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Internet-based individually guided versus group-guided self-help treatment for Social Anxiety DIsorder

Submission date
10/10/2013

Recruitment status
No longer recruiting

Registration date
23/10/2013

Overall study status
Completed

Last Edited
21/08/2015

Condition category
Mental and Behavioural Disorders

[X] 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
Social anxiety disorder (SAD) is one of the most common mental disorders. Although effective treatments exist, a lot of people do not receive professional help. Internet-based treatments are an easily accessible alternative and have been shown to be effective in treating SAD. It remains unclear how much support is needed during an internet-based treatment. This study aims at investigating if the patients' mutual support via a discussion forum will increase the treatment success of a web-based intervention.

Who can participate?
150 people will participate. To participate you must suffer from anxiety in social situations. Furthermore, participants have to be at least 18 years old, need access to the internet and have sufficient German language skills. Participants cannot undergo any other psychological treatment for the duration of the study. The study does not apply to persons with severe psychiatric disorders such as psychotic or bipolar disorder.

What does the study involve?
Participants will be randomly allocated to one of three groups. All groups will receive access to the web-based treatment but at different time points. Group 1 will receive a web-based self-help approach with individual therapist support conducted via email. Group 2 will receive the same web-based self-help approach, but with therapist-guided group support (six participants working together with the self-help program). Group 3 will receive the same intervention as group 2 but after 12 weeks.

What are the possible benefits and risks of participating?
Possible benefits of the study are the reduction of symptoms of SAD. Previous studies have shown that users of the web-based interventions felt better and more content after the treatment. There are no known negative side effects related to the treatment. However, it is unclear to what extent support by other participants improves the treatment outcome.

Where is the study run from?
The intervention is delivered via the internet. Thus, participants have to go on our website: http://www.online-therapy.ch/studie.The study will be run from the University of Bern, Switzerland.

When is the study starting and how long is it expected to run for?
The study will start in November 2013 and will continue to recruit participants until June 2014. The study will run until November 2014.

Who is the main contact?
Prof. Dr Thomas Berger
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Study website
http://www.online-therapy.ch/studie

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
Internet-based individually guided versus group-guided self-help treatment for Social Anxiety DIsorder: a randomized controlled trial

Acronym
SADI

Study objectives
The primary aim of the study is to investigate whether peer support in small groups of six participants has a positive effect on the treatment outcome of Internet-based guided self-help for Social Anxiety Disorder (SAD). To test this question, we will compare a condition with individually guided self-help with a condition with group-guided self-help and a wait-list control group. It is assumed that both active conditions show a greater reduction of social phobic symptoms than the wait-list control condition and that the condition with additional peer support will be superior to the condition with individual support regarding social phobic symptoms and diagnostic status. Furthermore, we will conduct exploratory analyses to identify potential predictors, moderators and mediators of treatment outcome (such as treatment expectation and adherence to treatment). In addition, variables of the treatment process (such as group processes in the peer group condition) and economic aspects regarding the estimated cost of each treatment condition will be examined.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cantonal Ethics Committee Bern, 14/06/2013, Nr. 062/13

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the following link to request the patient information sheet: http://www.online-therapy.ch/studie

Health condition(s) or problem(s) studied
Social Anxiety Disorder

Interventions
A randomized controlled trial aiming at investigating the additional value of therapist-guided peer support in small groups on the treatment outcome of a web-based self-help intervention for SAD.

Two active conditions:
1. First active condition: web-based self-help approach with individual therapist support conducted via email
2. Second active condition: the same web-based self-help approach, but with therapist-guided group support (six participants working together with the self-help program)
3. Wait-list control group

Total duration of the interventions: 12 weeks.
Timepoints of assessment for primary outcomes: pre-intervention, post-intervention (12 weeks), follow-up (6 months)
The wait-list group will receive the group-guided intervention after 12 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Symptoms of SAD (Social Phobia Scale [SPS], Social Interaction Anxiety Scale [SIAS], Liebowitz Social Anxiety Scale-Self-Report [LSAS-SR]): pre, post (12 weeks), follow-up (6 months)
2. Diagnostic status (Structured Clinical Interview for DSM-IV Axis I Disorders [SCID-I]): pre, post (12 weeks), follow-up (6 months)

Secondary outcome measures
1. Depression (Beck Depression Inventory [BDI-II]): pre, post (12 weeks), follow-up (6 months)
2. General symptomatology (Brief Symptom Inventory [BSI]): pre, post (12 weeks), follow-up (6 months)
3. Interpersonal problems (IIP-64): pre, post (12 weeks), follow-up (6 months)
4. Quality of life (SF-12): pre, post (12 weeks), follow-up (6 months)
5. Client Satisfaction (ZUF-8): post (12 weeks)
6. Several process measures:
6.1. Change in SAD symptoms: week 2, 4, 6, 8, 10
6.2. Individual condition - Working Alliance Inventory-Short Revised (WAI-SR): week 2, 4, 6, 8, 10
6.3. Peer support condition - group processes (GQ-D): week 2, 4, 6, 8, 10
6.4. Treatment expectancy - Credibility/Expectancy Questionnaire (CEQ): week 2

Overall study start date
11/11/2013

Completion date
11/11/2014

Eligibility

Key inclusion criteria
1. Male and female at least 18 years of age
2. Provided written consent
3. Sufficient German language skills
4. Access to computer with internet connection
5. Exceeding pre-defined cut-off scores in one of the social anxiety measures

6. Meeting the diagnostic criteria for SAD according to the diagnostic telephone interview
7. Agreeing to undergo no other psychological treatment for the duration of the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Active suicidal plans (according to the suicide item of the Beck Depression Inventory (BDI) or the diagnostic telephone interview)
2. History of psychotic or bipolar disorders
3. Prescribed medication for anxiety or depression only if the dosage has been changed during the last month prior to the study

Date of first enrolment
11/11/2013

Date of final enrolment
11/06/2014

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Bern
Bern
Switzerland
3012

Sponsor information

Organisation

Swiss National Science Foundation (Switzerland)

Sponsor details
Abteilung Karrieren
SNF-Förderungsprofessuren
Wildhainweg 3
Postfach 8232
Bern
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3012

Sponsor type
Research organisation

Website
http://www.snf.ch

ROR
https://ror.org/00yjd3n13

Funder(s)

Funder type
Research organisation

Funder Name
Swiss National Science Foundation (Switzerland) Reference number: PP00P1_144824 / 1

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

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?
Protocol article	protocol	15/04/2014		Yes	No