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Is internet cognitive therapy more effective than a waitlist at treating social anxiety disorder in adolescents?

Submission date
30/01/2019

Recruitment status
No longer recruiting

Registration date
06/02/2019

Overall study status
Completed

Last Edited
10/08/2022

Condition category
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
Adolescent social anxiety disorder (SAD) is common, impairing and persistent. There is a need to intervene early to avert its long-term consequences. Cognitive Therapy for SAD is the leading treatment for adults and shows promise for adolescents. However, given the scale of the problem of adolescent SAD and the limited availability of psychological therapists in child and adolescent mental health services, there is a substantial gap in service provision. Delivering therapy via the Internet may provide part of the solution to this problem. An Internet version of adult Cognitive Therapy for SAD has been developed, with outcomes similar to face-to-face therapy. We have recently adapted this treatment for use with adolescents with SAD. Online social anxiety cognitive therapy for adolescents (OSCA) includes all of the key elements of treatment found in face-to-face therapy. In addition, users can access video demonstrations of key procedures before they try them themselves, they can also practice giving presentations to virtual audiences in preparation for real life situations, and they can receive encouragement from a remote therapist using secure messaging. The main aim of the trial is to compare the effectiveness of OSCA to waitlist. This trial will provide preliminary evidence on whether this intervention, requiring relatively low levels of therapist input, is safe and clinically effective. If this is shown to be the case, OSCA has the potential to provide a service to the large population of adolescents with untreated SAD.

Who can take part?
Adolescents attending partnering comprehensive schools aged 14 to 18 years of age with a diagnosis of social anxiety disorder as their main presenting problem.

What does the study involve?
OSCA will be compared with a wait-list control. Adolescents with social anxiety disorder will be randomly allocated to either a 14-week wait-list, or OSCA (14 weeks with email and phone support from a therapist). The wait-list group is included to determine whether OSCA is superior to no treatment. Patients allocated to the wait-list will receive OSCA at the end of the wait period. Adolescents who are randomly allocated to receive OSCA will be followed up at 3 and 6 months after the end of treatment, to see if the benefits have been maintained. Main

assessments will take place at baseline (pre-treatment/wait), mid-treatment/mid-wait (8 weeks), end of treatment/End-wait (15 weeks), 3 month post-treatment follow-up and 6 month post-treatment follow-up.

What are the possible benefits and risks of participating?
All participants will receive treatment for social anxiety disorder from a team that specialises in treatment of the disorder, either immediately or after a 3 month wait. At the end of treatment they will be followed up for a further 6 months to assess the stability of treatment gains. Weekly measures of social anxiety and depressed mood will be taken and so in the unlikely event that symptoms worsen appropriate procedures will be followed to ensure the individual is helped to access services as needed.

Where is the study run from?
Oxford Centre for Anxiety Disorders and Trauma (UK)

When is the study starting and how long is it expected to run for?
March 2019 to May 2021

Who is funding the study?
Wellcome Trust (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
OSCA Protocol v1.

Study information

Scientific Title
Online Social anxiety Cognitive therapy for Adolescents: a randomised controlled trial

Acronym
OSCA

Study objectives
1. Is OSCA an effective therapy for social anxiety disorder in adolescents, compared to waitlist.
2. What is the mechanism by which OSCA achieves its effects?
3. Can we predict which young people are likely to benefit?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/11/2018, University of Oxford Medical Sciences Division Ethics Committee (University of Oxford, Wellington Square, Oxford, OX1 2JD; +441865 (6)16577; ethics@medsci.ox.ac.uk), ref: R60464/RE001.

Study design
Two-arm randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Internet-based cognitive therapy for adolescent social anxiety disorder (OSCA) is an adapted version of an adult internet cognitive therapy programme based on the Clark & Wells (1995) model and developed by the Oxford-London Wellcome Anxiety Research Team. The internet cognitive therapy for adult social anxiety has been compared to face-to-face cognitive therapy in a randomised controlled trial (ISRCTN95458747) and found to have similar effects.

We undertook a consultation study with adolescents to determine what changes were required to the adult internet treatment to ensure it was acceptable and appropriate for adolescents. The treatment was well-received by the adolescents and only minor changes were suggested. Specifically, it was suggested that the video material, scenarios and clinical vignettes be updated to ensure they are relevant to adolescents (e.g. changing work settings to schools).

OSCA covers all the main steps included in adult internet therapy (which includes all the main steps in face-to-face therapy). Adolescents receive Internet treatment for 14 weeks, with the duration of all brief therapist contact recorded. During the 14 weeks, patients will have a 10-15 minute phone conversation with their therapist each week. In addition, they will receive encouragement and support via secure messaging (e-mail) within the internet programme and SMS texts. Following this, they will retain access to the site for 1 year without therapist contact.

14 week wait list control condition, after which patients will receive OSCA.

OSCA (intervention arm): The intervention lasts for 14 weeks.
Waitlist (control arm): Those randomised to the waitlist condition will being OSCA following a 14-week wait period.

The principal assessment points will be at baseline, midtreatment/wait, posttreatment/wait, and three and six month follow-up.

Randomisation process: Participants will be randomised in a 1:1 ratio using block randomisation with varying block size. Allocation will be stratified by age and gender.

Intervention Type
Other

Primary outcome(s)
1. Severity of social anxiety will be measured using the self-report version of the Liebowitz Social Anxiety Scale for Children and Adolescents (Masia, Klein, & Liebowitz, 1999). The principal assessment points are baseline, midtreatment/wait, posttreatment/wait, and at 3 and 6 month follow-up.
2. Recovery from social anxiety disorder will be measured using the proportion of adolescents who continue to meet DSM-5 diagnostic criteria for SAD at posttreatment/wait. Diagnosis will be made using The Anxiety Disorders Interview Schedule IV for Children and Parents (Silverman & Albano, 1996). Assessments will be completed face-to-face or over the telephone by trained assessors blind to treatment condition. All participants will be interviewed with the child version and parents will be interviewed where possible. Participants who withdraw from the study will also be invited to complete the assessments..

Key secondary outcome(s))
1. Social anxiety will be measured using the Adolescent Social Phobia Weekly Summary Scale (Clark, 2003). The principal assessment points are baseline, midtreatment/wait, posttreatment

/wait, and at 3 and 6 month follow-up.
2. General anxiety will be measured using the Revised Child Anxiety & Depression Scale (RCADS, self-report; Chorpita et al. (2000)) at baseline, posttreatment/wait, and at 3 and 6 month follow-up.
3. Depression will be measured using the Short Mood and Feelings Questionnaire (SMFQ; Angold et al. (1995)). The principal assessment points are baseline, midtreatment/wait, posttreatment /wait, and at 3 and 6 month follow-up.
4. Social functioning (including social satisfaction, friendship quality, and peer victimization) will be assessed using self-report questionnaires at baseline, midtreatment/wait, posttreatment /wait, and at 3 and 6 month follow-up.
5. School functioning will be determined using:
5.1. % attendance and grade average (either internal or external examination scores or grade estimate) at baseline, posttreatment/wait and at 6 months follow-up.
5.2. Self-reported ability to concentrate in class (Leigh & Clark, 2016). The principal assessment points are baseline, midtreatment/wait, posttreatment/wait, and at 3 and 6 month follow-up.
6. Thoughts related to social anxiety will be measured using the Adolescent Social Cognitions Questionnaire. The principal assessment points are baseline, midtreatment/wait, posttreatment /wait, and at 3 and 6 month follow-up.
7. Safety behaviours related to social anxiety will be measured using the Adolescent Social Behaviours Questionnaire at baseline, midtreatment/wait, posttreatment/wait, and at 3 and 6 month follow-up.
8. Social attitudes will be measured using the Adolescent Social Attitudes Questionnaire at baseline, midtreatment/wait, posttreatment/wait, and at 3 and 6 month follow-up.
9. How believable, convincing and logical the treatment is will be measured using the treatment credibility scale (Borkovec and Nau, 1972). This will be measured two weeks after the start of treatment.
10. The strength of the therapeutic relationship will be measured using the working alliance inventory (Tracey & Kokotovic, 1989). This will be measured two weeks after the start of treatment.

Completion date
01/05/2021

Eligibility

Key inclusion criteria
1. Adolescents aged between 14-18 years
2. Meet diagnostic criteria for social anxiety disorder (SAD)
3. Able to read and write in English

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
14 years

Upper age limit
18 years

Sex
All

Total final enrolment
43

Key exclusion criteria
1. Currently receiving any other psychological intervention
2. Previously received Cognitive Therapy or CBT for SAD
3. Autism spectrum disorder
4. Learning disability
5. Current alcohol or substance dependence
6. Presence or suspected presence of psychosis
7. Suicidal intent or recurrent self-harming behaviour
8. Identified by social services as currently ‘at risk’ due to child protection concerns.

Date of first enrolment
01/03/2019

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford Centre for Anxiety Disorders & Trauma
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
After the study has finished, the anonymous datasets analysed during the study will be stored at the University of Oxford via the Bodleian ORA-Data archive for 20 years.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/08/2022	10/08/2022	Yes	No
Protocol article	protocol	07/10/2019	10/10/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes