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A study of internet-delivered cognitive therapy for social anxiety disorder (iCT-SAD) in Japan

Submission date
18/01/2024

Recruitment status
No longer recruiting

Registration date
19/01/2024

Overall study status
Ongoing

Last Edited
08/05/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Cognitive therapy (CT) has proven to be effective for treating social anxiety disorder (SAD) and is recommended in various national guidelines. However, making sure that people around the world can access evidence-based psychological therapies, such as CT for SAD, is a significant challenge.

To address this issue, an online version of the treatment called iCT-SAD has been developed. It has been shown to produce similar results to traditional face-to-face CT for SAD but requires less time from therapists. Initial evidence also suggests that it can be used in different cultures without losing effectiveness. However, the studies conducted in other cultural settings used the English-language program and only included participants who were fluent in English as a second language.

The big question now is how well this program will work when translated and adapted for a different cultural context. This trial aims to assess the clinical effectiveness of the Japanese version of iCT-SAD when combined with the standard treatment (TAU) for individuals with social anxiety disorder.

Who can participate?
Patients aged 18 years or older, with SAD.

What does the study involve?
This research study is designed as a fair test with two groups to figure out if one treatment is better than another. The plan is to have about 60 participants, and they will be randomly assigned to either receive the Japanese online therapy for social anxiety (iCT-SAD) along with the usual treatment (iCT-SAD + TAU) or just the usual treatment alone (TAU). It's like flipping a coin to decide which group each person will be in.

The main thing they're looking at to see if the treatment works is a self-report survey called the Liebowitz Social Anxiety Scale. They will also look at other things like how people feel, how well they function, and how they respond to the treatment. Additionally, they want to know if people find the treatment acceptable, and they will ask participants for their thoughts about it.

The researchers will check in with participants at the beginning, middle, and end of the treatment, and then again after three months to see how things are going for those in the iCT-SAD + TAU group.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement in their social anxiety and general well-being through receiving iCT-SAD. 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?
University of Miyazaki (Japan)

When is the study starting and how long is it expected to run for?
November 2023 to June 2026

Who is funding the study?
1. Japan Society for the Promotion of Science (JSPS) (Japan)
2. Daiwa Anglo-Japanese Foundation (Japan)
3. Wellcome Trust (UK)
4. Oxford Health NIHR Biomedical Research Centre (UK)

Who is the main contact?
Prof Yoshinaga, naoki-y@med.miyazaki-u.ac.jp

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title

A randomised controlled trial of internet-delivered cognitive therapy for social anxiety disorder (iCT-SAD) in Japan

Study objectives
The primary objective of the current trial is to examine whether a Japanese version of iCT-SAD in combination with treatment as usual (iCT-SAD + TAU) is superior to TAU alone.

The secondary objectives are as follows:
1. To examine whether the Japanese iCT-SAD programme is acceptable to clients
2. To evaluate how the outcomes of the iCT-SAD + TAU intervention compare to previous studies of the iCT-SAD programme in the UK and Hong Kong
3. An exploratory examination of whether baseline clinical and demographic characteristics are associated with clinical outcomes in the iCT-SAD + TAU arm
4. An exploratory examination of candidate mediators of the relationship between treatment arm and clinical outcome

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/11/2023, Research Ethics Committee at the University of Miyazaki (5200 Kihara, Kiyotake, Miyazaki, 889-1692, Japan; +81-985-85-9403; rinken@med.miyazaki-u.ac.jp), ref: I-0070

Study design
Two-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Intervention: iCT-SAD + TAU, therapist-guided modular online cognitive therapy for social anxiety based on the Clark and Wells (1995) cognitive model in addition to treatment as usual (14 weeks + 3-month booster phase, N=30)

Control: Treatment as usual (TAU) alone, provided by a primary psychiatrist including medication monitoring and supportive counselling, with at least monthly visit (14 weeks, N=30)

Participants are randomised into groups using an internet-based central randomization system.

Intervention Type
Behavioural

Primary outcome(s)
Liebowitz Social Anxiety Scale (LSAS) (self-report) [Pre (week 0), Mid (week 8), Post (week 15), 3-mo FU (week 27, Intervention arm only)]

Key secondary outcome(s))
1. Efficacy measures:
1.1. Proportion of participants who met the SAD diagnostic criteria evaluated using the Anxiety and Related Disorders Interview Schedule for DSM-5 (ADIS-5) [Pre (week 0), Post (week 15), 3-mo FU (week 27, Intervention arm only)]
1.2. Social Cognitions Questionnaire (SCQ) [Pre (week 0), Mid (week 8), Post (week 15), 3-mo FU (week 27, Intervention arm only)]
1.3. Social Behavioural Questionnaire (SBQ) [Pre (week 0), Mid (week 8), Post (week 15), 3-mo FU (week 27, Intervention arm only)]
1.4. Social Attitudes Questionnaire (SAQ) [Pre (week 0), Mid (week 8), Post (week 15), 3-mo FU (week 27, Intervention arm only)]
1.5. Social Phobia Weekly Summary Scale (SPWSS) [Pre (week 0), Mid (week 8), Post (week 15), 3-mo FU (week 27, Intervention arm only)]
1.6. Social Participation and Satisfaction Scale (SPSS) [Pre (week 0), Mid (week 8), Post (week 15), 3-mo FU (week 27, Intervention arm only)]
1.7. Patient Health Questionnaire-9 (PHQ-9) [Pre (week 0), Mid (week 8), Post (week 15), 3-mo FU (week 27, Intervention arm only)]
1.8. Generalized Anxiety Disorder-7 (GAD-7) [Pre (week 0), Mid (week 8), Post (week 15), 3-mo FU (week 27, Intervention arm only)]
1.9. Work and Social Adjustment Scale (WSAS) [Pre (week 0), Mid (week 8), Post (week 15), 3-mo FU (week 27, Intervention arm only)]

2. Response to treatment:
2.1. Response: Improvement in the LSAS between pre- and post-treatment greater than 31%
2.2. Remission: Decrease in the LSAS score of at least 12 points and post-treatment score of 38 points or less
2.3. Reliable deterioration: Increase of at least 12 points in the LSAS score

3. Acceptability measures:
3.1. Dropout rate
3.2. Rates of module completion (Intervention arm only)
3.3. Participants' feedback about their experience with iCT-SAD (Intervention arm only)

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Primary diagnosis of SAD based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)
2. Aged 18 years or over
3. Regular, private access to an appropriate internet enable device
4. Resident in Japan and proficient in Japanese (written and spoken)
5. Able to visit their primary psychiatrist regularly during the study (at least monthly in person) for safety monitoring
6. Participant not currently undertaking other structured psychological therapy and agrees not to start such interventions during the study

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Current psychosis, bipolar disorder, or antisocial personality disorder
2. Current alcohol/substance use disorder (moderate or severe)
3. Active suicidal ideation with intent or plan
4. Previously received CT or cognitive behavioural therapy for SAD (defined as at least 5 sessions and including an exposure component)

Date of first enrolment
31/01/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Japan

Study participating centre
University of Miyazaki
5200 Kihara, Kiyotake
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Japan
889-1692

Sponsor information

Organisation
University of Miyazaki

ROR

https://ror.org/0447kww10

Funder(s)

Funder type
Government

Funder Name
Japan Society for the Promotion of Science (JSPS)

Funder Name
Daiwa Anglo-Japanese Foundation

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

Funder Name
Oxford Health NIHR Biomedical Research Centre

Results and Publications

Individual participant data (IPD) sharing plan
A de-identified individual-level dataset will be made available through a publicly accessible online repository after the primary findings of this trial are published.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/07/2024	22/07/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes