

Relaxation and stress reduction through a virtual reality intervention

Submission date 22/01/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 03/03/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/11/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Prevention

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 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(s)

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

Key secondary outcome(s)

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

Completion date

31/10/2021

Eligibility

Key inclusion criteria

1. Aged ≥ 18 years

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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Siegen

Germany

57068

Sponsor information**Organisation**

University of Siegen

ROR

<https://ror.org/02azyry73>

Funder(s)

Funder type

Government

Funder Name

Bundesministerium für Bildung und Forschung

Alternative Name(s)

Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

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?
Results article		01/09/2023	17/11/2023	Yes	No
Protocol article		09/05/2022	10/05/2022	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes