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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
11/01/2022		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/01/2022	Completed  Condition category  Mental and Behavioural Disorders	☐ Results		
Last Edited		Individual participant data		
23/05/2022		<ul><li>Record updated in last year</li></ul>		

#### 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

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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?
<u>Protocol article</u>		21/05/2022	23/05/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes