VR Moodboost in the treatment of depression

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON55986

Source
ToetsingOnline

Brief title
VR Moodboost

Condition

- Mood disorders and disturbances NEC

Synonym
depressed mood, sadness

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: GGZ Delfland

Intervention

Keyword: Depression, Positive affect, Virtual reality

Outcome measures

Primary outcome

- Positive and negative affect

Secondary outcome

- Depressive symptoms

- Activation

- Quality of life

- Self-efficacy

- Acceptability

- Usability

- Active involvement in VR

- Presence in VR

Study description

Background summary

Depression is the most common and expensive mental disorder amongst adolescents in The Netherlands and has a tremendous daily life impact. Despite effective treatments, only 50% of all depressive patients fully recover or experience a clinically meaningful reduction in symptoms. Recent research shows that available treatments are even less effective in adolescents compared to adults. Novel, more effective treatments are necessary to help adolescents recover from their depression, in order to prevent chronicity and improve quality of life and return to daily activities.
Positive and negative affect dynamics play an important role in depression. Positive affect is the ability to experience and express positive feelings and emotions including cheerfulness, pride and enthusiasm. The same counts for negative feelings and emotions in negative affect, like sadness, distress and

disgust. Most traditional treatments for depression focus on reduction of negative affect. However, positive affect dynamics are also disturbed in depression. Anhedonia or loss of pleasure in depression is associated with poor prognosis, increased chance of suicide and future depression symptoms. Moreover, the majority of patients with depression see the recovery of positive mood as the main treatment goal. Especially adolescents indicate the importance of being able to experience positive emotions, life satisfaction and personal growth. Positive affect could therefore be a potentially powerful target for treatment.

Neurobiological research shows that a lack of positive affect is related to a less active reward system. In addition, neurobiological research in adolescents at high risk for depression shows reduced reward response compared to adolescents without depression, especially during reward anticipation. Previous approaches focused on increasing positive affect in individuals with depression show promising results. Also, as experimental studies indicate that non-verbal stimuli have a stronger impact on activation of positive affect than verbal stimuli, the power of targeting positive affect may even be stronger when also including non-verbal elements.

Based on these recent scientific insights, in a unique collaboration of GGZ Delfland and AMC Psychiatry, we created a novel and innovative intervention called Virtual Reality-Moodboost (VR-Moodboost). The aim of VR-Moodboost is to increase positive affect in 12 sessions by combining elements of reward processing, positive goalsetting and affect labeling, using direct exposure to visual stimuli through Virtual Reality. In a proof of concept study, we aim to provide the first evidence that this novel intervention is effective in treating depression.

Study objective

The overall aim of this explorative proof-of-concept study is to provide first evidence that treatment with VR-Moodboost will lead to symptom improvement in patients with depression.

Primary objective:
We hypothesize that VR-Moodboost will lead to an increase in positive affect and a decrease in negative affect.

Secondary objectives:
In addition, we hypothesize that the VR-depression will lead to a reduction in depressive symptoms, an increase in activity level, quality of life and self-efficacy, high patient acceptability and high usability for both patient and therapist. We want to use the feedback provided by both patients and therapists in the set-up of a large RCT comparing VR-Moodboost to CBT.

Study design

We will conduct a multiple case study with an A-B design. Since this is a proof-of-concept study, we will include 10 outpatients with a mild-severe depression. Participants will first engage in a baseline (A-phase) condition for 3 or 5 weeks (which will be randomized), during which no treatment takes place. This baseline period is similar to the regular waitlist until treatment. Patients will make a signalling plan in this period with their therapist. After this baseline period, a trained psychologist performs the 12 session VR-Moodboost (B-phase). Subsequently, there will be a phase without active intervention (C-phase). We will measure the primary and secondary outcomes at start baseline, start intervention, post intervention after a 1-month and 6-month follow-up period (C-phase). During the A- and B-phase up to and including two months after the B-phase, patients will keep track of their mood using a patient diary by means of a smartphone app.

Intervention

The VR-Moodboost environment is designed to activate positive affect, using visual and auditory stimuli. In the VR environment, the participant enters an art gallery and gets to choose an activity out of four categories. The categories include solo-, group- inside- and outside activities. Each category is represented by a painting in the gallery. Within every category the participant can choose out of multiple activities, such as watching a sunset, playing a game or taking photographs in a city park. These include both 360 degrees and animated VR activities. To strengthen the experience of the positive affect induced by the activity, the participant is encouraged to label his emotions during the activity, after which the therapist will add a textual label which can be seen in the virtual activity.
When the participant has finished the activity the emotional/textual label will be presented in the main gallery as a virtual reward. At the end of each session the therapist encourages the participant to convey his virtual activity in a real-life activity, which would evoke the same positive feeling as the virtual activity, which he can perform in the upcoming week. Each next session starts with discussing the real-life activity of the previous week, and labeling the emotion the participant felt during the real-life activity. Then the participant chooses another virtual reward (art object), which is added to the gallery. Therefore, performing both a virtual and a real-life activity will result in a reward in the virtual gallery. At the end of the therapy, the participant will receive an actual reward in the form of a small poster containing all the labels he attributed to the performed virtual and real-life activities; a *reward tree*.

Study burden and risks

We expect participating patients are expected to benefit from the VR-moodboost

treatment. We expect an improvement of depressive symptoms, a decrease of negative affect and an increase of positive affect, quality of life and self-efficacy. Worsening of symptoms is not expected to happen. Since we are studying a new treatment method in a proof-of-concept study, there is a minor risk the participants will not benefit from the VR-moodboost treatment. However, we consider the theoretical rationale of VR-moodboost as strong and former studies have shown beneficial effects of psychotherapies focussing on positive affect and behavioural activation. If this proof-of-concept study shows a positive effect of the VR-moodboost treatment, it provides an essential step towards adding a novel psychotherapy technique to the treatment of depression for adolescents, which would be of enormous value. The 3-5 weeks baseline phase and the 12 sessions of treatment are comparable to regular psychotherapy for depression (CBT). Participants can withdrawal from the treatment or from the study at any time and this has no effect on their care as usual.
There are no known risks associated with the VR-moodboost environment. Some participants might experience some nausea (e.g. cybersickness) whilst wearing the Head Mounted Display (HMD). The experience of patients so far is that this usually disappears quickly after removing the HMD.
Also, the VR moodboost environment is designed with 90 PFS (frames per second), to prevent cybersickness. During the activity the participant will be standing mostly in one spot, this also reduces the risk of nausea. Therefore the risks of participation can be considered negligible minor and the burden minimal.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

- A principal diagnosis of mild to severe depression, either a first or recurrent episode, as determined by a BIG-registered psychologist (clinical or GZ) or psychiatrist.
- Age between 15 to 23.
- Written informed consent by the patient to participate in the study if they are over 18 years old or written informed consent by the patient*s parent/caregiver if they are under 18 years old.

Exclusion criteria

- Intellectual disability in the patient's history.
- A principal diagnosis of depression with psychotic features.
- Current high suicidality risk (suicidality plans).
- Severe comorbid psychiatric disorders including schizophrenia-like disorders, bipolar disorder or addictive disorders in the past six months.
- Current use of antipsychotics or sedatives.
- Current trajectory of adjusting or switching antidepressants (a stable dose of antidepressants at time of inclusion is allowed)
- Abnormal hearing and/or uncorrected vision.

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-09-2022
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Social Worlds VR-CBT
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-11-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-10-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389

mecamc@amsterdamumc.nl

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	NL77018.018.21