11/2023	Yes	No