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Treatment of social phobia using virtual reality

Submission date	Recruitment status	[X] Prospectively registered
16/06/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/07/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/06/2015	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Social phobia is a mental disorder with an early onset and chronic course , which has a significant negative effect on the lives of sufferers . Among the most common symptoms are palpitations, excessive sweating , trembling and blushing, in addition to avoidance of social situations and performance. One of the most commonly used treatments is the live exposure, involving confronting the fear of social occasions by placing the patients in those situations. Recently virtual reality, which uses 3D imagery, has emerged as an effective alternative treatment because it leads to a sense of strong immersion in the virtual environment , and is conducted so that the scenes can be seen a considerable number of times. . This study will compare these two treatments. It is expected that both work equally well at treating of social phobia .

Who can participate?
Adults suffering from social phobia who have enrolled in the Anxiety Program and the Psychotherapy Service of Department and Institute of Psychiatry, University of São Paulo.

What does the study involve?
Each patient is randomly placed into one of two groups. Those in group 1 receive virtual reality exposure therapy. Those in group 2 receive live exposure therapy. Patients of both groups will be submitted to 12 sessions once a week and 3 months evaluation follow up

What are the possible benefits and risks of participating?
Benefits: Reduction of social anxiety.
Risks: The procedures applied offer minimum discomfort or risk to the patient's health. Among them is the risk of feeling anxious during the sessions of exposure to social situations. However this risk is small since, in both groups, exposure is performed slowly . Moreover, this anxiety is necessary for improvement.

Where is the study run from?
Department and Institute of Psychiatry, University of São Paulo (Brazil)

When is the study starting and how long is it expected to run for?
July 2014 to May 2016

Who is funding the study?
The Anxiety Program at the Department and Institute of Psychiatry, University of São Paulo (Brazil) and FAPESP, a research support foundation.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Virtual reality exposure in social phobia patients: a controlled clinical trial

Study objectives
Main hypothesis: Virtual reality exposure to treat social phobia program (RVFS PROGRAM) is as effective as live exposure in the treatment of social phobia.

Secondary hypothesis:
Participants RVFS PROGRAM will present at the end of treatment:
1. Greater adherence to treatment;
2. Exposure time for the occurrence of lower habituation ;
3. Shorter duration of therapy;
4. Greater improvement in depressive symptoms and social adjustment ;
5. Satisfaction with treatment is greater;
6. Bond with the therapist is better;

7. The lower disability ;
8. More exhibitions. Here it is important to point out that the scenes of RVFS PROGRAM can be viewed and reviewed by the patients a lot of times , thereby increasing the effectiveness of exposure by repeating the scenes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coordinating body of research ethics (ECA) Department and Institute of Psychiatry, University of São Paulo, 11/03/2015, ref: 981.031

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
82 patients with social phobia diagnosis will be randomly distributed into two treatment groups: virtual exhibition or live exposure. Therapists with expertise in cognitive behavioral therapy will be responsible for treating these patients . Each group has a protocol to be followed by the therapists. There will be 12 sessions of therapy for each patient.

Intervention Type

Primary outcome measure
Efficacy will be assessed by:
1. Down 25% to 50% in the LSAS scores will be considered partial response, and above 50% remission
2. Clinical Global Impression presenting scores 0 or 1 on the subscales of severity and improves
3. Sheehan Disability Scale presenting scores 0-3 in each of the three subscales (Work, Social Life and Family Life)

Secondary outcome measures

Secondary measures:
1. Accession shall be assessed by the number of dropouts
2. The habituation, decreased anxiety during the exposure procedure is assessed by the duration in minutes for the sessions that subjective discomfort units fall from 25% to 50%
3. The duration of therapy will be evaluated by the number of sessions required for habituation to occur
4. Depressive symptoms will be assessed by the Beck Depression Inventory for (BDI) considering improves a lower score than 10
5. Improved quality of life will be assessed by Scale Social-EAS Adequacy (Weissman and Bothwell, 1976)
6. Customer satisfaction with treatment will be evaluated by CSQ-8
7. The therapeutic alliance (bond) will be evaluated by WAI

Overall study start date
08/07/2014

Completion date
16/05/2016

Eligibility

Key inclusion criteria
Patients:
1. Treated at the Psychotherapy Service and Anxiety Program (AMBAN)
2. Aged 18 - 65
3. Can read and write
4. Diagnosised with FS , according to the DSM -5

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
82 patients, 41in the virtual reality exposure group and 41in the live exposure group

Key exclusion criteria
Patients:
1. With severe major depression
2. At risk for suicide, substance abuse or dependence psychotic disorders
3. Who are in psychotherapy

Date of first enrolment

03/08/2015

Date of final enrolment
03/02/2016

Locations

Countries of recruitment
Brazil

Study participating centre
Psychotherapy Service and Anxiety Program of the Department and Institute of Psychiatry, University of São Paulo
Rua Dr. Ovídio Pires de Campos
785 São Paulo
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Sponsor information

Organisation
Anxiety Program at the Institute of Psychiatry Faculty of Medicine University of São Paulo

Sponsor details
Institute of Psychiatry HCFMUSP
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Sponsor type
University/education

ROR
https://ror.org/036rp1748

Funder(s)

Funder type
University/education

Funder Name

Anxiety Program at the Institute of Psychiatry Faculty of Medicine University of São Paulo (Brazil).

Funder Name
Research Support Foundation (Brazil)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration