VR as preparation for care as usual for patients with a panic disorder or social phobia.

Published: 18-06-2020
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The objective of this study is to investigate if VR as a pre-module improves the willingness to start with exposure in vivo.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON48032

Source
ToetsingOnline

Brief title
VR in patients (12-18 or 18+) with panic disorder or sociale phobia.

Condition

- Anxiety disorders and symptoms

Synonym
Social phobia and panic disorder

Research involving
Human

Sponsors and support

Primary sponsor: ProPersona (Nijmegen)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Panic Disorder, Social phobia, Virtual Reality

Outcome measures

Primary outcome

- willingness to take part in exposure in vivo

Measured with the Friedman-test (non-parametric).

When they differ significantly we will use post-hoc analyses (Wilcoxon Signed

Rank Test with a Bonferroni correction).

Secondary outcome

Anxiety Expectancy, activation of anxiety, approachability and course of

symptoms (anxiety/depression) will be visual reproduced as descriptive

statistics.

Study description

Background summary

CBT in adolescents and adults with a panic disorder or social phobia needs improvement.
Patients drop-out during the treatment or it's difficult to motivate for exposure in vivo to anxiety induced environments.
Virtual reality seems to be an promising intervention. A lot of studies studied the effects of VR as a treatment for anxiety disorders.
The objective of this study is to investigate if VR as a pre-module improves the willingness to start with exposure in vivo.

Study objective

The objective of this study is to investigate if VR as a pre-module improves the willingness to start with exposure in vivo.

Study design

The study design which will be used for this study is a single casedesign with repeated measures.

Intervention

Four VR sessions in which participants will be exposed to public traffic, a supermarket, a shopping district and a party in the garden.

Study burden and risks

The risk of participation in this study can be cybersickness.
Participants will be informed about this and it's always a possibility to stop their participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

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

Inclusion criteria

- DSM-5 diagnosis: panic disorder or social phobia, measured with the MINI KID (adolescents) or MINI (adults)
- Age between 12 and 18 (adolescents) of 18+

Exclusion criteria

- patients are diagnosed with a severe depressive disorder for which they need immediate treatment (measured with the MINI or MINI KID)
- patients are diagnosed with a psychosis for which they need immediate treatment (measured with the MINI or MINI KID)
- Mental retardation (IQ below 70)
- Substance abuse or dependence or alcohol abuse or dependence
- Psychofarmacology is changed in the last 8 weeks

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2020
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	18-06-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL72392.091.19