

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

<b>Submission date</b> 05/05/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/05/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/03/2024	<b>Condition category</b> 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

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

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Home, University/medical school/dental school

**Study type(s)**

Treatment

**Participant information sheet**

See study outputs table

**Health condition(s) or problem(s) studied**

High level of social anxiety

**Interventions**

Intervention: self-training program of virtual reality exposure 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 measure**

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

## **Secondary outcome measures**

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, satisfaction 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.

## **Overall study start date**

20/04/2022

## **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

60

**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).

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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

200062

# Sponsor information

## Organisation

East China Normal University

## Sponsor details

School of Psychological and Cognitive Sciences

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## Sponsor type

University/education

## Website

<http://www.ecnu.edu.cn/>

## 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 Wěiyuánhùi, 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

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

01/04/2024

**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?
<a href="#">Participant information sheet</a>			09/05/2023	No	Yes