ISRCTN11357117 https://doi.org/10.1186/ISRCTN11357117

Internet-based cognitive therapy for social anxiety disorder in Hong Kong

Submission date
16/10/2017

Recruitment status
No longer recruiting

Registration date
24/10/2017

Overall study status
Completed

Last Edited
03/05/2022

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 (SAD) is a marked and persistent fear of social situations and interactions, where people are fearful of saying or doing something that might lead to humiliation or rejection. It typically starts in childhood or adolescence, and without treatment, natural recovery is rare. As a result many people find their whole lives are affected, including educational achievement, work, social, and family functioning. Cognitive Therapy (CT) is a psychological therapy that helps people overcome their anxiety by understanding the thoughts, beliefs, and behaviours that are keeping it going. In the UK, individual CT based on the Clark and Wells (1995) model is a first-line recommended treatment for SAD according to the National Institute for Health and Care Excellence (NICE) guidelines. iCT-SAD is an online form of the Clark and Wells CT treatment, developed in the UK, where people work through a series of modules containing text, videos, and exercises to complete. They are supported by a therapist who they communicate with via messaging, telephone, and webcam. This study aims to assess whether the iCT-SAD intervention is effective when it is delivered in a different culture to where it was developed.

Who can participate?
English-speaking adults in Hong Kong who are experiencing social anxiety

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the iCT-SAD treatment, which lasts for 14 weeks, and a further 3-month follow-up period. Those in the second group receive the same treatment after a waiting period of 14 weeks. At the start, middle, end, and follow-up stages, all participants complete a range of questionnaires to assess their social anxiety and general wellbeing.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their social anxiety and general wellbeing because they are receiving psychological therapy. The risks of participating are minimal, although as with any therapy, participants will be discussing and working on situations they find difficult, which can at times cause some feelings of distress. They can share any concerns with their therapist who will support them.

Where is the study run from?
The study is being run in Hong Kong. It is a collaboration between the Chinese University of Hong Kong, University of Oxford, Hong Kong Hospital Authority, and the New Life Psychiatric Rehabilitation Association.

When is study starting and how long is it expected to run for?
September 2016 to December 2018

Who is funding the study?
1. Wellcome Trust (UK) [102176]
2. NIHR Biomedical Research Centre (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
iCT-SAD-HK_1.1

Study information

Scientific Title
Internet-based cognitive therapy for social anxiety disorder in Hong Kong: a randomised controlled trial

Acronym
iCT-SAD-HK

Study objectives
The aim of the study is to investigate the hypothesis that iCT-SAD is superior to waitlist at reducing symptoms of SAD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee, 11/8/2017, ref: 2016.611-T
2. University of Oxford Tropical Research Ethics Committee, 31/08/2017, ref: 531-17

Study design
Single-centre interventional 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

Interventions
Participants will be recruited from the local population via advertisements in social and print media. Potential participants will be initially screened for eligibility using the social anxiety items of the Psychiatric Diagnostic Screening Questionnaire. Where respondents' scores suggest they may meet criteria for SAD, they will be invited to attend an appointment to assess trial eligibility. If eligible, they will be randomised (stratification by social anxiety severity) to either the intervention or control arm.

iCT-SAD arm (intervention arm): iCT-SAD will be delivered on a 1:1 basis by one of three trained therapists using the online programme. The intervention lasts for 14 weeks, with the participant working through a series of online modules, with regular contact with their therapist via messaging, weekly telephone calls (15-20 minutes), and occasionally via webcam. The treatment is based on the Clark and Wells (1995) cognitive model of social anxiety. It aims to replicate the content and procedures of the face-to-face cognitive therapy (CT) protocol (see Clark et al., 2006), and is based around an individualised formulation. The iCT-SAD programme was developed by Clark and Ehlers' research group, which is funded by the Wellcome Trust.

Waitlist (control arm): Those randomised to waitlist will begin the iCT-SAD intervention following a 14-week wait period.

The principal assessment points will be pretreatment/prewait, midtreatment/midwait, posttreatment/postwait, and three month follow up. Participants will complete a pack of self-report questionnaires assessing social anxiety and general wellbeing. At the posttreatment /postwait assessment, they will also complete a brief clinical interview with an independent assessor who is blinded to their group allocation. Adverse events/effects will be monitored throughout treatment and follow-up (phonecalls with therapist). Dropout, or premature termination from the study or treatment at any point after randomisation, will also be recorded along with reason for discontinuation or termination.

Intervention Type
Other

Primary outcome measure
Severity of social anxiety, measured using the self-report version of the Liebowitz Social Anxiety Scale (Baker, Heinrichs, Kim, & Hofmann, 2002). The principal assessment points are pretreatment/prewait, midtreatment/midwait, posttreatment/postwait, and three month follow up.

Secondary outcome measures
1. Social anxiety, measured using:
1.1. Anxiety and Related Disorders Interview Schedule for DSM-5 (ADIS-5; Brown & Barlow, 2014). A clinical interview conducted by an independent assessor blind to treatment condition, at the posttreatment/postwait assessment point
1.2. Social Phobia Weekly Summary Scale (Clark, 1995)

1.3. Social Cognitions Questionnaire (Clark, 1995)
1.4. Social Phobia Inventory (Connor et al., 2000)
1.5. Social Behaviour Questionnaire (Clark, 1995)
1.6. Social Attitudes Questionnaire (Clark, 1995)
1.7. Fear of Negative Evaluation Scale (Watson & Friend, 1969)
1.8. Social Phobia Scale and Social Interaction Anxiety Scale (Mattick & Clarke, 1998)
1.9. Social Participation (Alden & Taylor, 2011)
1.10. Social Satisfaction (Alden & Taylor, 2011)
2.. Depression, measured using PHQ-9 (Kroencke, Spitzer, & Williams, 2001)
3. Generalised anxiety, measured using GAD-7 (Spitzer, Kroenke, Williams, & Löwe, 2006)
4. General functioning, measured using Work and Social Adjustment Scale (Mundt, Marks, Shear, & Greist, 2002)
5. Generalised learning, measured using Generalised Learning Questionnaire (in development)
The principal assessment points are pretreatment/prewait, midtreatment/midwait, posttreatment/postwait, and three month follow up.

Overall study start date
26/09/2016

Completion date
11/01/2019

Eligibility

Key inclusion criteria
1. Meets DSM-5 criteria for SAD
2. Social anxiety problem has lasted at least six months
3. Participant considers SAD to be their main problem
4. Age 18-65 (inclusive)
5. Not currently taking psychotropic mediation, or on a stable dose for at least two months without improvement, and willing to remain at this dose throughout trial
6. Participant agrees not to start any other forms of treatment (medication or psychological) during the trial
7. Participant is a Chinese resident of Hong Kong, with sufficient proficiency in English to understand the treatment content
8. Regular access to an internet-connected computer or mobile device

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex

Both

Target number of participants
40

Total final enrolment
44

Key exclusion criteria
1. Current or past psychosis, bipolar disorder, or borderline personality disorder
2. Active suicidality
3. Dependence on alcohol or substances
4. Currently receiving psychological treatment
5. Having completed a course of CBT for social anxiety previously (defined as at least 5 sessions, and including an exposure component)

Date of first enrolment
01/11/2017

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
Hong Kong

Study participating centre
Chinese University of Hong Kong
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Sponsor information

Organisation
Chinese University of Hong Kong

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Sponsor type
University/education

Website
http://www.cuhk.edu.hk/english/index.html

ROR
https://ror.org/00t33hh48

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
National Institute for Health Research - Biomedical Research Centre (Oxford)

Results and Publications

Publication and dissemination plan
Additional study documents are available on request. Planned publication of the findings in a peer reviewed journal following the conclusion of the study.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan

Requests for data sharing as part of research collaborations will be considered after the primary trial analyses have been published. Researchers should contact Dr Graham Thew in the first instance (graham.thew@psy.ox.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	pilot	15/05/2019	10/12/2019	Yes	No
Results article		18/04/2022	03/05/2022	Yes	No