

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 17/01/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/05/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

Mr Jari Planert

ORCID ID

<https://orcid.org/0000-0002-8088-2511>

Contact details

DFG-Research Training Group 2493

Hölderlinstr. 3

Siegen

Germany

57076

+49(0) 271-740-3887

jari.planert@uni-siegen.de

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 severity 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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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)

Secondary outcome measures

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

Overall study start date

11/04/2021

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

Age group

Adult

Sex

Both

Target number of participants

40 (20 per group)

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

Sponsor details

Adolf-Reichwein-Straße 2

Siegen

Germany

57076

+49 2717400

presse@uni-siegen.de

Sponsor type

University/education

Website

<https://www.uni-siegen.de/start/index.html.en?lang=en>

ROR

<https://ror.org/02azyry73>

Funder(s)

Funder type

Charity

Funder Name

Deutsche Forschungsgemeinschaft

Alternative Name(s)

German Research Association, German Research Foundation, DFG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Publication and dissemination plan

Planned publication of the study protocol in Trials

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

24/01/2025

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