VRelax: reducing impact of stress in patients with psychiatric disorders - a virtual reality pilot study

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To develop a 360o video VR relaxation program (VRelax) for reducing impact of stress in patients with depressive, anxiety and psychotic disorders. Feasibility, user-friendliness and immediate effects on subjective and objective stress reactivity…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON43327

Source
ToetsingOnline

Brief title
VRelax

Condition

- Psychiatric and behavioural symptoms NEC

Synonym
psychiatric disorders, stress

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Centrum Psychiatrie
Source(s) of monetary or material Support: Ministerie van OC&W,in kind bijdrage VR bedrijf VIEMR (gebruik films),VIEMR

Intervention

Keyword: Relaxation, Stress, Virtual Reality

Outcome measures

Primary outcome

The main goal of the study is to investigate the feasibility of the VRelax tool and to evaluate the efficacy of the tool for reducing subjective and objective stress, as preparation for a larger RCT.

- Subjective stress: baseline and after last session: Perceived Stress Scale, a 10-item scale to measure the degree to which situations in the last week have been appraised as stressful. Before and after each session: ecological momentary assessment single items, assessing perceived stress, anxiety, paranoia, positive and negative affect on a 1-7 ordinal scale.

- Physiological stress

Heart rate (HR) and skin conductance level (SCL) are recorded on the non-dominant hand in standing position for 5 minutes at baseline before session 1 but after introduction of the VRelax tool, and for 5 minutes after the first and after the last session. Skin conductance level (SCL) is measured using a sensor with two finger electrodes on the middle and ring finger of the same hand with a sampling rate of 10 Hz. Heart rate (HR) is assessed by non-invasive pulse wave measurement using a Nexus 4 with a photo-electric plethysmograph on the index finger.

- Feasibility and user-friendliness will be measured using a qualitative interview after the last session (e.g., are enough patients willing to participate?, technical problems, was the intervention pleasurable / helpful, was the frequency and duration of sessions appropriate?).

Secondary outcome

- Type of VR environment - two conditions will be compared: dolphin and landscape environments.

- Psychopathology: baseline and after last session: Inventory of Depressive Symptomatology-Self-Rated, Beck Anxiety Inventory, Green Paranoid Thoughts Scale.

- Cyber sickness - Simulator sickness questionnaire (SSQ): measures simulator sickness on symptom level.

- Use of anxiolytic / sedative medication - Information on frequency and dose of medication use will be collected from the patient file.

- Substance use - Self-report at baseline and before each session, units of coffee, tea, cigarettes, alcohol, cannabis, illicit drugs last 24 hours or since previous session.

Study description

Background summary

Heightened stress reactivity plays a central role in theories of onset and course of psychiatric disorders, as it has been related to both onset and recurrence of mood, anxiety as well as psychotic disorders. Personal stress reactivity may be altered by changing negative cognitive schemas or reducing level of arousal, tension and rumination. Changing negative schemas with cognitive behavioral therapy (CBT) requires great effort of therapists and patients. Effect sizes of CBT on symptoms are modest in depressive disorders and schizophrenia. Focusing awareness on the present moment and relaxation by breathing exercises, imagery visualization and progressive muscle relaxation may be more directly targeted to breaking the vicious circle of stress reactivity and psychiatric symptoms. Virtual Reality offers opportunities to improve relaxation interventions. For reducing stress, arousal and tension, exposure should be to a relaxing environment, such as a walk in the forest, scuba diving amidst tropical fishes, or watching the sunset. A combination of visual and auditory stimuli in VR can be used to create an immersive experience that is stronger than the individual*s current mental state of distress and anxiety. Recently, a few preliminary VR stress management studies were published, suggesting that this is a promising approach for relaxation and stress recovery, with high potential for further development.

Study objective

To develop a 360o video VR relaxation program (VRelax) for reducing impact of stress in patients with depressive, anxiety and psychotic disorders. Feasibility, user-friendliness and immediate effects on subjective and objective stress reactivity will be investigated.

Study design

In this pilot study, a multidisciplinary team with researchers, clinicians, VR video experts and intended end-users will develop the intervention. Parts of the VRelax program will be developed in sprint cycles of three weeks:
a. Development of first prototype in scrum - all team members
b. Testing of first prototype - two clinicians and two end-users
c. Development of second prototype in scrum - all team members
d. Pilot study in order to investigate feasibility and proof of concept, as preparation for a larger randomized controlled trial (RCT).

Pilot study
Pilot study with 30 subjects. Sample size is based on recommendations for a clinical pilot as feasibility and proof of concept study. Participants will be randomly assigned (10 in each condition) to:
a. virtual landscape environment,
b. virtual dolphin environment,

c. control condition: watching 2D video clips of a landscape or dolphins.

Design
After informed consent, patients are randomized to one of the three conditions. Research assistants will administer baseline measures, including psychiatric symptoms, subjective and physiological stress measures. Patients will be instructed to use the VRelax tool or watch the video clips twice daily for 15 minutes, once in the morning and once in the evening. The first session will be done in the presence of a researcher and a nurse, for technical assistance and safety. After the first session, subjective and physiological stress measures are repeated, cyber sickness is assessed and user experiences recorded. From the second session onwards, patients will use the VRelax / video clips alone. At day 7, after the last session, a research assistant will repeat the baseline measures, and will conduct a qualitative interview on user experiences.

Intervention

Patients will be instructed to use the VRelax tool or watch the video clips twice daily for 15 minutes, once in the morning and once in the evening. The first session will be done in the presence of a researcher and a research assistant, for technical assistance and safety. After the first session, subjective and physiological stress measures are repeated, cyber sickness is assessed and user experiences recorded. From the second session onwards, patients will use the VRelax / video clips alone. At day 7, after the last session, a research assistant will repeat the baseline measures, and will conduct a qualitative interview on user experiences.

Study burden and risks

Burden:
- pre and post measures: 60 minutes of questionnaires, physiological measures (heart rate, skin conductance), qualitative interview about user experiences
- twice daily 15 minutes of intervention and 15 minutes preparation / short questionnaire

Risks:
- cyber sickness in VR, ie, transient nausea or dizziness

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

- Patient in clinical department of mood/anxiety disorders or psychotic disorders
- DSM-IV diagnosis of depressive disorder, anxiety disorder or psychotic disorder
- Age >18

Exclusion criteria

- DSM-IV diagnosis of substance abuse or dependence
- Specific phobia dolphins or water
- Benzodiazepine use > 10 mg / day diazepam equivalent
- Involuntary admission (IBS or RM)
- Diagnosis of epilepsy or organic brain damage
- Insufficient command of Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-06-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	28-06-2016
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL57378.042.16