ISRCTN72832736 https://doi.org/10.1186/ISRCTN72832736

Internet treatment for social anxiety in IAPT

Submission date
08/10/2021

Recruitment status
No longer recruiting

Registration date
15/11/2021

Overall study status
Completed

Last Edited
15/11/2021

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 disorder (SAD) is a common and disabling mental health problem. Cognitive therapy for SAD (CT-SAD) is an effective treatment for this condition. A therapist-assisted internet-delivered version of this treatment (iCT-SAD) has also been found to be acceptable to patients and effective in research studies as patients can complete online treatment modules that cover all components of CT-SAD at a time and place convenient to them. A therapist guides them remotely through the treatment and supports them through messages and phone/video calls.

The aim of this study is to investigate how effective iCT-SAD is in routine clinical care and who benefits from it. The clinical outcomes of patients treated with iCT-SAD will be assessed and compared with national targets for IAPT services and with the outcomes previously observed in the services.

Who can participate?
Adults with social anxiety disorder who are being seen at one of the participating Improving Access to Psychological Therapies (IAPT) NHS services and agree to participate in the study. About 30 therapists from participating IAPT NHS services will also be involved in the study.

What does the study involve?
For participating patients, the study involves completing the iCT-SAD treatment programme online with the support of messages and phone/ video calls with an IAPT therapist. It also involves completing questionnaires about symptoms, anxiety related thoughts & behaviours, and satisfaction with treatment.

Participating therapists will be trained to guide and support patients with SAD in completing the iCT-SAD treatment programme. They will then treat patients with SAD with iCT-SAD and receive supervision. At the end of the study, therapists complete a questionnaire and a focus group on their experience with delivering the treatment.

What are the possible benefits and risks of participating?
All participating patients will receive internet-based psychological therapy for social anxiety disorder with support from an IAPT therapist who has received specialist training and supervision. Undertaking treatment for social anxiety can be challenging. Like in-person therapy,

iCT-SAD encourages participants to reflect on their difficulties in order to understand how social anxiety works, and supports participants in tackling situations that they may have previously avoided. While doing this may temporarily increase distress, facing these challenges is an important step towards overcoming social anxiety.

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

When is the study starting and how long is it expected to run for?
April 2016 to July 2022

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

Who is the main contact?
Sophie Grant
sophie.grant@psy.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof David M. Clark

ORCID ID
http://orcid.org/0000-0002-8173-6022

Contact details
Oxford Centre for Anxiety Disorders and Trauma
Department of Experimental Psychology
University of Oxford
The Old Rectory
Paradise Square
Oxford
United Kingdom
OX1 1TW
+441865818600
david.clark@psy.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
286369

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
IRAS 286369, WT 200796/Z/16/Z

Study information

Scientific Title
A study of the implementation of internet-based cognitive therapy for Social Anxiety Disorder within NHS Improving Access to Psychological Therapies (IAPT) services (Overcome-SAD)

Acronym
Overcome-SAD

Study objectives
The study aims to assess iCT-SAD clinical outcomes in comparison to National IAPT targets for the treatment of common mental health disorders (i.e. at least 50% of patients recover, with many others showing reliable improvement).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/10/2020, North East - Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0)207 104 8052; tyneandwearsouth.rec@hra.nhs.uk), ref: 20/NE/0241

Study design
Interventional multicentre non-randomized implementation study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Participant information sheet available from the clinical team in participating IAPT services

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

Interventions

Cognitive therapy for social anxiety disorder (CT-SAD) is a cognitive behavioural treatment for posttraumatic stress disorder recommended by NICE (2013) and international treatment guidelines. It is usually delivered in face-to-face sessions. A therapist-assisted internet-delivered version (iCT-SAD) has recently been found to be efficacious and acceptable to patients. Patients are guided through the online treatment programme by a therapist. Patients work through the therapy modules of iCT-SAD on a secure website, as well as completing treatment-related tasks and activities as part of their daily routine. The therapist releases the modules that are relevant to the patients and supports them through messages and phone/video calls. This study will evaluate the effectiveness of this treatment in IAPT services. IAPT therapists who consented to be part of the study, have been trained in iCT-SAD and are receiving supervision. The total duration of treatment is up to 7 months, with a 4-month main treatment phase with weekly calls and a 3-month booster phase with monthly calls.

Intervention Type
Behavioural

Primary outcome measure
Recovery (as defined in IAPT by cut-offs scores below the clinical cut-off) measured using the Social Phobia Inventory (SPIN) and Patient Health Questionnaire (PHQ-9) at baseline and 7 months

Secondary outcome measures
1. Social anxiety symptoms measured using the Social Anxiety Inventory (SPIN) and Liebowitz Social Anxiety Scale (LSAS-SR) collected by the internet programme each week between baseline and 4 months, and at 5, 6, and 7 months
2. Depression symptoms measured with the PHQ-9 completed at baseline, 4, and 7 months. The PHQ-9 is given weekly during the weekly therapy phase as is standard in IAPT services.
3. Anxiety symptoms measured with the Generalised Anxiety Disorder Questionnaire (GAD-7) completed at baseline, 4, and 7 months. The GAD-7 is given weekly during the weekly therapy phase as is standard in IAPT services.
4. Disability measured with the Work and Social Adjustment Scale (WSAS) completed at baseline, 4, and 7 months. The WSAS is given weekly during the weekly therapy phase as is standard in IAPT services.
5. Satisfaction with treatment assessed with the IAPT Patient Experience Questionnaire at 7 months

Process measures:
1. Credibility of treatment measured with the Borkovec and Nau Credibility scale at 2 weeks.
2. Working alliance measured with the Working Alliance Scale completed by patients and therapists at 2 weeks
3. Key variables in the Clark & Wells (1995) cognitive model of SAD (social anxiety-related beliefs, safety behaviours, and focus of attention) are assessed repeatedly during treatment with relevant questionnaires
4. Patient activity on the online programme measured using data collected by the internet programme such as time spent on the programme and modules completed during treatment between baseline and 4 months
5. Therapist activity with the online programme measured using data collected by the internet programme such as number of calls and messages with patient during treatment between baseline and 4 months

User experience with iCT-SAD:
1. Therapists' experience with delivering iCT-SAD measured using the Therapist-Questionnaire and focus group discussion at the end of the study
2. Patients' experience measured using ratings of helpfulness and free comments provided at the end of each module

Overall study start date
01/04/2016

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. Social Anxiety Disorder is the main difficulty, and the client's priority to work on in therapy
2. Social Phobia Inventory (SPIN) score >25 at initial assessment
3. Regular, private access to internet-enabled device with webcam and reliable internet connection
4. Able to take phone calls from their therapist within normal IAPT clinic hours, and have enough time in their week to be able to log in and work on the programme regularly (i.e. at least 20 mins on 3-4 days each week)
5. Able to speak, read and write English
6. If on medication for mood/anxiety, the participant agrees not to change medication during the study
7. Aged 16 to 80 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
240

Key exclusion criteria
1. Marked clinical risk based on the service's intake assessment
2. Dependence on alcohol or substances.
3. Currently participating in another clinical research study
4. Current psychosis/bipolar affective disorder/emotionally unstable personality disorder (These conditions are not typically treated within IAPT services)

Date of first enrolment
24/10/2020

Date of final enrolment

31/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Talking Space Plus, Oxford Health
Abell House
Slade Site
Horspath Driftway
Oxford
United Kingdom
OX3 7JH

Study participating centre
Berkshire Talking Therapies IAPT Service
Fitzwilliam House
Skimped Hill Lane
Bracknell
United Kingdom
RG12 1QB

Study participating centre
Healthy Minds - The Buckinghamshire IAPT Service
Floor 2, Prospect House
High Wycombe
United Kingdom
HP13 6LA

Study participating centre
iCope Camden and iCope Islington Psychological Therapies Service
South Wing
St Pancras Hospital
4 St Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
Lambeth Talking Therapies Service
Dalbury House
Ferndale Road
London
United Kingdom
SW9 8AP

Study participating centre
Greenwich Time to Talk
135-143 Eltham High Street
London
United Kingdom
SE9 1TJ

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials and Research Governance
Joint Research Office
1st Floor Boundary Brook House
Churchill Drive
Headington
Oxford
England
United Kingdom
OX3 7GB
+44 (0)1865 (2)89885
ctrg@admin.ox.ac.uk

Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned open access publication in peer-reviewed journal

Intention to publish date
30/09/2023

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No