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Investigating the effects of a self-guided, internet-based self-help program for people with anxiety disorders

Submission date
26/02/2016

Recruitment status
No longer recruiting

Registration date
26/02/2016

Overall study status
Completed

Last Edited
26/02/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Anxiety disorders are a group of common disorders in which a person experiences overwhelming and often disabling anxiety. The most common types of anxiety disorder are social anxiety disorder, in which the sufferer feels a persistent and overwhelming fear of social situations; panic disorder, in which the sufferer experiences sudden periods of extreme fear with no prior warming, in the form of a severe panic attack which may be accompanied by agoraphobia (in which the person fears being in situations and places where they feel trapped or in danger, often because of openness or crowdedness); and generalized anxiety disorder, in which the sufferer experiences a constant state of anxiety which is not triggered by a specific situation or event. Cognitive behavioural therapy (CBT) is a type of talking therapy which works by changing the way that people think and behave. It can be very effective in treating people suffering from anxiety disorders however courses are often time-consuming, expensive and difficult to access. In recent years, internet-based cognitive behavioural therapy (ICBT), in which the therapy is delivered in a series of modules online, has become more common yet it is still not widely available. The aim of this study is to find out whether taking part in ICBT in addition to usual care is more affective at reducing the symptoms of anxiety disorders than usual care alone.

Who can participate?
Adults with social anxiety disorder, panic disorder (with or without agoraphobia) or generalized anxiety disorder.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive care as usual (CAU), but are also given access to an internet-based, unguided self-help program. The program is made up of six treatment modules which can be completed in 60-90 minutes. The specific focus is on the three anxiety disorders mentioned above, and users are asked early on to choose which of these seems most relevant. Suggestions for homework exercises or tasks are given after each section. Those in the second group receive CAU for the first nine weeks of the study. They are then given access to the self-help program for six months. At the start of the study and after the nine week treatment period, participants in both groups complete a number

of questionnaires in order to find out whether their anxiety symptoms have improved. The participants also complete the assessments at six months, in order to assess whether any improvements from the treatment are maintained after six months in the first group (the participants in the second group only complete these assessments for fairness and safety reasons, and their results are not compared to the first group).

What are the possible benefits and risks of participating?
Participants who use the self-help program may benefit from a reduction in their anxiety symptoms. There are no notable risks involved with taking part in this study.

Where is the study run from?
University of Bern (Switzerland)

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

Who is funding the study?
Swiss National Science Foundation (Switzerland)

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

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
Effects of a Self-Guided Transdiagnostic Internet Intervention (velibra) for Anxiety Disorders in Primary Care: A Randomized Controlled Trial

Acronym
VELIBRA

Study objectives
The aim of this study is to evaluate the effectiveness of a transdiagnostic Internet-based self-help program in the treatment of social anxiety disorder, panic disorder with/without agoraphobia and/or generalized anxiety disorder used by participants recruited in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Canton of Bern, 28/10/2013, ref: 158/13

Study design
Single-centre 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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Anxiety Disorder: Social Anxiety Disorder, Panic Disorder with/without Agoraphobia and/or Generalized Anxiety Disorder

Interventions
Participants are randomly allocated to one of two groups. A stratified randomization procedure will be applied such that a balanced distribution of primary diagnostic groups in the two conditions will be ensured. The randomization list will be created by an independent researcher using an automated, web-based randomization program.

Care as usual (CAU) group: Participants do not immediately receive access to the Internet-based self-help program and continue to receive care as usual. However, after filling out the questionnaires at 9 weeks (post-treatment), they also receive access to the Internet-based self-help program for 6 months.

CAU and internet-based self-help group: Participants receive CAU, as well as receiving access to an Internet-based unguided self-help program immediately after randomization. The self-help program is delivered by the University of Bern and consists of 6 treatment modules, the first five of which are followed by a training session. Each module can be completed in approximately 60-90 minutes, depending on reading speed, engagement with audio recordings and personal paths through each section. The program is cognitive-behavioral in orientation (CBT) and emphasizes transdiagnostic principles, such as anxiety as an evolutionary adaptive emotion, the “false alarm” model of anxiety, experiential avoidance, and the role of approach versus avoidance motivation. The specific focus is on three anxiety disorders: Generalized anxiety disorder, social anxiety disorder, and panic disorder, and users are asked early on to choose which of these seems most relevant. Suggestions for homework exercises or tasks are given after each section, based on evidence suggesting the utility of homework in CBT. Participants receive access to the self-help program for 6 months.

Participants in both groups are assessed at baseline, 9 weeks (post treatment for the CAU and internet-based self-help group). Six months post-randomisation, the assessments are repeated in order to assess whether treatment gains are maintained in the treatment group till 6 months after randomization. The CAU group also complete this assessment, however this is only done for fairness and safety reasons.

Intervention Type
Behavioural

Primary outcome measure
Depression, anxiety and tension/stress is measured using Depression Anxiety Stress Scales (DASS-21) at baseline, 9 weeks and 6 months.

Secondary outcome measures
1. Diagnostic status is determined using the Structured Clinical Interview for DSM Disorders (SCID-I) at baseline and 9 weeks
2. Depression, anxiety and tension/stress is measured using the Depression Anxiety Stress Scales (DASS-21) at baseline and 6 months
3. Anxiety is measured using the Beck Anxiety Inventory (BAI) at baseline, 9 weeks and 6 months
4. Depression is measured using the Beck Depression Inventory (BDI-II) at baseline, 9 weeks and 6 months
5. General symptomatology is measured using the Brief Symptom Inventory (BSI) at baseline, 9 weeks and 6 months
6. Social Anxiety is measured using the Social Phobia Scale (SPS) at baseline, 9 weeks and 6 months
7. Social Anxiety is measured using the Social Interaction Anxiety Scale (SIAS) at baseline, 9

weeks and 6 months
8. Agoraphobic cognitions are measured using the Agoraphobic Cognitions Questionnaire (ACQ) at baseline, 9 weeks and 6 months
9. Fear of body sensations is measured using the Body Sensations Questionnaire (BSQ) at baseline, 9 weeks and 6 months
10. Agoraphobic avoidance is measured using the Mobility Inventory (MIA & MIB) at baseline, 9 weeks and 6 months
11. Worry severity is measured using the Penn State Worry Questionnaire (PSWQ) at baseline, 9 weeks and 6 months

Overall study start date
01/05/2014

Completion date
01/05/2016

Eligibility

Key inclusion criteria
1. Written informed consent
2. Written declaration of no objection signed by a medical doctor
3. Aged 18 years or over
4. Access to the Internet
5. Sufficient knowledge of German
6. Primary diagnosis of Social Anxiety Disorder, Panic Disorder with/without Agoraphobia, or Generalized Anxiety Disorder according to DSM-IV (assessed with a clinical interview)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. History of a psychotic or bipolar disorder
2. Suicidal ideation or plans (assessed by the suicide item of the Beck Depression Inventory and in a diagnostic interview)

Date of first enrolment
01/05/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Austria

Germany

Switzerland

Study participating centre
University of Bern
Fabrikstrasse 8
Bern
Switzerland
3012

Sponsor information

Organisation
Swiss National Science Foundation

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

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/08/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available