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Self-guided virtual reality therapy for social anxiety disorder

Submission date
31/01/2022

Recruitment status
No longer recruiting

Registration date
02/02/2022

Overall study status
Completed

Last Edited
30/08/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[X] Individual participant data
[_] 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
Remission, measured via Mini-DIPS at the baseline and follow-up assessment

Completion date
01/01/2024

Eligibility

Key inclusion criteria
Social anxiety disorder (F40.1)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

ROR
https://ror.org/02azyry73

Funder(s)

Funder type
Research organisation

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 (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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes