VRelax for reducing stress

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21150

Source
NTR

Brief title
VRelax

Health condition

Patients with burn-out, or a DSM-5 diagnosis of depressive disorder, bipolar disorder, anxiety disorder or psychotic disorder.

Sponsors and support

Primary sponsor: University Medical Center Groningen, Groningen, the Netherlands
Source(s) of monetary or material Support: University Medical Center Groningen, Groningen, the Netherlands

Intervention

Outcome measures

Primary outcome

1. The immediate effect on level of subjective stress, measured with Visual Analogue Scales (range 0-100) embedded in the VRelax and standard relaxation tools. Eight Ecological Momentary Assessment items are selected that have been used in previous studies.

2. VRelax user experiences are collected with interviews (previous experiences with relaxation exercises and VR, expectations met or not, ease and pleasure of using, quality, intensity, use of interactive elements), questionnaires (presence [IGroup Presence Questionnaire]), cyber sickness [Simulator Sickness Questionnaire SSQ]) and logging of use, including frequency, duration, time of day, type of environment visited.

Secondary outcome

Short-term effects on perceived stress:

- Perceived Stress Scale assesses stress level over the past week, will be administered at baseline and after both intervention periods.

Symptoms of depression, anxiety and psychosis:

- Depression: Inventory of Depressive Symptomatology-Self-Rated (IDS-SR): measures the severity of depressive symptoms on a 30 item questionnaire.

- Anxiety: Beck Anxiety Inventory (BAI): measures the severity of anxiety on a 21 item questionnaire.

- Paranoia: Green Paranoid Thoughts Scale (GPTS): measures two dimensions of paranoid thinking with a 20 item questionnaire: ideas of social reference and ideas of social persecution.

Use of medication:

Names and daily dosage of medication (both prescribed and over-the-counter medication) are listed at baseline and reported over the ten-day periods by the participants.

Use of psychoactive substances:

Units of coffee, tea, cigarettes, alcohol, cannabis, illicit drugs are assessed at baseline and reported over the ten-day periods by the participants.

Study description

Background summary

Rationale: Patients with psychological and/or psychiatric problems often have an increased level of stress, which
makes it more difficult to recover from their symptoms. Relaxation exercises, involving imaginary visualization of pleasant environments, can have a positive effect on the level of tension and arousal, but are often difficult to perform for people with psychiatric symptoms. Virtual Reality (VR) may help to relax. We previously conducted a feasibility pilot study with a first VR relaxation prototype. This second pilot study examines whether Virtual Reality (VR) 360o films (VRelax) can help patients with current psychiatric symptoms to reduce level of subjective stress.

Objective: To test a second VRelax prototype for reducing impact of stress in patients with burn-out, depressive disorder, bipolar disorder, anxiety disorder or psychotic disorder. User experiences and immediate effects on subjective stress and arousal will be investigated and compared to standard relaxation exercises.

Study design: This pilot study is a randomized cross-over trial with two relaxation tools: 1) the VRelax relaxation app and 2) standard relaxation exercises. Participants will use both tools consecutively for 10 days at home. Participants will be randomly assigned to order of the interventions.
Study population: 50 patients receiving ambulatory treatment for burn-out, or a DSM-5 diagnosis of depressive disorder, bipolar disorder, anxiety disorder or psychotic disorder, age > 18.
Intervention(s):

- VRelax: the tool is used with a smartphone that is connected to a head mounted display. When activated, the participant is on a beach, from which he/she can choose where to go. The 360o videos of relaxing environments include a variety of nature landscapes. Interactive elements and relaxation exercises are embedded in the environments. Participants navigate through the environments by looking at hotspots.

- Standard relaxation exercises: 2D nature videos and audio tracks with guided meditation / progressive muscle relaxation.

Participants can use the interventions as much as they like, but minimally once daily for at least 10 minutes. Before and after each session, momentary subjective stress is measured with Visual Analogue Scales.

Main study parameters/endpoints:

Primary outcome: momentary subjective stress, user experiences.
Secondary outcomes: perceived stress, psychiatric symptoms, use of benzodiazepines and psychoactive substances.

Study objective

A 360 degree video virtual reality tool is more effective for reducing level of subjective stress than conventional relaxation exercises.

Study design

1. Preceding the first intervention period, baseline measures will be taken and use of the relaxation tools is explained. Participants receive the VRelax set or USB stick with a user manual.

2. During 10 days, participants use the first relaxation tool at home and complete the VAS scales before and after each use.

3. After 10 days, the second study visit takes place, with the same measures as at baseline. In addition, a short interview is conducted with questions about user experiences.

4. During 10 days, participants use the second relaxation tool at home and complete the VAS scales before and after each use.

5. After 10 days, the third study visit takes place, with the same measures as at baseline. Again, a short interview is conducted with questions about user experiences.

Intervention

VRelax

The VRelax tool is used with a Samsung Galaxy S6 or S7 smartphone that is connected to a head mounted display, the Samsung Gear VR. When activated, the participant is on a beach, from which he/she can choose where to go. The 360o videos of relaxing environments include nature landscapes, a coral reef, a drone flight, a scuba diving experience with dolphins, a mountain meadow with animals, and a session of Tibetan sound bowls. Participants can navigate through the environments by looking at hotspots within their field of view, that will be activated after three seconds. 3D audio is played with headphones. One of the hotspots activates a voiceover with guided meditation or a progressive relaxation exercise. In some of the environments, interactive visual elements are added, such as underwater air bubbles that pop when you look at them.

Participants receive a VRelax set to take home, including Gear VR, smartphone and headphones. They are instructed how to use it and are invited to use the VRelax app as often as they wish, but minimally once daily for at least 10 minutes. After 10 days, they return the VR set to the study team.

Standard relaxation

As control intervention, participants receive headphones and a USB stick with 2D nature videos with spoken guided meditation and progressive relaxation exercises. They can play the tracks on devices they have at home (desktop or laptop computer). They are instructed how to use it and are invited to use the USB stick as often as they wish, but minimally once daily for at least 10 minutes. After 10 days, they return the headphones and USB stick to the study team.

Contacts

Public
University Medical Center Groningen

Bart Lestestuiver
PO Box 30.001

Groningen 9700 RB
The Netherlands
+31 50 3612367
Scientific
University Medical Center Groningen

Bart Lestestuiver
PO Box 30.001

Groningen 9700 RB
The Netherlands
+31 50 3612367

Eligibility criteria

Inclusion criteria

• Currently receiving ambulatory treatment for surmenage or burn-out, or DSM-5 depressive disorder, bipolar disorder, anxiety disorder or psychotic disorder.

• At least moderate level of perceived stress, based on self-report or clinician report

• Age >18

Exclusion criteria

• DSM-5 diagnosis of substance use disorder

• Benzodiazepine use > 10 mg / day diazepam equivalent

• Diagnosis of epilepsy or organic brain damage

• Insufficient command of Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2018
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-06-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46448
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7096
NTR-old	NTR7294
CCMO	NL64380.042.17
OMON	NL-OMON46448

Study results