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Effectiveness of self-training program using the virtual reality exposure therapy in college students with social anxiety

Submission date
05/05/2023

Recruitment status
No longer recruiting

Registration date
10/05/2023

Overall study status
Completed

Last Edited
18/03/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The lifetime prevalence of social anxiety disorder (SAD) ranges from 2.3% to 12.1%. According to the current survey of college students in China, the prevalence rate is above 8.8%. Exposure therapy is a classic intervention method for social anxiety disorder. With the advancement of technology, the application of virtual reality (VR) has led to the birth of virtual reality exposure therapy (VRET).

Who can participate?
This study plans to recruit 60 participants with high levels of social anxiety, and the sources of the participants are students in the colleges of Shanghai. They were randomly divided into an intervention group and a waiting group, with 30 participants in both groups.

What does the study involve?
To explore the self-training intervention effect of VRET on social anxiety of subclinical college students. Specifically, a single-factor inter-participant design was adopted, the independent variable was exposure therapy intervention (intervention, no intervention), and the dependent variable included the following items: 1. Social anxiety level, 2. Global distress, 3. Affect, 4. Heart rate, 5. Blood pressure.

What are the possible benefits and risks of participating?
Participating in this study, the participants can get a free 14-day self-training intervention program, which may alleviate the social anxiety symptoms of the participants after extensive research abroad.

Where is the study run from?
The pre-test and post-test will be arranged at the laboratory of East China Normal University Zhongbei Campus (No. 3663 Zhongshan North Road, Putuo District, Shanghai). The other self-training program will be exerted by the subjects themselves at home.

When is the study starting and how long is it expected to run for?
The Enrollment was started on 12/05/2023. The intervention will be started on 23/05/2023 and expected to run for 1 year.

Who is funding the study?
The funders are the National Natural Science Foundation of China (31900767), the Research Project of Shanghai Science and Technology Commission(20dz2260300), and Fundamental Research Funds for the Central Universities.

Who is the main contact?
Examiner: Kan Chinghsiang (Address: School of Psychology and Cognitive Science, East China Normal University, No. 3663 Zhongshan North Road, Putuo District, Shanghai, WeChat ID: animalfarmkang, E-mail: animalfarmkang@msn.com, Tel: +86 13585700546).

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
31900767, 20dz2260300

Study information

Scientific Title
Recharge for Social Anxlien: VRET Self-training Program

Acronym

STPVRET

Study objectives
The study aims to examine the self-training intervention program is effective to alleviate the anxiety level of college students with high social anxiety.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/02/2023, East China Normal University Committee on Human Research Protection (3663 Zhongshan Road North, Shanghai 200062, China; +86 21 6223 3333; ask.irb@admin.ecnu.edu.cn), ref: HR2-0008-2023

Study design
Single-center single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
High level of social anxiety

Interventions
Intervention: self-training program of virtual reality exprosure therapy
Total duration of treatment: 14 days
Dose: 8 video courses, each about 15 minutes, the participants used the WeChat mini-program at home to watch social scene videos with gradually increasing anxiety levels through VR glasses.
Pre-test and post-test: The experimenter personally administers the test in the school laboratory.
Follow-up practice and follow-up test: On the 44th to 45th day, the participants will complete by themselves after receiving the VR glasses from the experimenter, and then send the VR glasses back.
Randomisation: 60 participants were randomly divided into an intervention group and a waiting group using the function of "Data-Case Selection-Random Case Sample" in SPSS, with 30 participants in both groups.

Intervention Type
Behavioural

Primary outcome(s)
Anxiety is measured using the Social Phobia Inventory (SPIN) and the Liebowitz Social Anxiety Scale (LSAS) at 1, 14, and 45 d.

Key secondary outcome(s))
1. Global distress is measured using the Clinical Outcome in Routine Evaluation-Outcome Measure (COREOM) and the Clinical Outcome in Routine Evaluation-10 (CORE-10) at 1, 3, 6, 9, 12, 14, and 45 d.

2. Affect is measured using the Positive and Negative Affect Schedule or (PANAS) at 1, 3, 6, 9, 12, 14, and 45 d.
3. Heart rate is measured using the commercially available conventional heart rate monitor at 1, 14, and 45 d.
4. Blood pressure is measured using the commercially available conventional blood pressure monitor at 1, 14, and 45 d.
5. Simulator is measured using the Simulator Sickness Questionnaire (SSQ) at 1 d.
6. Competence of task, satisfication of performance, and change of behavior are measure using the Likert 4-point Scale at 1, 2, 4, 5, 7, 8, 10, 11, 13, 14, 44, 45 d.

Completion date
15/11/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/05/2023:
1. Age: 18+ years
2. Status: College students in colleges and universities in Shanghai (undergraduate to doctoral students)
3. Anxiety level: a total score of 31 or more on the SPIN scale or a total score of 35 or more on the LSAS scale

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Previous inclusion criteria:
1. Age: 18+ years
2. Status: College students in colleges and universities in Shanghai (undergraduate to doctoral students)
3. Anxiety level: a total score of 31 or more on the SPIN scale or a total score of 30 or more on the LSAS scale

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
61

Key exclusion criteria

Current exclusion criteria as of 18/05/2023:
1. Diagnosed mental disorders other than social anxiety disorder or a total score of 29 or more on the BDI-II scale.
2. Suicide and self-injury high-risk groups (CORE-10).
3. People who are strongly uncomfortable with VR videos (SSQ).

Previous exclusion criteria:
1. Diagnosed mental disorders other than social anxiety disorder.
2. Suicide and self-injury high-risk groups (CORE-10).
3. People who are strongly uncomfortable with VR videos (SSQ).

Date of first enrolment
10/05/2023

Date of final enrolment
10/06/2023

Locations

Countries of recruitment
China

Study participating centre
School of Psychological and Cognitive Sciences, East China Normal University
No. 3663, Zhongshan North Road, Putuo District
Shanghai
China
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Sponsor information

Organisation
East China Normal University

ROR
https://ror.org/02n96ep67

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Research Project of Shanghai Science and Technology Commission

Funder Name
Fundamental Research Funds for the Central Universities

Alternative Name(s)
Fundamental Research Funds for the Central Universities of China, Fundamental Research Fund for the Central Universities

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from.
Name: Kan Chinghsiang
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Type of data that will be shared: All data except participant's private information
When the data will become available and for how long: Available after publication and for permanence
By what access criteria data will be shared including with whom: Research with public registration
For what types of analyses: All
By what mechanism: Email
Whether consent from participants was obtained: Consent in advance with Participant Statement
Comments on data anonymisation: No providing of participant's private information
Ethical or legal restrictions: Abiding by the law and ethics guidelines of China

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			09/05/2023	No	Yes