ISRCTN15819951 https://doi.org/10.1186/ISRCTN15819951

Self-help internet tool for social anxiety symptoms

Submission date	Recruitment status
15/12/2015	No longer recruiting
Registration date	**Overall study status**
21/01/2016	Completed
Last Edited	**Condition category**
19/01/2021	Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Social anxiety disorder, also known as social phobia, is a common type of anxiety disorders, in which a person feels a persistent and overwhelming fear of social situations. The symptoms can range from very mild to so severe that it causes major problems in day-to-day life. The problems tend to last for years and people often do not seek help. Seeing a therapist for face-to-face cognitive behavioural therapy is recommended by NICE as the most effective approach for social anxiety disorder. Some people are said to have 'sub-clinical' social anxiety symptoms, which cause them problems but are not severe enough to be diagnosed as 'social anxiety disorder'. Many of these people turn to the internet to look for help and there is a wide range of unguided self-help tools available, however there is very little evidence to say whether or not these are actually helpful. The aim of this study is to find out whether a specific web-based training programme can help people with sub-clinical social anxiety symptoms in the general population to feel more comfortable in social situations.

Who can participate?
Adults living in England who are suffering from social anxiety symptoms.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group are asked to complete the social anxiety module which includes elements of cognitive behavioural therapy (teaching ways of changing behaviour) and face-to-face talking therapy. Participants in the second group are placed on a waiting list, and so do not receive access to the social anxiety module throughout the study. At the start of the study, and again after 6-weeks (added 29/05/2019), 3, 6 and 12 months, participants in both groups complete a number of questionnaires in order to measure their levels of anxiety.

What are the possible benefits and risks of participating?
Participants benefit from receiving treatment that they would not otherwise have access to (in the form of the online module), which could be an effective treatment for their anxiety. There are no significant risks of taking part however the online module could cause distress to some participants.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
June 2015 to March 2018

Who is funding the study?
MQ: Transforming Mental Health (UK)

Who is the main contact?
Mrs Angela Martin

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT02451878

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness and cost-effectiveness of a fully self-guided internet-based intervention for sub-clinical social anxiety symptoms: pragmatic, population-based randomised controlled trial

Acronym
SocWell

Study objectives
A fully self-guided internet based self-help intervention for sub-clinical social anxiety symptoms in the general population is effective in reducing social anxiety symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Medical Sciences Inter-Divisional Research Ethics Committee (University of Oxford), 26/08/2015, ref: MS-IDREC-C1-2015-167
2. Human Ethics committee (ANU), 04/06/2015, ref: 2015/229

Study design
Pragmatic randomised 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
Social anxiety symptoms

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: will be asked to complete an online social anxiety module (https://ecouch.anu.edu.au), which is based on cognitive behavioural therapy principles and includes components of known effectiveness in face-to-face therapy. This module contains a literacy section and 5 toolkits comprising exposure practice, cognitive restructuring (modifying your thinking), attention practice, social skills training and relaxation. E-Couch is designed to be completed at the participant's own pace.

Control group: Participants are placed on a "waiting list" to receive the intervention, and do not receive any additional treatment for the duration of the study.

Both groups will be asked to complete outcome measure and self-reported use of services at baseline, 6 weeks, 3 months, 6 months and 12 months. Around 20 participants from the intervention arm will be asked to take part in a one off interview at the end of the study, to explore their experience of the intervention.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 29/05/2019:
Change in self-reported social anxiety measured using the Social Phobia Inventory (SPIN) at 6 weeks.

Previous primary outcome measure:
Change in self-reported social anxiety measured using the Social Phobia Inventory (SPIN) at 6 weeks, 3, 6 and 12 months.

Secondary outcome measures
Current secondary outcome measures:
1. Fear of negative evaluation is measured using the Brief Fear of Negative Evaluation scale (8 item BFNE-S) at 6 weeks, 3, 6 and 12 months
2. Depression is measured using the Center for Epidemiologic Studies Depression Scale (CES-D) at 6 weeks, 3, 6 and 12 months
3. Mental wellbeing is measured using the Warwick-Edinburgh Mental Well-being scale (WEMWEBS) at 6 weeks, 3, 6 and 12 months
4. Quality of life is measured using the Short Form (36) Health Survey (SF36) at 6 weeks, 3, 6 and 12 months
5. Use of mental health services is measured using self-reported health service contact at 6 weeks, 3, 6 and 12 months
6. Safety events are measured using by monitoring participant feedback at 6 weeks, 3, 6 and 12 months
7. Adherence, retention and attrition rates are measured by recording and monitoring usage data and number of components of e-couch completed at 6 weeks, 3, 6 and 12 months

Previous secondary outcome measures:
1. Fear of negative evaluation is measured using the Brief Fear of Negative Evaluation scale (8 item BFNE-S) at 6 weeks, 3, 6 and 12 months
2. Social anxiety symptoms are is measured using the SOPHS Social Phobia screener at 6 weeks, 3, 6 and 12 months
3. Anxiety is measured using the GAD7 Anxiety Test Questionnaire at 6 weeks, 3, 6 and 12 months
4. Depression is measured using the Center for Epidemiologic Studies Depression Scale (CES-D) at 6 weeks, 3, 6 and 12 months
5. Mental wellbeing is measured using the Warwick-Edinburgh Mental Well-being scale (WEMWEBS) at 6 weeks, 3, 6 and 12 months
6. Quality of life is measured using the Short Form (36) Health Survey (SF36) at 6 weeks, 3, 6 and 12 months
7. Use of mental health services is measured using self-reported health service contact at 6 weeks, 3, 6 and 12 months
8. Safety events are measured using by monitoring participant feedback at 6 weeks, 3, 6 and 12 months
9. Adherence, retention and attrition rates are measured by recording and monitoring usage data and number of components of e-couch completed at 6 weeks, 3, 6 and 12 months

Overall study start date
01/06/2015

Completion date
01/12/2018

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Resident of England
3. Willing to provide a working e-mail address and mobile phone number
4. Suffering from social anxiety symptoms

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2104

Total final enrolment

2116

Key exclusion criteria
Current participant exclusion criteria as of 29/05/2019:
1. Receiving therapist-guided treatment for social anxiety disorder
2. SPIN score <13

Previous participant exclusion criteria:
1. Receiving therapist-guided treatment for social anxiety disorder
2. SPIN score <13
3. SPIN score >19

Date of first enrolment
01/02/2016

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
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Sponsor information

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Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
MQ: Transforming Mental Health

Results and Publications

Publication and dissemination plan
1. Planned publication of results in peer-reviewed publications (open access where possible).
2. Presentation of results at conferences presentations
3. A full report will be disseminated to the funder (MQ)
4. Summaries of each output will be produced for lay, policy and practitioner audiences
5. Findings will be shared on social media and through press releases (in conjunction with MQ)
6. Findings will be presented at a final workshop targeting key audiences including patients, public and their representatives

Intention to publish date
01/10/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/04/2017	10/04/2019	Yes	No

Results article	results	10/01/2020	19/01/2021	Yes	No