Virtual Reality relaxation for self-management of stress in patients with psychiatric symptoms - a randomized cross-over pilot study

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To develop a second VRelax prototype for reducing impact of stress and test it in patients with depressive, bipolar, anxiety and psychotic disorders. User experiences and immediate effects on subjective stress and arousal will be investigated and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON46448

Source
ToetsingOnline

Brief title
VRelax for reducing stress

Condition

- Psychiatric disorders NEC

Synonym
anxiety, depression, psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Atmosphaeres, maker van 360 graden VR films, heeft een aantal films beschikbaar gesteld voor het onderzoek,in kind bijdrage van Viemr, Virtual Reality bedrijf dat VR tool bouwt,Subsidie van Universitair Medisch Centrum Groningen

Intervention

Keyword: Relaxation, Selfmanagement, Stress, Virtual Reality

Outcome measures

Primary outcome

Primary outcomes: momentary subjective stress, user experiences.

Secondary outcome

Secondary outcomes: perceived stress, psychiatric symptoms, use of

benzodiazepines and psychoactive substances.

Study description

Background summary

Patients with psychiatric disorders 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 VR 360o films (VRelax) can help patients with current psychiatric symptoms to reduce level of subjective stress.

Study objective

To develop a second VRelax prototype for reducing impact of stress and test it in patients with depressive, bipolar, anxiety and psychotic disorders. 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.

Intervention

- 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.

Study burden and risks

Pre and post-intervention assessments include questionnaires and a qualitative interview about user experiences, with an average total duration of 3x120 minutes. Interventions take minimally 200 minutes at home. We expect patients to benefit from the intervention by primary reduced level of stress and secondary less psychiatric symptoms. Some patients may experience mild cyber sickness during the VR video, i.e. transient nausea or dizziness. No major adverse events are expected or have been documented.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Currently receiving ambulatory treatment for 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	26-02-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-09-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21150
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64380.042.17
OMON	NL-OMON21150