ISRCTN99747069 https://doi.org/10.1186/ISRCTN99747069

Using virtual reality to treat social phobia

Submission date	Recruitment status	[ ] Prospectively registered
18/08/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/09/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/12/2020	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Stephane Bouchard

Contact details
Université du Québec en Outaouais
Dept. de Psychoéducation et de psychologie
CP 1250
Succ Hull
Quebec
Gatineau
Canada
J8X 3X7
+1 819 595 3900/2360
stephane.bouchard@uqo.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A comparative study of virtual reality versus in vivo exposure in the cognitive behavior treatment of social phobia

Acronym
VRCVB

Study objectives
1. Aims:
1.1. To compare Cognitive Behaviour Therapy (CBT) treatments that differ only by the use of exposure in vivo or in virtuo and a waiting list control condition
1.2. To explore the efficacy of a combined Virtual Reality (VR) and in vivo treatment

2. Hypotheses:
2.1 Both non-combined treatments would be superior to the waiting list
2.2. The combined treatment would be more effective than the other two treatments

Ethics approval required
Old ethics approval format

Ethics approval(s)
The local ethics committee (Comité d'Éthique de la Recherche of the Université du Quebec en Outaouais) approved on the 7th of October 2009 (ref: 807). Ethics approval is due for renewal on the 7th of October 2010

Study design
3 arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet [in French]

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

Interventions

After receiving an appropriate diagnosis and completing the ethics procedures, participants will be randomly assigned to one of the following three conditions:
1. Tradd-CBT: Traditional individual CBT with in vivo exposure
2. VR-CBT: Traditional individual CBT with in virtuo exposure
3. Control: Waiting list to be treated later with a combined Tradd- and VR-CBT treatment

For in Tradd-CBT condition, the therapy will be similar to what is being used in other research centers, with treatment beginning by a case conceptualization, followed by cognitive restructuring, in vivo exposure (in real-life situations outside the therapists office) and relapse prevention. The only difference between Tradd-CBT and VR-CBT will be the use of four VR scenarios to conduct in virtuo exposure: speaking at a meeting, introducing oneself to new people, engaging in conversations in a restaurant and asserting oneself. There wont be any in vivo exposure exercise in the VR-CBT. All treatments will last 14 sessions and will be supervised by the principal investigator (SB).
The treatment will be delivered by graduate students experienced in CBT and the treatment of anxiety disorders. The therapists also possesses a full year of practical experience in using VR in CBT. The in virtuo exposure scenarios will be produced by an IBM computer (Pentium III, 4.2Ghz, 1 Go RAM) equipped with a nVIDIA Gforce Ti 4200 graphics card, an InertiaCube motion tracker from Intersense, an nVISOR head mounted display by nVIS and a wireless mouse by Gyration.

A standardized treatment will be conducted for 14 weekly 60-minutes sessions delivered by experienced therapists. Treatment differentiation will be enhanced by the use of treatment manuals while treatment fidelity will be maximize by weekly supervisions. Adherence to the research protocol (treatment differentiation and fidelity) will be assessed regularly by independent raters who will review videotapes of therapy sessions.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Liebowitz Social Anxiety Scale (LSAS)
It is a self-report consisting of 24 items that has been used in most of the recent outcome studies on SAD. Eleven items correspond to fear and avoidance of social interactions and 13 to performance fears. It is an excellent measure of SAD symptoms. Participant anxiety and avoidance are assessed. A total score is obtained, as well as fear and avoidance subscores.

All outcomes will be assessed at baseline, post-treatment at at 6 month follow up.

Secondary outcome measures
1. Rathus Assertiveness Schedule
This self-report measures social assertiveness. Thirty items, under the form of assertions concerning the way of behaving in different social situations, are proposed. The subject must indicate to which degree these assertions are typical of him/her and select one of the six possible answers ranging from +3 (really typical) to 3 (really not typical).
2. Questionnaire on Social Contexts Inducing Anxiety
This questionnaire enables to establish a typology of social anxieties (focused or generalized phobia, and type of subgroup: performance, assertiveness, intimacy or scrutiny anxiety) where the participant assesses the degree of her/his anxiety.

3. Behavior Avoidance Test
Participants have to give an impromptu speech to a small audience (video recorded), for 6 minutes. Heart-rate variability and subjective anxiety are recorded and behavioral manifestations are coded by three independent assessors 'blind' to the hypotheses of the study.

All outcomes will be assessed at baseline, post-treatment at at 6 month follow up.

Overall study start date
18/09/2010

Completion date
18/08/2011

Eligibility

Key inclusion criteria
1. Ambulatory men and women
2. At least 18 years old and at most 65 years old
3. French speaking
4. Receiving a principal diagnosis of social anxiety disorder (SAD) according to DSM-IV-TRs diagnostic criteria. Assessed at a psychiatric interview, standardized with the Structured Clinical Interview for DSM (SCID)
5. Suffering from SAD since at least two years
6. If currently taking medication for SAD, pharmacotherapy must be stabilized (same type and dosage) for at least six months and the social phobia remained stable and uncured (i.e., still meeting diagnostic criteria despite take the medication)
Note that there is no perfect solution to the problem of medication since most severe cases already receive Selective Serotonin Reuptake Inhibitor (SSRI) from their doctors when they seek psychological treatments (thus, recruiting non-medicated participants would threaten the feasibility of the study and could lead to the selection of less severe cases) and stopping medication would induce other methodological problems (e.g., withdrawal symptoms, artificial peak of severity at pre-treatment, ethical issues).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45 (15 per group)

Total final enrolment
59

Key exclusion criteria
1. Currently suffering from a severe organic disease, dementia, mental retardation, schizophrenia, amnesia, psychosis or bipolar disorder
2. The SAD being secondary to any DSM-IV Axis-III diagnosis
3. Receiving any form of concurrent psychotherapy

Date of first enrolment
18/09/2010

Date of final enrolment
18/08/2011

Locations

Countries of recruitment
Canada

Study participating centre
Université du Québec en Outaouais
Gatineau
Canada
J8X 3X7

Sponsor information

Organisation
Social Sciences and Humanities Research Council (Canada)

Sponsor details
350 Albert Street
P.O. Box 1610
Ottawa
Canada
K1P 6G4
+1 613 992 3145
patricia.emery@sshrc-crsh.gc.ca

Sponsor type
Research council

Website
http://www.sshrc-crsh.gc.ca/home-accueil-eng.aspx

ROR
https://ror.org/04j5jqy92

Funder(s)

Funder type
Research council

Funder Name
Social Sciences and Humanities Research Council (Canada) (Project: 7032024)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2017	18/12/2020	Yes	No