ISRCTN01715124 https://doi.org/10.1186/ISRCTN01715124

Attention training in Social Phobia/Social anxiety disorder

Submission date	Recruitment status	[ ] Prospectively registered
08/05/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/03/2020	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.sofie9.nu/

Contact information

Type(s)
Scientific

Contact name
Prof Per Carlbring

Contact details
Institute for Psychology
Umeå University
Umeå
Sweden
90187
+46 (0)90 786 7833
per.carlbring@psy.umu.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2009-0222

Study information

Scientific Title
Attention training in Social Phobia/Social anxiety disorder: a single-centre, randomised controlled interventional trial

Acronym
SOFIEsjunio

Study objectives
The aim of this research is to evaluate the effectiveness of an Internet-based attention modification program in the treatment of social phobia/social anxiety disorder. This project will use a randomised controlled trial to assess:
1. Whether a self-administered Internet-based attention modification training program is effective in reducing symptoms of social phobia, anxiety, and depression and increasing quality of life
2. Whether instructions to induce arousal immediately before the training optimizes the effectiveness

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Ethical Review Board (Centrala etikprövningsnämnden) Umeå, Sweden (Reference number: 2010-307-31Ö)

Study design
Single-centre randomised controlled interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.kbt.info/sofie9 (Swedish)

Health condition(s) or problem(s) studied
Social phobia/social anxiety disorder

Interventions

1. Study 1:
1.1. Participants were either assigned to the real attention modification program or to a placebo version
1.2. Everything was identical in both conditions except for the location of the probe
1.3. Hence, in both conditions a trial began with a fixation cross (+) presented in the centre of the screen for 500ms
1.4. Immediately following termination of the fixation cue, the web based flash program in full screen mode presented two faces of the same person, one face on the top and one on the bottom, with each pair displaying one of two combinations of emotions
1.5. Either neutral-disgust, or neutral-neutral
1.6. After presentation of the faces for 500 ms, a probe appeared in the location of one of the two faces
1.7. Participants were instructed to indicate whether the probe was the letter E or F by pressing the corresponding arrow on the keyboard using their dominant hand
1.8. The probe remained on the screen until a response was given, after which the next trial began
1.9. During each session 160 trials with various combinations of probe type (E/F), probe position (top/bottom), face type (neutral/disgust) and person (four male/four female were presented)
1.10. In the real condition the probe was always presented (100% of the trials) at the ocation of the neutral face if there also was a disgust face present (n=128 trials)
1.11. In contrast, in the placebo condition the location of the probe could not be predicted since the probe appeared with equal frequency in the position of the disgust face and the neutral face
1.12. Participants were encouraged to do the training on Tuesdays and Thursdays
1.13. They received an email and a SMS reminding them to do the training on the training days
1.14. If a session was missed a reminder was sent the following day
1.15. The participants could only do the training between 5 AM and 11 PM, and there should always be least one day between the sessions.
2. Study 2:
2.1. Half the participants were randomised to either an internet-based tailored 9-week treatment for social phobia/social anxiety disorder with therapist support or to an attention modification as described above but with the addition of a specific instruction
2.2. The instruction was that immediately before starting the attention modification training he /she should invoke arousal by doing something anxiety provoking

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Study part 1:
Liebowitz Social Anxiety Scale self-report evaluated at three time points: pre, after week 1, after week 2, after week 3, post and 4 month follow-up
2. Study part 2:
Liebowitz Social Anxiety Scale self-report evaluated at three time points: pre, post and 4 month follow-up

Secondary outcome measures
1. Social Phobia Scale
2. Social Interaction Anxiety Scale

3. Social Phobia Screening Questionnaire
4. Beck Anxiety Inventory
5. Montgomery Asberg Depression Rating Scale
6. Quality of Life Inventory
7. Evaluated at three time points: pre, post and 4 month follow-up.

Overall study start date
01/01/2007

Completion date
01/01/2012

Eligibility

Key inclusion criteria
1. A Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSMIV) diagnosis of social anxiety disorder according to the Social Phobia Screening Questionnaire
2. Scoring below 31 on the self-rated version of the Montgomery and Åsberg Depression Rating Scale depression scale and below 4 on the suicide item of this scale (to prevent the inclusion of individuals in strong need of specialist consultation)
3. Not undergoing any other psychological treatment during the study period
4. If prescribed drugs for anxiety or depression, the dosage had to be constant for 2 months before the treatment onset and kept constant throughout the study
5. Being at least 18 years old
6. Living in Sweden
7. Having access to a computer with internet connection
8. Not having a having a significant vision impairment
9. Not admitting another serious or dominant disorder (e.g. psychosis, substance misuse) that could be expected to influence the outcome of the study
10. Having a primary diagnosis of social anxiety disorder according to the Structured Clinical Interview for DSMIV Axis I Disorders

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2007

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
Sweden

Study participating centre
Institute for Psychology
Umeå
Sweden
90187

Sponsor information

Organisation
Swedish Council for Working Life and Social Research (Sweden)

Sponsor details
FAS
Box 2220
Stockholm
Sweden
10315
+46 (0)87 754 070
fas@fas.se

Sponsor type
Research council

Website
http://www.fas.se

ROR
https://ror.org/02d290r06

Funder(s)

Funder type

Research council

Funder Name
Swedish Council for Working Life and Social Research (Sweden) (grant number: 2009-0222)

Alternative Name(s)
Swedish Council for Working Life and Social Research, FAS

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Sweden

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	25/06/2012		Yes	No
Results article	results	01/02/2014		Yes	No