ISRCTN12882676 https://doi.org/10.1186/ISRCTN12882676

Using virtual reality (VR) to reduce social avoidance

Submission date
29/08/2019

Recruitment status
No longer recruiting

Registration date
13/09/2019

Overall study status
Completed

Last Edited
02/11/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
By putting on a headset, participants can enter a three-dimensional Virtual Reality (VR) computer-generated simulation of the world. VR is often used to play computer games. The researchers wish to learn about the effects of their new VR programme on social avoidance. Participants will be guided by an avatar within the VR to go through a series of graded tasks in different environments that reflect everyday situations (e.g., cafe, bus, street, doctor's waiting room).

Who can participate?
Individuals who are 18 or above who find themselves anxious about social situations. As the intervention will be conducted in Cantonese, the participants will need to be able to understand Cantonese.

What does the study involve?
If participants are happy to take part in the study, they will sign a consent form. If they consent to take part, they will be randomly allocated to one of two groups: the VR treatment group or the control group. If they are in the treatment group they will attend around 6 sessions of VR. Each session will take about 30 minutes. Two sessions may be run consecutively. They will be asked to complete questionnaires about social avoidance at the beginning, immediately after, and one month after the programme. At the beginning and at the end of each VR session, participants will be asked to fill out some assessments to help keep track of their progress. For the control group, they will be asked to complete a set of questionnaires about social avoidance three times: once at the beginning, once after 3-5 weeks (i.e. post-assessment), and finally 4 weeks after the post-assessment. They will be offered the opportunity to receive the virtual reality treatment after the study has ended. This means everyone can receive the VR treatment if they take part.

What are the possible benefits and risks of participating?
It is possible participants may feel less anxious after the programme. The researchers hope to learn more about these aspects of VR on social avoidance from this study. There are very minimal risks in participating in this study. Some people, with some VR programmes/games, can occasionally experience motion sickness, similar to travel sickness. The researchers recommend

people to stop using the VR if they start to feel sick. The way they have designed the VR programme reduces the likelihood that anyone will experience motion sickness. It is also the case that participants may feel anxious when experiencing social situations in VR. This is part of the programme, allowing them to learn that they will be okay. The headset is cleaned after a person uses it.

Where is the study run from?
The CUHK Medical Clinic (Hong Kong)

When is the study starting and how long is it expected to run for?
February 2019 to October 2021 (updated 02/03/2021, previously: July 2021; updated 01/03/2021, previously: June 2021)

Who is funding the study?
AXA China Region Insurance Company Limited

Who is the main contact?
1. Prof. Winnie Wing Sze Mak
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2. Dr Amy Chan
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Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NTEC-2019-0250

Study information

Scientific Title
Using Virtual Reality (VR) to reduce social avoidance: a pilot and a randomized controlled trial of a virtual reality cognitive behavioral therapy based program for social avoidance

Acronym
VR Social Avoidance

Study objectives
Compared with usual care (i.e. waitlist control), the VR intervention group will experience a significant reduction in social avoidance symptoms after treatment and this benefit will persist until the 4-week follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/09/2019, The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (The Joint CUHK-NTEC CREC) (8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, Hong Kong; Tel: +852 (0)3505 3935; Email: crec@cuhk.edu.hk), Applying Cluster: NTEC, IRB/ REC Reference No. : 2019.254, Submission Reference No.: NTEC-2019-0250

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Social avoidance

Interventions
Randomization method is block-randomization.

The current VR intervention will be designed to help people feel safer and more confident in social situations. Participants will be guided by a virtual coach through a series of graded tasks in different environments that reflect everyday situations (e.g., café, bus, street, doctor's waiting room) for people who might avoid social situations. By testing beliefs that inhibit confidence in a safe and controlled environment, participants will complete tasks with increasing difficulty and learn that they can cope in situations that they previously avoid. This program is intended for use by adults who are 18 or above.

Control group will be a wait-list control. After submitting the 1-month follow-up survey, the control group will be eligible to receive the same VR intervention as the intervention group.

There will be a total of 4 visits to the study venue. Participants will be asked to complete a baseline questionnaire before they get randomized to either intervention or control group. For the intervention group, they will visit the study venue 3 more times to receive the VR treatment. The last visit will also end with the completion of the post-survey. Participants will be notified to complete the online one-month follow-up survey on their own. The entire intervention should take about 1 month, followed by 1-month follow-up survey.

Intervention Type
Behavioural

Primary outcome(s)
Social avoidance measured at baseline, post-intervention and 1-month follow-up using:
1. Mobility Inventory for Agoraphobia
2. Liebowitz Social Anxiety Scale (LSAS)
3. Social Interaction Anxiety Scale (SIAS)
4. Oxford Behavioural Avoidance Task (OBAT)

Key secondary outcome(s))
Measured at baseline, post-intervention and 1-month follow-up:
1. Depression-related symptoms assessed using Patient Health Questionnaire (PHQ-9)
2. Anxiety-related symptoms assessed using Generalized Anxiety Disorder Assessment (GAD-7)
3. Work and social adjustment assessed using Work and Social Adjustment Scale (WSAS)

Completion date
31/10/2021

Eligibility

Key inclusion criteria
1. Age 18 or above
2. Can read traditional Chinese and understand Cantonese
3. Self report on experiencing social avoidance symptoms

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
272

Key exclusion criteria
1. People who are currently receiving psychological intervention for social avoidance
2. People who have participated in the pilot study of this project
3. History of photosensitive epilepsy
4. Impairment of stereoscopic vision
5. Balance problems

Date of first enrolment
17/06/2019

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
Hong Kong

Study participating centre
The CUHK Medical Clinic
5/F, Podium Plaza
5 Hanoi Road
Tsim Sha Tsui
Kowloon
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Sponsor information

Organisation
AXA China Region Insurance Company Limited

ROR
https://ror.org/013z4qk72

Funder(s)

Funder type
Industry

Funder Name
AXA China Region Insurance Company Limited

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 Prof. Winnie Wing Sze Mak (wwsmak@cuhk.edu.hk). The data will be in CSV format and will become available after the data collection and analysis. All personally identifiable information will be removed from the dataset prior to any kind of sharing. data sharing will require permission from all collaborating parties.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version V1.1	13/08/2019	18/02/2020	No	No
Protocol file	version V2.0	07/05/2020	03/07/2020	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes