ISRCTN11162338 https://doi.org/10.1186/ISRCTN11162338

Relaxation and stress reduction through a virtual reality intervention

Submission date
22/01/2021

Recruitment status
No longer recruiting

Registration date
03/03/2021

Overall study status
Completed

Last Edited
17/11/2023

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
Stress is widespread in contemporary, Western societies and is a major source of disease. The study team has developed a virtual reality (VR) intervention for relaxation and stress reduction and will test how effective this is for stress reduction and relaxation against a freely chosen relaxation method.

Who can participate?
Participants aged 18 years and over with no current psychiatric disorder or cardiovascular disease and no current intake of psychoactive or neuroactive drugs.

What does the study involve?
Study participants will be asked to complete a laboratory testing and three online surveys (two before the laboratory testing and one following the laboratory testing).

At the laboratory testing, participants will be subject to stress using the same method for each participant, and then a relaxation period with either the VR intervention or a freely chosen relaxation method. Participants receiving the VR intervention will be randomly chosen. The VR involves an image of a landscape with fields and trees. There will simultaneously be an image of a blue sphere that increases and decreases in size. This image will be accompanied by calming music, nature sounds, and general instruction to focus on breathing via headphones. Participants will be sat on a cantilever chair with a massage mat placed on its surface, and during the guided breathing, the pillow will vibrate in time with the instructions.

During laboratory testing, participant physical reactions (such as heart rate, breathing rate, and blood pressure) and emotional states will be assessed. The laboratory testing will involve measurements at the start of the session, when stress is introduced, when relaxation is introduced, and at the end of the session.

What are the possible benefits and risks of participating?
Possible benefits are stress reduction and relaxation during testing and a potential transfer of relaxation skills to real life.

A potential risk is that the stress test induces negative feelings and physiological arousal.

Where is the study run from?
Department of Clinical Psychology at the University of Siegen (Germany)

When is the study starting and how long is it expected to run for?
From July 2020 to October 2021

Who is funding the study?
This work is funded by the Bundesministerium für Bildung und Forschung (BMBF) (Germany)

Who is the main contact?
Miriam Kampa
miriam.kampa@uni-siegen.de

Study website
https://www.interaktive-technologien.de/projekte/nostress

Contact information

Type(s)
Scientific

Contact name
Dr Miriam Kampa

ORCID ID
http://orcid.org/0000-0001-8639-8547

Contact details
Adolf-Reichwein-Str. 2a
Siegen
Germany
57068
+49 641 99 26340
miriam.kampa@uni-siegen.de

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
BMBF funding number: 16SV8068

Study information

Scientific Title
Facilitating relaxation and stress reduction through a virtual reality intervention: a randomized controlled trial

Acronym
NoStress

Study objectives
Virtual reality (VR) reduces self-reported stress and increases self-reported relaxation and will demonstrate non-inferiority when compared to an active control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/09/2020, Universität Siegen, Rat für Ethik in der Forschung (Adolf-Reichwein-Str. 2a, 57076 Siegen, Germany; +49 271 740-4819; Katrin.Mayer@zv.uni-siegen.de), ref: ER_21/2020 "NoStress"

Study design
Single-center interventional randomized controlled trial with a 2 (condition) x 10 (time) factorial design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Stress and stress-related disorders

Interventions
Participants will be randomly assigned to either the treatment (virtual reality, VR) or the active control group (freely chosen relaxation method) according to an externally constructed randomization plan plan with a 1:1 ratio. A computerized simple randomization will be implemented to control for equal size of study groups.

Research flow for treatment and control group will be as follows:
1. Recruitment
2. Online surveys 1 + 2
3. Laboratory testing
4. Online survey 3 in the evening of laboratory testing

Participants will be blinded to the experimental group until relaxation. Laboratory testing will comprise a baseline measurement, a stress induction, the relaxation intervention, and a recovery measurement. A standardized protocol will be used for stress induction (MMST, Reinhardt et al., 2012). The multi-sensory VR includes visual, acoustic, and haptic features to increase the sense of presence. The VR shows a landscape with fields and trees; during the relaxation phase, sunrise is simulated. Via headphones calming music and nature sounds will be presented to the participants. During the relaxation phase, participants will be seated on a cantilever chair with a massage mat placed on its surface. As an intervention, a blue sphere depicts a pattern of respiration by increasing for inhalation and shrinking for exhalation to lower participants' respiratory rates. The intervention will further be supported by audio-guided instructions on relaxation and respiration (relaxing narrative) and a pillow vibrating synchronously to the increase in the size of the blue sphere. During laboratory testing, physiological parameters will be recorded and emotional states will repeatedly be assessed.

Intervention Type
Behavioural

Primary outcome measure
1. Stress ratings measured with a visual analogue scale (VAS) on a Likert scale ranging from 0 (not stressed) to 9 (very stressed) at pre-baseline, post-baseline, pre-stress, mid stress, post-stress, pre-relaxation, post-relaxation, pre-recovery, post-recovery and in the evening of the day of laboratory testing
2. Relaxation ratings will be measured with a VAS on a Likert scale ranging from 0 (not relaxed) to 9 (very relaxed) at pre-baseline, post-baseline, pre-stress, mid stress, post-stress, pre-relaxation, post-relaxation, pre-recovery, post-recovery and in the evening of the day of laboratory testing

Secondary outcome measures
1. Heart rate variability measured with an electrocardiogram, analyzed using the Pan Tompkins algorithm, and estimated with the root mean square of successive differences (RMSSD) throughout baseline, stress, relaxation, and recovery
2. Tonic skin conductance level measured using galvanic skin conductance (GSR) recording and analyzed using Ledalab throughout baseline, stress, relaxation, and recovery
3. Number of phasic non-specific skin conductance responses measured using GSR recording and analyzed using Ledalab throughout baseline, stress, relaxation, and recovery
4 Systolic and diastolic blood pressure measured using an automated oscillometric blood pressure monitor at 1 min from the end of the baseline, stress, relaxation, and recovery phases
5. Respiratory rate measured using a respiration belt throughout baseline, stress, relaxation, and recovery
6. State mood measured using Der Mehrdimensionale Befindlichkeitsfragebogen (MDBF) questionnaire at pre-stress, post-stress, post-relaxation, and in the evening of the day of laboratory testing
7. State rumination measured using Der Response Styles Questionnaire (RSQ-D, adapted for state) at pre-stress, post-stress, post-relaxation, and in the evening of the day of laboratory testing

8. Post-event processing measured using Post-Event Processing Record (PEPR) questionnaire (translated to German) at post-relaxation and in the evening of the day of laboratory testing

Overall study start date
01/07/2020

Completion date
31/10/2021

Eligibility

Key inclusion criteria
1. Aged ≥18 years

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
102

Key exclusion criteria
1. Current psychiatric disorder or cardiovascular disease
2. Current intake of psychoactive or neuroactive drugs

Date of first enrolment
01/10/2020

Date of final enrolment
20/05/2021

Locations

Countries of recruitment
Germany

Study participating centre

Clinical Psychology, University of Siegen
Adolf-Reichwein Str. 2a
Siegen
Germany
57068

Sponsor information

Organisation
University of Siegen

Sponsor details
Adolf-Reichweinstr. 2a
Siegen
Germany
57068
+49 271 740-4490
tim.klucken@psychologie.uni-siegen.de

Sponsor type
University/education

Website
https://www.uni-siegen.de/start/index.html.en?lang=en

ROR
https://ror.org/02azyry73

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
Planned publication of the study protocol in Trials and planned publication of the study results in a high-impact peer-reviewed journal.

Intention to publish date
01/10/2022

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available after the publication of study results upon request from the corresponding author (miriam.kampa@uni-siegen.de).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/05/2022	10/05/2022	Yes	No
Results article		01/09/2023	17/11/2023	Yes	No