Self-management of stress and sleep disturbances with eHealth applications for people with burn-out, mood, anxiety or psychotic disorders

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To test the effectiveness and cost-effectiveness of adding VRelax to treatment as usual (TAU) in improving functional and symptomatic outcomes in patients with anxiety, bipolar, burn-out, depressive, psychotic or post-traumatic disorder compared to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54388

Source
ToetsingOnline

Brief title
Relax-XL

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
anxiety, anxiety disorders

Health condition

burn-out, bipolaire, depressieve, psychotische en posttraumatische stressstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: eHealth, relaxation, self-management, Virtual Reality

Outcome measures

Primary outcome

Primary outcome is level of symptoms measured with the Dutch version of the Symptom Checklist-90-Revised (SCL-90-R). Participants will complete the SCL-90-R at baseline (T0) and after six weeks of using VRelax or controlled use of relaxation exercises (T1).

Secondary outcome

The secondary outcomes are psyciatric symptoms (measured with BAI, PSYRATS, HRSD, BAT, MDQ, and PCL-5) psychosocial functioning and medication use (measured with WHO-DAS II), functioning and recovering (measured with MANSA and Recovery Assessment Scale), substance use (measured with ASSIST), perceived stress (measured with perceived stress scale), sleep (measured with PSQI), cost-effectiveness (measured with TiC-P and EQ-5D-5L) and physical health (measured with SF-36).

Three questions are asked about preferences for VRelax or relaxation exercises, personal experiences that participants bring after using VRelax or relaxation exercises, and activities undertaken regarding stress and stress management.

Level of calmness and relaxation will be measured daily with Visual Analogue Scales.

Physiological parameters of stress and sleep will be measured during the intervention period using ambulatory measurements. In addition, a daily sleep questionnaire is administered to gain a better understanding of sleep.

Physiological parameters of stress will also be measured in a lab setting at the UMCG. Physiological markers of comorbid somatic diseases are measured by physical examination (including weight, blood pressure, and blood sampling).

Study description

Background summary

Stress is a well-established factor in the onset and continuation of burn-out anxiety, mood, psychotic, and post-traumatic disorders. Furthermore, sleep disturbances predispose and exacerbate mental health symptoms of the condition. In people with mental health problems, higher (social) stress-reactivity and impaired stress-recovery are present which is further aggravated by sleep disturbances and sleep deprivation. Relaxation reduces the stress, which in turn may reduce mental health symptoms, improve daily life functioning and quality of life. The burden of burn-out and psychiatric illness can be decreased by stress-reducing interventions which have been shown to improve quality of life and social and occupational functioning. Although current stress-reducing interventions appear to be effective, it must be taken into account that they require mental effort (i.e. attention and concentration of patients). These skills are often impared in people with burn-out or psychiatric disorders

To bridge this gap, VRelax was developed. VRelax is a virtual reality self-management stress-reduction tool. This tool requires far less effort than traditional relaxation exercises due to its immersive properties, and has an immediate effect on perceived stress and emotional mental states. In this study, the short-, medium- and long term effect of VRelax with treatment as usual on symptomatic recovery, level of social functioning, healthcare

consumption and societal costs will be investigated.

Study objective

To test the effectiveness and cost-effectiveness of adding VRelax to treatment as usual (TAU) in improving functional and symptomatic outcomes in patients with anxiety, bipolar, burn-out, depressive, psychotic or post-traumatic disorder compared to TAU with regulated use of relaxation exercises.

Study design

Multi-centre single-blind randomized controlled trial (RCT) with two arms: VRelax + treatment as usual and treatment as usual + regulated use of relaxation exercises.

Intervention

VRelax is a VR self-management tool aimed at reducing stress and sleep disturbances that can be used as a self-help intervention at home without the guidance of a professional. Patients wear a standalone head mounted display, through which they can access the VRelax app. The VRelax app contains 360* VR videos of relaxing natural environments. The variety of landscapes includes beaches, mountains, being in proximity to animals, etc. Interactive elements are embedded in the videos, e.g., a game of popping underwater air bubbles, shooting stars in a night sky and audio tracks of relaxation exercises. Participants use VRelax for a minimum of 20 minutes, at least five days a week for six weeks. The VRelax intervention is compared to treatment as usual with regulated use of relaxation exercises. The relaxation exercises consist of recorded texts of breathing exercises, muscle relaxation and guided meditation. The use of the relaxation exercises is regulated (minimum 20 minutes per day, minimum of five days per week, for six weeks) to ensure the same is demanded of these participants.

Study burden and risks

Assessments will take place at four time points (baseline [T0], post-treatment [T1], 26 weeks after baseline [T2] and 52 weeks after baseline [T3]).

The assessments at T0 and T1 include questionnaires, interviews, physical examination (including weight, blood pressure, and blood sampling), and physiological measurements in a lab setting at the UMCG and will take approximately 120-180 minutes.
The (online) assessments at T2 and T3 include questionnaires and interviews and will take 100-120 minutes.

Participants will use VRelax or relaxation exercises at least once a day, five

days a week, for six weeks and complete pre and post-session assessments (20 x 5 x 6 = 600 minutes).
The daily assessment consists of six questions and will take 1 - 2 minutes to complete (5 x 6 x 1-2 minutes = 30-60 minutes).

Only for two weeks, participants will fill in the daily sleep questionnaire.
The daily sleep questionnaire consists of four questions and will take 1 minute to complete (1 x 7 x 2 = 14 minutes)

We expect the patients to benefit from both the VRelax tool as the relaxation exercises. Concerning VRelax, it is possible some patients may experience mild cyber sickness during VRelax, 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)

Inclusion criteria

- Currently receiving treatment for burn-out which is defined according to the Dutch GP *Overspanning
en burn-out* guideline, and includes the International Classification of Primary Care (ICPC) categories of *surmenage* (P78) and *burn-out*(Z29.01), or diagnosed with anxiety disorder, bipolar disorder, depressive disorder, psychotic disorder or post-traumatic stress disorder according to the criteria of the Diagnostic and Statistical Manual of Mental Disorders (DSM), 5th edition.
- Complaints of stress and/or sleep disturbances as reported by patient or therapist
- Age > 18 .

Exclusion criteria

- DSM-5 diagnosis of substance use disorder.
- Photosensitive epilepsy with seizure in the past year or organic brain damage.
- Intellectual disability (estimated IQ < 70)
- Insufficient command of Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-06-2022
Enrollment:	171
Type:	Actual

Medical products/devices used

Generic name:	VRelax
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-02-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-06-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-09-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-12-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-11-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-07-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL79365.042.21