

Self-guided virtual reality therapy for social anxiety disorder

Submission date 31/01/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 02/02/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/08/2024	Condition category Mental and Behavioural Disorders	<input checked="" type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Social anxiety disorder (SAD), also called social phobia, is a long-term and overwhelming fear of social situations. Cognitive behavior therapy (CBT) is therapy that helps you identify negative thought patterns and behaviours, and change them. CBT is the first-line treatment for SAD, yet its accessibility is often constrained with long waiting times. Digital therapeutic applications, including psychoeducation and self-guided behavioral experiments in virtual reality (VR), could facilitate access and reduce waiting times. Psychoeducation involves learning about and understanding mental health and wellbeing. The study aims to investigate if self-guided digital therapeutic applications, offering ultra-short-time therapy combined with VR components, can reduce the severity of SAD.

Who can participate?

Patients with Social Anxiety Disorder as a primary disorder.

What does the study involve?

Participants take part in a brief diagnostic process containing a phone screening and two therapeutic appointments. If a social anxiety disorder is diagnosed, participants are randomized into an experimental or a control group. Participants in the experimental group receive a prescription for a therapeutic application. After six weeks, in which they must complete psychoeducation, they meet with a therapist, and the virtual reality exposition is activated. After four weeks, participants have a final appointment to reflect on their experience. At each appointment and on a six-week follow-up, questionnaires are filled in. The control group also has an equal amount of appointments with a therapist but does not get a prescription for the therapeutic application until the fifth appointment (six-week follow up).

What are the possible benefits and risks of participating?

A possible benefit is that the application-based therapy may help to reduce participants' anxiety. Including VR in therapy could relieve therapists and help reduce the waiting time for patients. The results of this study can have a great impact on therapeutic interventions and inform future research on VR in therapy. There are no significant risks of participating in the 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 January 2024

Who is funding the study?
DFG-Graduiertenkolleg 2493 "Folgen Sozialer Hilfen" (<https://folgensozialerhilfen.de/>)
(Germany)

Who is the main contact?
Anne Sophie Hildebrand, anne.hildebrand@uni-siegen.de

Contact information

Type(s)
Scientific

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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 virtual reality therapy for social anxiety disorder: a study protocol for a randomized controlled trial

Study objectives

We expect that patients who receive application-based treatment will show less symptoms of social anxiety at an interim, a post, and a 6-weeks follow-up assessment, compared to the control group. To test a clinically relevant change, the remission rates of patients between both groups will be compared at the follow-up assessment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/11/2019, Ethics Committee of the University of Siegen (Jonas Kameboge, Adolf-Reichwein-Str. 2a, NA, 57076, Germany; +490271 740-4819; ethikrat@uni-siegen.de), ref: ER_84_2021

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Self-guided treatment for patients with social anxiety disorder

Interventions

The study is a single-center randomized controlled trial. Relative changes in SAD symptoms (interim vs. baseline, post vs. baseline, follow-up vs. baseline) will be compared between a group receiving a digital (VR) application and a control group will be compared in a superiority design. The study employs a 2 (condition: application-based vs. control treatment) x 4 (time: baseline assessment, interim assessment, post assessment, and 6-weeks-follow-up) design.

Participants will be randomly assigned to the experimental (EG) or control group (CG), according to an externally constructed randomization plan.

EG: Four meetings with a therapist + psychoeducation and virtual reality exposition via the application Invirto

CG: Four meetings with a therapist

Intervention Type

Behavioural

Primary outcome measure

Questionnaire on social anxiety and social competence deficits (SASKO) measured on the second, third and fourth appointment

Secondary outcome measures

Remission, measured via Mini-DIPS at the baseline and follow-up assessment

Overall study start date

11/04/2021

Completion date

01/01/2024

Eligibility

Key inclusion criteria

Social anxiety disorder (F40.1)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

Total final enrolment

181

Key exclusion criteria

1. Stroke or coronary in the past
2. Angina pectoris
3. Cardiac arrhythmias
4. Hypertension
5. Asthma or a chronic obstructive pulmonary disease (COPD)
6. Pregnancy or the suspicion
7. Strong visual disorders
8. Epilepsy or seizures in the past
9. Psychological disorders with organic cause (for example dementia)

- 10. Vertigo
- 11. Vestibular impairments
- 12. Psychological or behavioral disorders because of the consumption of psychoactive substances
- 13. Schizophrenia, schizotypal or delusional disorders
- 14. Severe depression or mania
- 15. Acute suicidal tendencies or lack of capability to negotiate a no-suicide agreement
- 16. Not yet in therapy

Date of first enrolment

01/03/2022

Date of final enrolment

01/01/2024

Locations

Countries of recruitment

Germany

Study participating centre

Outpatient Center for Psychotherapy of the University of Siegen

Weidenauer Str. 167

Siegen

Germany

57076

Sponsor information

Organisation

University of Siegen

Sponsor details

Adolf-Reichwein-Straße 2

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Sponsor type

University/education

Website

<https://www.uni-siegen.de/start/>

ROR

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

Funder(s)

Funder type

Research organisation

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

10/01/2025

Individual participant data (IPD) sharing plan

The dataset will be available upon request from the corresponding author (Anne Sophie Hildebrand, anne.hildebrand@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		12/05/2022	16/05/2022	Yes	No
Dataset			21/08/2024	No	No