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Evaluation of an online cognitive-behavioural treatment programme for social anxiety for higher education students: the Participate programme.

Submission date
24/11/2015

Recruitment status
No longer recruiting

Registration date
03/12/2015

Overall study status
Completed

Last Edited
03/12/2015

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
Social anxiety describes a condition where someone is fearful of social situations. It is one of the most common types of psychological difficulty that people can face. The problem affects a significant number of higher-education students and it can cause them to struggle to progress academically or to succeed in a career. Social anxiety may also lead to isolation, depression and substance misuse. Research suggests that one-to-one cognitive-behavioural therapy (CBT) with a trained practitioner is the best treatment for social anxiety. However, there are not enough CBT therapists to treat the large numbers of students having difficulties, and, in any case, it is too expensive to do so. The aim of this study then is to test an online programme based on cognitive-behavioural therapy. The effect of the programme is measured by assessing the severity of social anxiety experienced by the participants before and after the treatment.

Who can participate?
Adult higher-education students suffering from social anxiety.

What does the study involve?
All students in participating higher-education institutions are sent an email with a link to a website where they can register to look at an introductory module that explains the CBT model of social anxiety, what the programme involves and how to apply. The application process involves consenting to take part in the research and completing questionnaires to assess social anxiety and depression. Applicants who meet the criteria for the research are then allocated randomly to one of three groups. One group can start the programme immediately, and have a personal supporter (a trained psychology graduate), who contacts the student every week with feedback on their progress. A second group undertake the online programme without a personal supporter, and a third group are allocated to the supported version of the programme, but have to wait for 3 months before they can begin.The online CBT programme, called Participate, consists of 5 essential and 1 optional module. Modules consist of text, videos, exercises and logs in which to record work. The modules help the participants to learn about the

thoughts and behaviours that maintain social anxiety, and how to change those thoughts and behaviours, so as to build confidence and overcome the condition. At the end of an 8-week period social anxiety and depression are assessed again for participants in each of the 3 groups.

What are the possible benefits and risks of participating?
Benefits of participating include a better understanding of social anxiety, a reduction in anxiety about social situations and increased participation in social and work-related activities. Potential risks of participating are insignificant, however some temporary increases in anxious feelings, while thinking about or engaging in social activities, may be experienced.

Where is the study run from?
1. School of Psychology, National University of Ireland, Galway (Ireland)
2. Dublin Institute of Technology, Aungier Street, Dublin (Ireland)
3. University of West Scotland, Hamilton (Scotland)

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

Who is funding the study?
National University of Ireland, Galway

Who is the main contact?
Éamonn Ó Dochartaigh

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
Participate_v2_supported_vs_unsupported

Study information

Scientific Title

A randomised controlled trial of the effectiveness of the Participate online cognitive-behavioural treatment programme for social anxiety for higher education students whose social anxiety scores exceed cut-off points on the SIAS-6/SPS-6 social anxiety scales, comparing changes in social anxiety score at programme end and 3-month follow-up for participants with weekly online support; those without weekly online support; and those on a waiting-list.

Acronym
Participate

Study objectives
Are the supported and the unsupported versions of the Participate programme effective for the treatment of social anxiety as measured by the short form of the combined Social Interaction Anxiety Scale (SIAS-6) and the Social Phobia Scale (SPS-6), in comparison with a wait-list control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the National University of Ireland, University Road, Galway, Ireland, 11/08/2014 (ref: 14/JUNE/06) and 14/08/2015 (ref: 15/JUL/12).

Study design
Multi-centre, interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Social anxiety.

Interventions
There are 3 arms to the trial:
1. Group 1 will undertake an online cognitive-behavioural programme for social anxiety with weekly support via email
2. Group 2 will undertake the same programme but without weekly support
3. Group 3 will be tested before and after the programme period without treatment, since they are on a waiting-list for the programme

Intervention Type
Behavioural

Primary outcome(s)
Primary outcome measures are to assess the severity of social anxiety. They consist of:
1. The 6-question short form of the Social Interaction Anxiety Scale (SIAS-6)
2. The 6-question short form of the Social Phobia Scale (SPS-6)

They are measured at completion of an introductory module; after 8 weeks (at programme end); and 3 months later in a follow-up.

Key secondary outcome(s))
1. Social anxiety, consisting of the short form of the Social Phobia Inventory (miniSPIN), and administered at weekly intervals during the 8-week programme
2. Severity of depression and suicidal ideation, consisting of the 9-question form of the Patient Health Questionnaire (PHQ-9) and administered at the end of an introductory module; after 8 weeks (at programme end); and 3 months later in a follow-up
3. Self-reported social, academic and occupational functioning, consisting of some purpose-designed questions, which are administered at weekly intervals during the 8-week programme, at programme end, and 3 months later in a follow-up

Completion date
01/09/2016

Eligibility

Key inclusion criteria
1. Participants must be registered students of the relevant higher-education institution
2. Participants must have a score 6 or more on the SIAS-6 questionnaire or 3 or more on the SPS-6 psychometric scales

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Participants must not:
1. be acutely suicidal
2. begin or change a dose of psychoactive medication in the period from 1 month preceding the programme until its end
3. be receiving psychotherapeutic treatment in the period from 1 month preceding the programme until its end
4. have a history of bipolar depression
5. have previously received cognitive-behavioural therapy

Date of first enrolment
01/09/2014

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
United Kingdom

Scotland

Ireland

Study participating centre
National University of Ireland, Galway
University Road
Galway
Ireland
-

Study participating centre
Dublin Institute of Technology
Aungier St
Dublin 2
Ireland
-

Study participating centre
University of West Scotland
Almada Street
Hamilton
South Lanarkshire
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ML3 0JB

Sponsor information

Organisation
National University of Ireland, Galway

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
University/education

Funder Name
Student Project Fund, National University of Ireland, Galway

Results and Publications

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes