

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

<b>Submission date</b> 16/10/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/10/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/05/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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?

Dr Graham Thew

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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**

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 medication, 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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Hong Kong

Hong Kong

Shatin, N.T.

## **Sponsor information**

**Organisation**

Chinese University of Hong Kong

**Sponsor details**

Shatin, NT

Hong Kong

Hong Kong

Shatin, NT, Hong Kong SAR

**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](mailto: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?
<a href="#">Other publications</a>	pilot	15/05/2019	10/12/2019	Yes	No
<a href="#">Results article</a>		18/04/2022	03/05/2022	Yes	No