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Investigating the efficacy of self-guided digital treatment with virtual reality for panic disorder and agoraphobia

Submission date
11/01/2022

Recruitment status
No longer recruiting

Registration date
17/01/2022

Overall study status
Completed

Last Edited
23/05/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
People with panic disorder interpret thoughts and bodily sensations as dangerous or even life-threatening, leading to sudden and intense fear reactions. These panic attacks are often experienced as overwhelming. In agoraphobia, patients have panic-like attacks in places in which the access to help is limited or areas that are difficult to oversee. Avoidance behavior is a consequence that is common in both disorders, causing impairment and distress for troubled individuals.
Cognitive behavioral therapy (CBT) is the first-line treatment for patients with panic disorder and agoraphobia. Yet, many patients remain untreated due to limited treatment resources. Digital self-guided short-term treatment applications may help to overcome this issue. While some therapeutic applications are already supported by health insurance companies, data on their efficacy is limited. The current study aims at providing insights on the efficacy of short-term treatment applications including psychoeducation and self-guided virtual reality exposure therapy.

Who can participate?
People, who meet the diagnostic criteria for agoraphobia, unspecified (ICD-10 F40.00), agoraphobia with panic disorder (ICD-10 F40.01), agoraphobia without panic disorder (ICD-10 F40.02), and panic disorder (ICD-10 F41.00) can participate.

What does the study involve?
Patients diagnosed with panic disorder and agoraphobia will be randomly assigned to either the experimental (EG) or the control group (CG). Participants of both groups will undergo baseline diagnostics in the first two sessions. The subsequent treatment for the EG consists of a self-guided six-week phase of application-based psychoeducation, one therapy session preparing for the virtual reality exposure therapy (VRET), and four weeks of application based self-guided VRET. To control for potential effects of the therapy session with the therapist, the CG will receive relaxation training instead. All patients will then undergo a closing session which terminates with the post-assessment and a follow up assessment six weeks following the closing session.

What are the possible benefits and risks of participating?
A possible benefit is that the patient profits from the proposed intervention. No significant risks are linked to the participation in this study.

Where is the study run from?
University of Siegen (Germany)

When is the study starting and how long is it expected to run for?
April 2021 to March 2024

Who is funding the study?
DFG-Research Training Group 2493: Consequences of Social Work
University of Siegen (Germany)

Who is the main contact?
Jari Planert, M.Sc., jari.planert@uni-siegen.de

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Self-guided digital treatment with virtual reality for panic disorder and agoraphobia: a study protocol for a randomized controlled trial

Study objectives
1. We expect that patients in the experimental condition experience a significant decline in severy of panic and agoraphobic symptoms compared to the control condition.
2. The secondary hypothesis is that at follow-up, significantly fewer participants in the experimental condition will meet the diagnostic criteria for panic disorder, agoraphobia, and panic disorder with agoraphobia, compared to the control condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/04/2021, Siegen University Council for Research Ethics (Adolf-Reichwein Str. 2a, 57076 Siegen, Germany; +49(0) 271 / 740-4311; ethikrat@uni-siegen.de), ref: ER_48_2021

Study design
Single center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Self-guided treatment for patients with panic disorder and agoraphobia

Interventions
First, all patients will have two psychotherapeutic sessions during which their symptoms will be assessed. At the end of the second session, random allocation to the research conditions will take place. The scheme that determines a patients' allocation will be generated before study initiation using R.4.1.4. At this point, patients in the experimental group (EG) will receive access to the psychoeducational part of the self-guided digital treatment, for which they have six weeks to complete.
Then, during the next session, patients in the EG will be prepared for the virtual reality part of the self-guided digital treatment, while patients in the control group (CG) receive relaxation training instead. Then, the EG has four weeks to complete the virtual reality part of the self-guided digital treatment. After that time, both groups will have a closing session, which will be used for the consolidation of learned behavior and relapse prevention. A follow-up session will take place six weeks after the closing session.

Intervention Type
Behavioural

Primary outcome(s)
Panic disorder and agoraphobia symptoms are measured using the German version of the Panic and Agoraphobia Scale (PAS) at baseline, interim (6 weeks), post-treatment (10 weeks), and follow-up (16 weeks)

Key secondary outcome(s))
Remission measured using the Mini-DIPS at baseline and follow-up (16 weeks)

Completion date
01/03/2024

Eligibility

Key inclusion criteria
One of the following diagnostic criteria:
- Agoraphobia, unspecified (ICD-10 F40.00)
- Agoraphobia with panic disorder (ICD-10 F40.01)
- Agoraphobia without panic disorder (ICD-10 F40.02)
- Panic disorder (ICD-10 F41.0)

Note: All listed diagnoses can be in comorbidity with or without depression

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Stroke or myocardial infarction in patient history
2. Angina pectoris
3. Cardiac dysrhythmia
4. Asthma, chronic obstructive pulmonary disease
5. Pregnancy (or assumed pregnancy)
6. Severely impaired vision
7. Epilepsy or other cramp attacks in patient history
8. Psychological disorder with organic origin (f.e. dementia)
9. Dizziness or vestibular impairment
10. Psychological disorder due to use of psychoactive substances
11. Schizophrenia, schizotypal or delusional disorder
12. Severe depression
13. Acute suicidality or missing agreement in presence of suicidality

Date of first enrolment
01/03/2022

Date of final enrolment
24/01/2024

Locations

Countries of recruitment
Germany

Study participating centre
Psychotherapeutische Hochschulambulanz der Universität Siegen
Weidenauer Straße 167a
Siegen
Germany
57076

Sponsor information

Organisation
University of Siegen

ROR
https://ror.org/02azyry73

Funder(s)

Funder type
Charity

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

The dataset will be available upon request from the corresponding author (Jari Planert; jari.planert@uni-siegen.de). The data will be available after the overall trial end.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/05/2022	23/05/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes