Virtual reality hypnotherapy for healthcare students

Submission date	Recruitment status	Prospectively registered
31/12/2023	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
03/01/2024	Completed	☐ Results
Last Edited	Condition category	Individual participant data
03/01/2024	Mental and Behavioural Disorders	Record updated in last year

Plain English summary of protocol

Background and study aims

Poor student mental health is a priority for universities and there is some evidence that both hypnotherapy and virtual reality (VR) can be helpful in reducing perceived stress in the general population. This is a feasibility trial of an intervention combining hypnotherapy and VR which was trialled in a group of healthcare students.

Who can participate?

Students aged over 18 years registered at St George's University of London

What does the study involve?

The students will be asked to try the VR hypnotherapy experience once a day over 3 days, and it lasts about 7 minutes.

The students will be asked to complete some questionnaires regarding their wellbeing and anxiety levels before and after the 3-day trial, and scales before and after each session measuring how relaxed/happy/sad they feel on a scale of 1 to 10. Pulse and blood pressure will be measured before and after each experience and at the end of the 3 days the students will be asked how they found it overall, what was good and what was bad about it.

What are the possible benefits and risks of participating?

The main risk is of feeling nauseous (cybersickness). Students will have an opportunity to try a novel experience.

Where is the study run from? St George's, University of London (UK)

When is the study starting and how long is it expected to run for? February 2021 to July 2022

Who is funding the study?
St George's, University of London (UK)

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Aileen O'Brien

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

22022.0122

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Virtual reality hypnotherapy for healthcare students: a feasibility trial

Study objectives

A virtual reality hypnotherapy experience will be tolerated and acceptable to healthcare students

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 06/06/2022, St George's Research Ethics Committee (SGREC) (SGUL, Cranmer Terrace, Tooting, London, SW17 7DJ, United Kingdom; +44 (0)208 266 6073; sgulrec@sgul.ac.uk), ref: 22022.0122

Study design

Single-arm non-randomized feasibility pilot trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

University/medical school/dental school

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Perceived stress

Interventions

This was a pilot so there was only one arm and no randomisation. Students who volunteered for the trial and met the eligibility criteria were allocated a project id and their sex, age group and ethnicity were recorded. Participants were asked to attend a quiet annex of the Student Union for a maximum of 1 hour each day (timed for the end of the teaching day) on three consecutive days. Students tried the virtual reality hypnotherapy experience over 3 days each lasting 7 minutes, involving the voice of a clinical hypnotherapist guiding the user through a series of virtual spaces.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Virtual reality hypnotherapy in oculus headset

Primary outcome measure

- 1. Wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at the start of the first session and the end of the third session
- 2. Perceived stress measured using the Perceived Stress Scale (PSS) at the start of the first session and the end of the third session

- 3. Depression measured using the Patient Health Questionnaire-2 (PHQ2) at the start of the first session and the end of the third session
- 4. Anxiety measured using the Generalized Anxiety Disorder (GAD-7) questionnaire at the start of the first session and the end of the third session
- 5. Stress, happiness, sadness, calm, and anxiety measured using visual analogue scales before and after each VR session
- 6. Students' experience of the VR assessed using qualitative analysis of an open-ended question at the end of the 3 days

Secondary outcome measures

Pulse and blood pressure readings assessed as proxy indicators of stress by junior doctors manually (pulse) and with an electronic blood pressure reader before and after each VR session

Overall study start date

01/02/2021

Completion date

26/07/2022

Eligibility

Key inclusion criteria

- 1. Aged over 18 years
- 2. Student at St George's University of London

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

20

Total final enrolment

14

Key exclusion criteria

- 1. Epilepsy
- 2. Pacemaker

Date of first enrolment

07/06/2022

Date of final enrolment

15/06/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre St George's University of London

Cranmer Terrace London United Kingdom SW17 7DJ

Sponsor information

Organisation

St George's, University of London

Sponsor details

Cranmer Terrace Tooting London England United Kingdom Sw177DJ +44 (0)2087255000

rallen@sgul.ac.uk

Sponsor type

University/education

Website

http://www.sgul.ac.uk/

Funder(s)

Funder type

University/education

Funder Name

St. George's, University of London

Alternative Name(s)

St. George's

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

To publish in a peer reviewed journal.

Intention to publish date

01/02/2024

Individual participant data (IPD) sharing plan

The datasets generated will be available on request from Dr Aileen O'Brien (aobrien@sgul.ac.uk).

IPD sharing plan summary

Available on request