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Internet-based cognitive therapy for social anxiety disorder

Submission date
08/11/2012

Recruitment status
No longer recruiting

Registration date
12/11/2012

Overall study status
Completed

Last Edited
15/07/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Social anxiety disorder (social phobia) is a common and disabling disorder, which generally runs a chronic course in the absence of treatment . Many patients are currently unable to access effective treatments. It would thus be desirable to make effective treatments more easily available. Cognitive therapy (CT) for social anxiety disorder has been shown to be an effective treatment that compares favourably with other interventions. Across six studies in the UK, Germany and Sweden, CT has been shown to be superior to several psychological treatments and to medication. In its original form, the treatment involves 14 weekly face-to-face sessions with a therapist, each lasting 90 minutes. In a recent trial we developed a briefer (7 session) self-study assisted version of the treatment. In order to make the treatment even more efficient in terms of therapist time, as well as more widely accessible, we have now developed an internet-based version of cognitive therapy for social anxiety disorder (iCT). In particular, patients 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 work, and they can receive encouragement from a remote therapist using secure messaging. The main aim of the trial is to compare the effectiveness of iCT with our original CT. If the internet based treatment is as effective as the standard treatment programme, the savings in therapist time, along with the ease of access to the internet, will mean that it will be possible to make the treatment available to a larger number of patients in a wide range of settings.

Who can take part?
Participants with a diagnosis of Social Anxiety Disorder as their main presenting problem

What does the study involve?
Internet based CT for social anxiety disorder will be compared with the standard CT treatment and 14 week wait-list control. Patients with social anxiety disorder will be randomly allocated to either a 14-week wait-list, standard cognitive therapy for social anxiety disorder (14 weekly sessions of 90 minutes each), or internet based cognitive therapy for social anxiety disorder (14 weeks with email and phone support from a therapist). The wait-list group is included to determine whether internet-based CT is superior to no treatment. The standard CT condition is included to determine whether internet-based CT is as effective as standard CT. Patients allocated to the wait-list will receive one of the CT treatments at the end of the wait period. As

social anxiety disorder is a chronic condition, it is important that treatments have a sustained effect. For this reason, the study includes a one-year follow-up after the end of treatment. Main assessments will take place at baseline (pre-treatment/wait), mid-treatment/mid-wait (7 weeks), end of treatment/End-wait (14 weeks), 3 month post-treatment follow-up and 12 month post-treatment follow-up

What are the possible benefits and risks of participating?
Participants will receive cognitive therapy for social anxiety disorder from a team that specialises in treatment of the disorder. They will be followed for one year after the end of treatment so that any worsening in symptoms can be detected and referrals for further treatment can be made. Participants will be withdrawn from the treatment trial if their clinical condition is such that it requires other urgent treatment. This is an unlikely event. There is only one instance of this having happened in our previous three studies of cognitive therapy for social anxiety disorder.

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?
January 2013 to December 2015

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Prof. David M Clark
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Wellcome Trust 069777

Study information

Scientific Title
A randomised controlled trial of internet-based cognitive therapy (iCT) and standard cognitive therapy (CT) for social anxiety disorder

Study objectives
1. Is internet-based cognitive therapy (iCT) an effective treatment for social anxiety disorder?
2. What is the mechanism by which iCT achieves its effects?
3. Can we predict who is particularly likely to benefit?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multi-centre 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 to request a patient information sheet

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

Interventions
Standard cognitive therapy for for social anxiety disorder. Patients will receive 14 weekly sessions of 90 minutes each, then three face to face follow-ups at monthly intervals post-treatment.

Internet-based cognitive therapy for social anxiety disorder will cover all the main steps in therapy, incorporating the content of the self-study modules, which were found to be highly effective and acceptable to patients in our previous trial. Patients 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. 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 one of the two forms of cognitive therapy.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Social phobia composite measure that is created by combining scores from six independent assessor and patient scales that are well validated measures of social anxiety disorder and related symptomatology. Scores on each scale are standardised (M = 0, SD = 1) across pre-treatment and post-treatment assessments by converting to Z-scores. The composite at each assessment occasion is the mean of the Z scores on that occasion. The procedure has been used in our last two social anxiety disorder trials (Clark et al., 2003) as well as in other trials in the field. The six scales that make up the social phobia composite are:
1. Anxiety Disorders Interview Schedule (Fear and Avoidance Scale) for DSM-IV (ADIS) (Brown, 1994)
2. Social Phobia Weekly Summary Scale (Clark et al., 2003)
3. Liebowitz Social Anxiety Scale (Liebowitz, 1987; Baker et al., 2002)
4. Fear of Negative Evaluation Scale (Watson & Friend, 1969)
5. Social Phobia Scale (Mattick and Clarke, 1998)
6. Social Interaction and Anxiety Scale (Mattick and Clarke, 1998)

Other measures of social anxiety disorder will be:
1. Proportion of patients who continue to meet diagnostic criteria for social anxiety disorder at post-treatment/wait and 3 and 12 month post-treatment follow-up [assessed by the Anxiety Disorders Interview Schedule (ADIS)]
2. A behaviour test in which patients engage in two social interactions and subsequently complete a 14-item checklist covering their perception of how well they performed (e.g. whether they were embarrassed or boring or whether their voice was quivering or their hands were shaking). A mean checklist score is computed. The checklist has good internal consistency (Cronbachs alpha .85). This test is common in social anxiety trials and is essential in internet treatments trial, where there is a risk, if analyses are restricted to self-report questionnaires, that people might over report improvement. We used the proposed behaviour test in a previous trial (Clark et al., 2006) based in Oxford and London and found that it was acceptable to patients.

Secondary outcome measures
1. The proportion of patients who continue to meet diagnostic criteria for avoidant personality disorder at 12-month follow-up (assessed using the Structured Clinical Interview for DSM-IV)
2. General mood, as assessed by the Patient Health Questionnaire (PHQ-9; Kroenke & Spitzer,

2002) and the Generalised Anxiety Disorder 7 item scale (GAD-7; Spitzer et al, 2006)
3. Social anxiety disorder related disability assessed by the Sheehan Disability Scale (American Psychiatric Association, 1983)
4. Measures of possible mediators of therapeutic improvement are:
4.1. Social cognitions questionnaire (Clark et al., 2005)
4.2. Social behaviours questionnaire (Clark et al., 2005)
4.3. Social attitudes questionnaire (Clark et al., 2005)
5. Measures of possible predictors of improvement with cognitive therapy are:
5.1. Treatment credibility scale (Borkovec and Nau, 1972)
5.2. Working alliance inventory (Tracey & Kokotovic, 1989)

Overall study start date
01/01/2013

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) (American Psychiatric Association, 1994) criteria for social anxiety disorder as the main presenting problem.
2. Duration of social anxiety disorder for at least 6 months
3. Age 18 - 65 years
4. Can read and write in English & have a high-speed internet connection at home (or are willing to have one installed)
5. Willing to accept random allocation to weekly cognitive therapy (CT) or internet-based CT, either immediately or after a 14 week wait
6. No psychotropic medication, or on a stable dose for at least 2 months (without clinical improvement) and willing to keep dosage constant during the trial
7. Agree not to start any non-protocol mental health treatment during the trial
8. Live within the broad catchment area for London (within the M25) or Oxford (Oxfordshire, Buckinghamshire and Berkshire) so that patients can travel to the hub for assessments and face-to-face therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
102

Total final enrolment
102

Key exclusion criteria
Participants who meet the inclusion criteria will be excluded if they also meet the following criteria:
1. Unable to attend weekly sessions
2. Previous CBT or exposure therapy for social anxiety disorder
3. Immediate suicide risk
4. Current substance dependence (abuse not dependency is acceptable)
5. Current or past psychosis
6. Meet criteria for borderline personality disorder

Date of first enrolment
01/01/2013

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
England

United Kingdom

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

Organisation
Clinical Trials and Research Governance (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust grant ref: 069777

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/07/2022	15/07/2022	Yes	No