PARTICIPANT INFORMATION SHEET

You are invited to participate in a research study. This information sheet provides you with information about the research study. Where "personal data" is used, it means data about you which makes you identifiable: (i) from such data or (ii) from such data and other information which the National University of Singapore (NUS) has or is likely to have. The Principal Investigator (the research doctor or the person in charge of this research) or his/her representative will also describe this research to you and answer all your questions. Read the information below and ask questions about anything you don't understand before deciding whether to take part.

PART I: General Information

NUS-IRB Reference Code: NUS-IRB-2025-562

1. Protocol title

Assessing the Clinical and Cost Effectiveness of Internet-Based Cognitive Behavioural Therapy (iCBT) for Anxiety and Depression in Singapore.

2. Principal Investigator and co-investigator(s), if any, with the contact number and address of organization

This research is conducted by the National University of Singapore, Saw Swee Hock School of Public Health (SSHSPH) in partnership with MOH Office for Healthcare Transformation (MOHT), Agency for Integrated Care (AIC), and Community Intervention Team (COMIT) providers. For all questions regarding this study, please contact the centre-specific contact number and address of the COMIT provider that you registered with for this pilot study.

Below are the main hotline numbers and emails for the three COMIT providers involved in this pilot.

S/N	Role	Name	Contact
1	Principal Investigator	Professor Gerald Koh (NUS SSHSPH, MOHT)	**Allkin** Contact Number: 6038 4400 Email: mentalhealthservice@allkin.org.sg **Fei Yue:** Contact Number: 6011 7658 Email: comit@fycs.org **Viriya:** Contact Number: 6256 1311 Email: mwh@viriya.org.sg / vtc@viriya.org.sg
2	Co-Investigator	Dr Alvin Neo (NUS SSHSPH, MOHT)	
3	Co-Investigator	Dr Charmaine Lim (MOHT)	
4	Co-Investigator	Dr Shilpa Tyagi (NUS SSHSPH, MOHT)	
5	Co-Investigator	Ms Sandra Yeo (NUS SSHSPH, MOHT)	
6	Co-Investigator	Ms Nicole Chia (MOHT)	

3. Whom should I call if I have any questions or problems?

Please contact your respective COMIT counsellor at the centre-specific telephone number and email for all research-related matters.

This study has undergone an ethics review by the National University of Singapore Institutional Review Board (NUS-IRB). For an independent opinion on the rights and welfare of research participants, you may contact a staff member of the NUS-IRB at (+65) 6516 1234 (Mondays to Thursdays, 8:30am – 6:00pm; Fridays, 8:30am – 5:30pm, excluding public holidays) or email irb@nus.edu.sg.

4. Who can participate in the research? What is the expected duration of my participation? What is the duration of this research?

You have been invited to participate because you have been identified as experiencing depression and/or anxiety and were referred for support through a COMIT counsellor. Your participation in the study will last between 8 to 10 months, with up to 6 study visits in total. Each study visit will take approximately 1 to 2 hours. In addition, participants in the intervention group will be required to complete weekly exercises on the iCBT app for 8 weeks at your own pace within each week. The entire duration of this research is expected to last for 3 years.

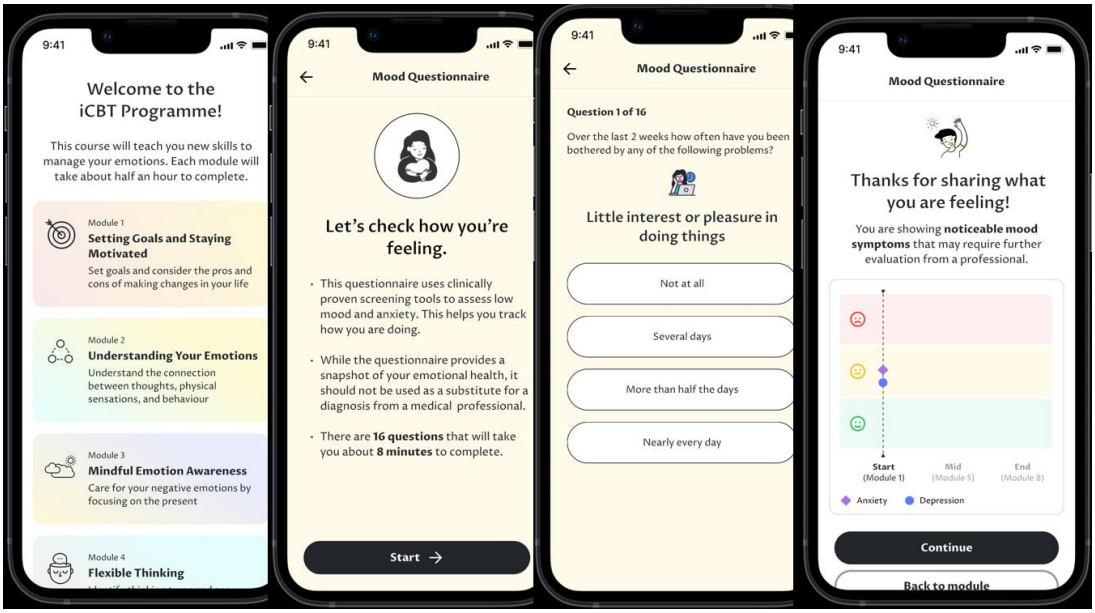
5. What is the approximate number of research subjects involved?

This study will recruit 390 participants.

6. What will be done if I take part in this research study?

If you take part in this study, you will be randomised to receive either (1) the iCBT intervention, or (2) usual care from your COMIT counsellor. Randomisation means assigning you to one of the 2 groups by chance, like tossing a coin or rolling a die.

If you have been randomly assigned to the iCBT intervention group, you will engage in 8 weeks of online modules covering core cognitive behavioural therapy (CBT) techniques, including interactive exercises and homework assignments delivered via the iCBT programme on a mobile application. Your counsellor will schedule regular check-ins at Weeks 3, 5, and 8 via face-to-face or video sessions to introduce the treatment rationale, practise skills, and assess your progress. Face-to-face visits shall take place at your assigned COMIT provider's venue. You will be required to download the iCBT mobile application on your mobile device and submit your email address for registration. The iCBT application *(refer to screenshots below)* is developed by MOHT and will not capture any other personal data.



If you have been randomly assigned to the control group, you will undergo the usual treatments as determined by your COMIT counsellor.

All participants will be required to complete a series of questionnaires to evaluate the effectiveness of the programme. These will be conducted by the research coordinator at (i) pre-treatment/baseline – Week 1, (ii) mid-treatment – Week 5, (iii) post-treatment – Week 8, (iv) 3 months from baseline, and (v) 6 months from baseline. Please refer to the table below for the Study Visit Schedule.

Study Visit Schedule*

Study Visit	iCBT Intervention	Usual Care
Week 1 *(Baseline)*	a) Eligibility screening b) Study questionnaires^ c) Randomisation of groups d) Orientation and training of iCBT programme (intervention group only)	
Week 3	a) Check-in session with COMIT counsellor	
Week 5 *(Mid-Treatment)*	a) Check-in session with COMIT counsellor b) Study questionnaires^	a) Study questionnaires^
Week 8 *(Post-Treatment)*	a) Check-in session with COMIT counsellor b) Study questionnaires^ c) Semi-structured user experience interview (selected participants only; may be conducted on a separate visit)	a) Study questionnaires^
3 Months from Baseline	a) Study questionnaires^	
6 Months from Baseline	a) Study questionnaires^	

**Schedule timeline may vary based on the availability of participants and COMIT counsellors.*

^Including but not limited to (1) anxiety, depression and functional questionnaires, (2) demographics, (3) user satisfaction surveys, (4) healthcare utilisation and related measures.

Between visits, you can contact your assigned COMIT counsellor or research assistant if you experience worsening symptoms or require additional support. All study visits are designed to minimise disruption to your daily routine while maintaining proper clinical care and research monitoring.

Selected participants from the intervention group may be invited for a 1-1 semi-structured interview pertaining to the user experience of this programme. By consenting to this study participation, you agree to be contacted by the study team for a 1-hour semi-structured interview that will be audio-recorded and/ or transcribed. This will be conducted online via video-conferencing. Key topics such as treatment experience, support from therapists, adherence and engagement, and suggestions for improvement may be covered in the interviews. The interview will be audio-recorded and/ or transcribed. Participant quotes may be included in the research publications/presentations, provided consent is obtained. All quotes will be anonymised. All participants selected will be reimbursed for their participation in the interview.

7. Will there be reimbursement for reasonable transport costs and time spent from my participation?

You will receive reimbursement for your time, travel expenses, and participation as follows:

a) $50 SGD (cash or equivalent value) for each completed study visit will apply to all participants:
   - Baseline (Week 1)
   - Mid-treatment (Week 5)
   - Post-treatment (Week 8)
   - 3 months from baseline
   - 6 months from baseline

b) $100 SGD (cash or equivalent value) for completion of semi-structured user experience interview (for selected participants only)

If you withdraw from the study, you will be reimbursed for all visits completed up to that point.

8. How will my privacy and the confidentiality of my research records be protected?

NUS has established data management policies and rules for protection of the personal data of human research subjects in NUS studies, including the collection, use and storage of such data.

Additionally, our researchers are required to comply with the Human Biomedical Research Act (HBRA) and other applicable laws. Under the HBRA and the Personal Data Protection Act (PDPA), researchers must take all reasonable steps and safeguards as needed to protect individually identifiable information or material against accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying, use or modification.

For purposes of validating the research findings and supporting future research work, research data (without personal identifiers) used in any publication will be kept for a minimum of 10 years before being discarded in accordance with the NUS Research Data Management Policy.

PART II: Information on this Human Biomedical Research

9. What is the nature of this biomedical research?

This research is investigational in nature, and we hope to discover new information which may contribute to scientific and/or medical knowledge. Treatments or interventions used in this research are under evaluation and are not currently validated as standard care or standard practice.

10. What is the purpose of this biomedical research?

Cognitive-behavioural therapy (CBT) has a robust evidence base for treating anxiety disorders and depression, including transdiagnostic CBT. Internet-based CBT (iCBT) offers a new approach to delivering these therapies. iCBT is a digital adaptation of traditional cognitive behavioural therapy (CBT) that leverages digital platforms to deliver similar therapeutic interventions. iCBT encompasses structured programmes that provide users with tools and techniques to manage mental health issues such as depression and anxiety. The digital format ensures timely access to CBT and typically includes interactive modules, videos, self-assessment tools, and virtual therapist support. This study aims to evaluate the effectiveness of iCBT in reducing symptoms of anxiety and depression, as well as its cost-effectiveness and acceptability in local context.

11. What are the possible risks, discomforts or inconveniences to me if I participate in this research?

Most participants find both online therapy and in-person counselling helpful. However, there may be associated risks which include:

a) Worsening of symptoms: Some participants may feel more anxious or low when engaging with emotionally sensitive content, particularly in the iCBT intervention group where real-time clinical support is limited.
b) Emotional distress: Reading or reflecting on personal challenges may bring up strong emotions. If this happens, support is available from trained counsellors.
c) Reduced personal contact: The online programme involves less face-to-face interaction, which some people may find isolating.
d) Technology-related issues: Frustration can occur if you have problems accessing the programme or face technical difficulties.

If at any point you feel overwhelmed or unsafe, you will be provided with details to contact your COMIT counsellor or research assistant. We will also provide you with emergency contact options. You may choose to withdraw from this study at any point by informing your COMIT counsellor or research assistant.

12. What benefits can I expect from participating in the research?

By participating in this trial, you may experience potential benefits, including an improvement in your anxiety and/ or depression symptoms if you are in the intervention group. If you are assigned to the control group, you will continue receiving usual care from your COMIT service provider. Any potential benefits to your anxiety or depression symptoms will be those expected from usual care.

Your participation will also contribute valuable knowledge to the scientific understanding of digital mental health treatments, potentially helping others facing similar challenges in the future.

13. Are there any alternative procedures or treatments available to me? What are the potential benefits and risks of such alternatives?

If you choose not to take part in this study, you will continue to receive the standard care and services for your condition from your COMIT counsellor.

14. If I am injured as a result of participating in this research, what are the compensation and treatments available to me?

If you sustain an injury directly resulting from your participation in this study while adhering to all protocol requirements and staff instructions, NUS will cover all medically necessary treatment expenses. Your consent to participate does not waive any legal rights, nor does it release the investigators, sponsors, or NUS from liability for negligence.

15. Do I have to incur any expenses by participating in this research?

If you take part in this study, you will not have to pay for any procedures or services provided by your COMIT counsellor.

16. Will my participation in this research involve the use of any information that will identify me?

Your personal data (i.e. name and contact details) will be collected in this study for scheduling and communication purposes.

17. How will my personal identifiers collected from me be kept confidential?

Your personal information, including your name and contact details, will remain strictly confidential. Access will be limited to only: (1) your COMIT service provider, (2) specific study staff who require access to perform their duties, and (3) authorised data processors assisting with research data.

We employ multiple safeguards to protect your privacy:

- All research data will be pseudonymized using unique code numbers.
- Your identifiable information will be stored separately from research data.
- The key linking your identity to your code will be stored on encrypted, NUS IT-approved platforms in accordance with NUS Data Management Policy.
- No personally identifiable information will be published or presented.

Please be aware that:

1. We may be legally obligated to disclose information in certain circumstances (such as under the Infectious Diseases Act).
2. While we implement industry-standard security measures, complete anonymity in research can never be absolutely guaranteed due to the small possibility of either accidental re-identification or unauthorised data access.

18. Will any identifiable information obtained from me be used for future biomedical research?

Your personal data will be retained for a period of 7 years after the study. If you consent, we may re-contact you for participation in future research and/or follow-up in this study.

19. Will I be re-identified in the event of incidental finding(s) arising during the biomedical research?

This study is not primarily designed to detect undiagnosed or emergent clinical conditions. However, incidental findings may arise during the course of data collection, particularly through responses to mental health questionnaires such as the PHQ-9 and GAD-7. For example, if a participant reports high levels of suicidal ideation or severe depressive or anxiety symptoms, the study team may identify the need for further clinical evaluation.

In such cases, participants will be promptly contacted by a qualified member of the research or clinical team or referred to appropriate mental health services or crisis support if necessary within 48 hours. All such responses will follow a pre-established risk management protocol approved by the study's clinical advisors and NUS Institutional Review Board.

It is possible that during the course of the research, we may discover pre-existing medical conditions that are not related to the study. These are known as "incidental findings". "Incidental findings" are findings that have potential health or reproductive importance to participants like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study.

You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you. The discovery of an incidental finding, at the discretion of the University, will be communicated to you for the purpose of seeking medical advice or treatment. In the event that you have indicated not to be re-identified and notified, but the University has determined that the incidental finding is of clinical significance, you may still be contacted to decide if you wish to be notified of the incidental finding at that time. Any medical treatment for conditions arising from incidental findings that are unrelated to the research will be at your own expense.

20. Can I withdraw my consent to the research at any time?

You can withdraw from the research at any time without giving any reasons, by informing the COMIT provider, research coordinator, or principal investigator verbally or in writing. Please note that the withdrawal of consent does not affect the research information obtained before the consent is withdrawn and such information may still be retained and used for research. There will be no penalties or damages imposed on you should you withdraw your consent to participate in this research.

Study participation is entirely voluntary. You are entitled to refuse to participate or discontinue participation at any time in this research. Refusal to participate or withdrawal from participation will not affect your medical management or cause loss of benefits to which you are otherwise entitled.

21. Will my personal data be shared and / or processed for use in research?

For this study, identifiable personal data will be collected solely for operational purposes such as scheduling of appointments, coordinating study-related activities, and completing surveys. This information will be accessible only to authorised members of the study team and will not be shared with any third party not named in this research.

Any data shared with collaborators will be in de-identified form, and the de-identification process will be performed by a limited number of designated study team

members. The purpose of such data sharing is to enable collaborative data analysis and reporting aligned with the study's objectives.

There is no intention to share identifiable personal data with third parties or to use it for future unrelated research. The study team will ensure that all data processing complies with institutional policies, relevant data protection regulations, and IRB-approved procedures.

Consent Form for Research Subjects

Protocol title:
Assessing the Clinical and Cost Effectiveness of Internet-based Cognitive Behavioural Therapy (iCBT) for Anxiety and Depression in Singapore

Principal Investigator with the contact number and organization:

Name: Professor Gerald Koh

Please use the center-specific contact number and address of the Community Intervention Team (COMIT) provider that you registered with for this pilot study. Below are the main hotline numbers and emails for the three COMIT providers involved in this pilot.

- **Allkin:**
  Contact Number: 6038 4400
  Email: mentalhealthservice@allkin.org.sg

- **Fei Yue:**
  Contact Number: 6011 7658
  Email: comit@fycs.org

- **Viriya:**
  Contact Number: 6256 1311
  Email: mwh@viriya.org.sg / vtc@viriya.org.sg

I hereby acknowledge that:

1. My signature is my acknowledgement that I have agreed to take part in the above research.

2. I have received a copy of this information sheet that explains the use of *data** in this research. I understand its contents and agree to donate my *data** for the use of this research. I confirm that I consent to the collection, use, disclosure and processing of my *data** for the purposes of the study.

3. I can withdraw from the research at any point of time by informing the COMIT provider, research coordinator, or Principal Investigator. I am aware that that the withdrawal of consent does not affect the research information obtained before the consent is withdrawn and such information may still be retained and used for research.

4. I will not have any financial benefits that result from the commercial development of this research.

5. For sharing of data (including personal data) with external public agencies who may require the data generally for their own purposes:

☐ 5.1 I agree to the sharing of my data in de-identified or anonymized form with the MOH Office of Healthcare Transformation (1 N Buona Vista Link, #09-02 Elementum, Singapore 139691) and other relevant government ministries, statutory boards and/or any other government agencies when they require for their purposes as permitted by law or regulations.

☐ 5.2 I do not agree to the sharing of my data in de-identified or anonymized form with the MOH Office of Healthcare Transformation (1 N Buona Vista Link, #09-02 Elementum, Singapore 139691) and other relevant government ministries, statutory boards and/or any other government agencies when they require for their purposes as permitted by law or regulations.

6. For *human data* collected **for use in future research**:

☐ 6.1 I agree to the sharing of my de-identified/anonymised data for the purposes of future research studies after the completion of this study which are approved by the IRB, relevant laws and/ or the Singapore Government, with other researchers, service providers, regulators or third parties as follows:

- MOH Office of Healthcare Transformation, 1 N Buona Vista Link, #09-02 Elementum, Singapore 139691

☐ 6.2 I do not agree to the sharing of my de-identified/anonymised data for the purposes of future research studies after the completion of this study which are approved by the IRB, relevant laws and/ or the Singapore Government, with other researchers, service providers, regulators or third parties.

7. For purposes of **re-contact**:

☐ 7.1 I agree to be re-contacted for future related studies. I understand that future studies will be subject to an Institutional Review Board's approval.

☐ 7.2 I do not agree to be re-contacted for future related studies. I understand that future studies will be subject to an Institutional Review Board's approval.

8. For participation in **1-1 semi-structured interviews**:

☐ 8.1 I agree to participate in 1-1 semi-structured interviews. I understand that this interview is only extended to selected participants from the iCBT intervention group.

☐ 8.2 I do not agree to participate in 1-1 semi-structured interviews.

9. For use of **audio-recordings**:

☐ 9.1 I agree to the audio-recording of my participation in the research. I understand that although my name will not be associated with the recordings used in publication/presentation, I may still be identified.

☐ 9.2 I do not agree to the audio-recording of my participation in the research.

Name and Signature (Research Subject) Date

I, the undersigned, certify to the following:

(a) I am 21 years of age or older.
(b) I have taken reasonable steps to ascertain the identity of the research subject.
(c) To the best of my knowledge, the research subject had the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
(d) I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Name and Signature (Witness) Date

Name and Signature (Consent Taker) Date