A virtual reality experience to improve psychoeducation for 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-OMON55901

Source
ToetsingOnline

Brief title
Virtual Reality for psycho-education on depression

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, Selfstigma, Virtual reality

Outcome measures

Primary outcome

The main study parameter is the difference in feelings of self-stigma, as measured by the Internalized Stigma of Mental Illness scale, before and after psychoeducation, after 1 week and after 10 weeks.

Secondary outcome

Secondary parameters include perceived social support, loneliness and depressive symptoms for the patient and burden of care and quality of life for relatives.

Study description

Background summary

Depression is a prevalent mental disorder, causing tremendous suffering for those affected and their relatives. Patients with depression often deal with stigma. We developed a virtual reality (VR) environment to experience a depression from the perspective of a patient and her relative (VR depression experience). We hypothesize that when patients and their relative experience the VR in a psychoeducation session, this will lead to less self-stigma, an increase in perceived social support, less loneliness and consequently less depressive symptoms for patients. We also hypothese that the VR experience will lead to a decrease in perceived burden of care, and an increase in quality of life of the relative.

Study objective

In the present study our main aim is to assess whether VR psycho-education will lead to a larger decrease in feelings of self-stigma for the patient, as compared to traditional psychoeducation. Our secondary aim would be to test the effect of the VR psychoeducation on social support, loneliness, and depressive symptoms for the patient, and perceived burden of care and quality of life of

the person closest to the patient, as compared to traditional psychoeducation.

Study design

We will conduct a randomized controlled trial in the four largest outpatient clinics within mental health care institution GGZ Delfland, and within the outpatient clinic for Psychiatry of the Amsterdam UMC. When the diagnosis is confirmed, the participant and a relative of their choice will be randomized into either the VR psychoeducation protocol or the standard psychoeducation protocol. After randomization, the patient and their relative are invited for the psychoeducation session. The patients will fill in questionnaires before and after the psychoeducation session, after 1 week and after 10 weeks during their further psychological treatment. The relatives will fill in questionnaires before the psychoeducation session, after one week and after 10 weeks.

Intervention

In both conditions, patients and their relative receive psychoeducation. This is manualized and consists of an explanation of the symptoms, possible causes, diagnosis and treatment of depression according to the Dutch CBT protocol book *Protocollaire behandelingen voor volwassenen*, section depressive disorder.

In addition to the above, in the VR psychoeducation condition, patients and relatives also watch the VR depression experience video. This consists of two 360º videos which summarize multiple fragments of a day in the life of a female depressive patient (1) from her perspective and (2) from the perspective of her male partner.The VR-experience includes getting up in the morning, having breakfast, interaction with the partner, sitting around in the afternoon not being able to undertake an activity and taking medication through the eyes of the patient whilst hearing her inner thoughts. The relative watches the video from the patient*s perspective, this takes 6 minutes. The study participant has the possibility to watch along on a screen. The study participant watches the VR-experience from the perspective of the partner, this experience takes 4 minutes in total. This experience includes mainly the same scenes; getting up in the morning, having breakfast, the evening after the partner returns from his job. This time, the study participant watches the scenes whilst hearing the inner thoughts of the partner, and the relative of the study participant has the possibility to watch along on a screen. After both the study participant and the relative have undergone the VR depression experience, the study participant and the relative will answer some questions related to the VR experience and the therapist will stimulate a mutual discussion about the content of the experience.

Study burden and risks

If a patient wants to participate, the researcher will conduct a semi structured interview by telephone, to conform the diagnosis. Furthermore, patients will answer four, and relatives two questionnaires at three time points (for patients there is one more measurement with one questionnaire). The total amount of time to fill in the questionnaires for the patient is 50 minutes, and for the relative 30 minutes.

Some participants might experience some nausea (e.g. cybersickness), dizziness or headache, whilst wearing the Head Mounted Display (HMD). The experience of patients so far is that this usually disappears quickly after removing the HMD.

The burden of participation is minimal for depressive patients and their relatives; they will receive psychoeducation as usual, with or without the VR depression experience. Session length will be the same, as will be the information about depression provided in the session. No additional site visits are required, questionnaires will be administered before a scheduled therapy session, or by telephone or digitally by means of Castor.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

* A principal diagnosis of depression (all severities), either a first or recurrent episode, as determined by a BIG-registered psychologist (clinical or GZ) or psychiatrist
* Age between 18-65
* Willing to involve a relative (partner, friend, family member)
* Scheduled to start psychotherapy individually or in a group at an outpatient clinic or psychology practice
* Written informed consent by both the patient and the relative to participate in the study

Exclusion criteria

* Intellectual disability in the history
* Severe comorbid psychiatric disorders including schizophrenia-like disorders, bipolar disorder or addictive disorders
* Abnormal hearing or uncorrected vision

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:	Recruiting
Start date (anticipated):	06-08-2021
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	21-10-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-09-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-11-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam)

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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: 27752
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL74955.018.20