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

<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
	☐ Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category  Montal and Robavioural Disorders	[] Individual participant data		
	No longer recruiting  Overall study status  Completed		

#### 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 graham.thew@psy.ox.ac.uk

# Contact information

#### Type(s)

Scientific

#### Contact name

Dr Graham Thew

#### **ORCID ID**

https://orcid.org/0000-0003-2851-1315

#### Contact details

Oxford Centre for Anxiety Disorders and Trauma (OxCADAT)
Department of Experimental Psychology
University of Oxford
The Old Rectory
Paradise Square
Oxford
United Kingdom
OX1 1TW
+44 (0)1865 618600
graham.thew@psy.ox.ac.uk

# Type(s)

Scientific

#### Contact name

**Prof Patrick Leung** 

#### Contact details

Department of Psychology The Chinese University of Hong Kong 3rd Floor, Sino Building, Shatin, N.T. Hong Kong

# Additional identifiers

#### Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

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.

## Key secondary outcome(s))

- 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.

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

65 years

#### Sex

Αll

#### 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

Department of Psychology
3rd Floor, Sino Building, Shatin, N.T.
Hong Kong
Hong Kong
Shatin, N.T.

# Sponsor information

#### Organisation

Chinese University of Hong Kong

#### **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**

## 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?
Results article		18/04/2022	03/05/2022	Yes	No
Other publications	pilot	15/05/2019	10/12/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes