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Internet-based guided self-help for social anxiety disorder administered through a mobile app

Submission date
09/06/2016

Recruitment status
No longer recruiting

Registration date
06/07/2016

Overall study status
Completed

Last Edited
22/05/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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, however, whether these treatments can be even more effective when provided though smartphones, making it easier for people to use as they go about their daily routine. This study is looking at whether patients are more likely to use an internet-based SAD treatment program delivered to a smartphone during the day, in different settings, and whether it results in a more successful treatment when compared to the same treatment that can only be accessed through a PC.

Who can participate?
Adults (aged at least 18) that suffer from anxiety in social situations.

What does the study involve?
Participants are randomly allocated to one of three groups. All groups receive access to the web-based treatment but at different time points. Group 1 receive a web-based self-help treatment along with individual therapist support via email. Group 2 receive the same self-help materials, but sent to them on their smartphones. Group 3 receive the same materials as group 2 but only after 12 weeks (at the end of the study).

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 (treatments) 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 smartphone delivery improves the treatment outcome.

Where is the study run from?
The intervention is delivered via the internet. Thus, participants have to go on the website: http://www.online-therapy.ch/studie2.
The study is run from the University of Bern (Switzerland)

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

Who is the main contact?
Prof. Dr Thomas Berger
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Study website
https://www.online-therapy.ch/studie2

Contact information

Type(s)
Scientific

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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 guided self-help for social anxiety disorder administered through a mobile app: a randomized controlled trial

Study objectives

The primary aim of the study is to investigate whether smartphone-delivery leads to facilitated usage in daily routine, and whether this has a positive effect on the treatment outcome compared to Internet-based guided self-help for social anxiety disorder (SAD). To test this question, we will compare a condition with pc-based guided self-help with a condition of mobile 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 smartphone-support will be superior to the condition with the pc-based program 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 usage patterns) 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, 13/05/2014, ref: 063/14

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
See additional files

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 for 12 weeks
2. Second active condition: the same self-help materials, including guidance, but administered through smart-phones for 12 weeks

and
3. Wait-list control group

The self-help materials include psychoeducation about social anxiety disorder, cognitive restructuring of maladaptive beliefs, and both relaxation and exposure exercises. All participants are followed-up for three months.

Intervention Type
Behavioural

Primary outcome measure
1. Symptoms of SAD (Social Phobia Scale [SPS], assessed using Social Interaction Anxiety Scale [SIAS], and 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, assessed using the Beck Depression Inventory [BDI-II]: pre, post (12 weeks), follow-up (6 months)
2. General symptomatology, assessed using the Brief Symptom Inventory [BSI]: pre, post (12 weeks), follow-up (6 months)
3. Interpersonal problems, assessed using the Inventory of Interpersonal Problems (IIP-64): pre, post (12 weeks), follow-up (6 months)
4. Quality of life, assessed using the SF-12 Health Survey: pre, post (12 weeks), follow-up (6 months)
5. Client Satisfaction, assessed using the ZUF-8 general satisfaction questionnaire: post (12 weeks)
6. Several process measures:
6.1. Change in SAD symptoms: week 2, 4, 6, 8, 10
6.2. Individual condition, assessed using the Working Alliance Inventory-Short Revised (WAI-SR): week 2, 4, 6, 8, 10
6.3. Treatment expectancy, assessed using the Credibility/Expectancy Questionnaire (CEQ): week 2

Overall study start date
01/11/2014

Completion date
30/11/2016

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
24/11/2014

Date of final enrolment
18/05/2016

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Bern
Bern
Switzerland
3012

Sponsor information

Organisation
Swiss National Science Foundation

Sponsor details
Abteilung Karrieren
SNF-Förderungsprofessuren
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Sponsor type
Research organisation

Website
http://www.snf.ch

ROR
https://ror.org/00yjd3n13

Funder(s)

Funder type
Research organisation

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

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

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		29/06/2016	13/07/2016	No	Yes
Results article	results	01/06/2018		Yes	No