RESEARCH STUDY PROTOCOL

PROTOCOL TITLE:

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

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1. BACKGROUND AND RATIONALE

The Burden

A recent WHO report indicates that the community point prevalence of depression is approximately 5%, while about 4% of the global population suffers from anxiety disorders.[1, 2] In Singapore, the community lifetime prevalence of mental illness is estimated at 13.9%, with almost 1 in 7 expected to experience at least one mental illness in their lifetime.[3] Within the primary care setting, it was noted in a cross-sectional study conducted in 2022 that the overall community point prevalence of clinical depression was 8.7% and the prevalence of clinical anxiety was 7.3%.[4] The most affected age groups are youths and working adults aged 18 to 49 years, who collectively account for over 60% of those impacted.[3]

The Treatment Gap

In Singapore, a significant 78.6% of individuals with mental disorders do not seek professional help, reflecting limited help-seeking behavior.[3] The Singapore Mental Health Study 2016 revealed that the average time between the onset of symptoms and seeking help is two years for Generalized Anxiety Disorder and one year for Major Depressive Disorder.[5] Various factors contribute to this gap, including long waiting times, stigma, lack of awareness about mental health services and inadequate accessibility to care.

In Singapore, the psychiatrist-to-population ratio is significantly lower compared to other Organisation for Economic Co-operation and Development (OECD) countries, with approximately 5 psychiatrists per 100,000 people, while countries like the UK and Canada have ratios exceeding 10.[6] Similarly, the psychologist-to-population ratio is about 10 per 100,000 in Singapore, which is low in comparison to other OECD nations.[6] This shortage of mental health professionals further exacerbates the barriers to accessing timely care.

Internet-based Cognitive Behavioural Therapy

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.[7, 8, 9] iCBT is a digital adaptation of traditional cognitive behavioural therapy (CBT) that leverages digital platforms to deliver 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 accessibility anytime and anywhere and typically includes interactive modules, videos, self-assessment tools, and virtual therapist support.

Research has demonstrated the clinical effectiveness of iCBT. A systematic review by Karyotaki et al. (2021) found that iCBT improves mental health outcomes and yields high user satisfaction.[10] Locally, a randomised controlled trial by Lu et al. found that a therapist-guided iCBT program significantly reduced symptoms of depression and psychological distress, with participants reporting high levels of satisfaction.[11]

iCBT also serves as a valuable tool for waitlist management, particularly in regions with a shortage of mental health professionals. By offering immediate access to therapy, iCBT can relieve pressure on mental health services, enabling individuals to start their treatment while awaiting in-person appointments. This is particularly crucial in Singapore where a shortage of mental health professionals often leads to wait times for care extending into months.

With nearly all households in Singapore having internet access (99%) and 90% having computer access as of 2022, local digital literacy is exceptionally high.[12] Additionally, smartphone ownership has reached an impressive 97%.[12] The hypothesis is that iCBT could effectively address the treatment gap for mental health

issues, particularly anxiety and depression. This hypothesis is further supported by the growing trend of individuals seeking digital solutions for their health needs because of easier access and relatively greater privacy compared to in-person CBT, indicating a readiness to engage with digital mental health resources.[13]

Knowledge and Evidence Gap

International studies have demonstrated iCBT effectively reduces symptoms of anxiety and depression, while also achieving high levels of user satisfaction. However, the applicability of these findings to Singapore's unique healthcare landscape, particularly in the primary care and community setting, is limited.

The effectiveness of low-intensity versus higher-intensity iCBT programs has not been validated in the local context of Singapore. Additionally, there are currently no established frameworks for integrating iCBT into the primary healthcare system. This project aims to address these gaps by developing localised protocols that will enable primary and community healthcare providers to effectively implement and utilise iCBT as part of standard mental health care.

2. HYPOTHESIS AND OBJECTIVES

Objective

The randomised controlled trial (RCT) aims to evaluate the effectiveness, cost-efficiency, and acceptability of iCBT, particularly within primary and community healthcare settings.

Hypotheses

Clinical-effectiveness Hypotheses:

- H1: Participants receiving iCBT will show a reduction in symptoms of anxiety and depression, as compared to compared to usual care.
- H2: The effectiveness of iCBT will vary based on individual user characteristics, such as severity of symptoms at baseline, age, and previous experience with digital interventions.

Adoption Hypotheses

- H3: Higher levels of training and resources related to iCBT are associated with increased acceptance and adoption rates among healthcare providers in primary care settings.
- H4: User engagement with iCBT will be positively associated with higher perceived ease of use, accessibility and satisfaction rates among Singaporean users.
- H5: Demographic factors (e.g., age, gender, socioeconomic status) influence the acceptance and engagement levels of iCBT among Singaporeans.

Cost-effectiveness Hypothesis

- H6: iCBT will be more cost-effective (e.g. by reducing overall healthcare costs associated with mental health treatment) when compared to usual care.

3. EXPECTED RISKS AND BENEFITS

Participants in the intervention group may experience some expected risks and benefits from iCBT as compared to those receiving usual care in the control group.

Potential Benefits

- Greater convenience and accessibility: iCBT's flexibility in time and location, as well as a shorter waiting time, allows for a greater convenience and accessibility to therapy.
- Higher privacy: The online format of iCBT may offer a deeper sense of privacy.
- Cost and time savings: Reduction in travel time and transportation expenses.

Potential Risks

Participant-related

- Worsening of symptoms: Participants may experience transient increase in anxiety or depressive symptoms when engaging with emotionally sensitive content, particularly in the iCBT arm where real-time clinical support is limited.
- Delayed help-seeking: Participants using the iCBT platform may underreport or delay escalation of worsening symptoms, potentially postponing necessary clinical intervention.
- Reduced interpersonal support: The iCBT intervention is mostly self-guided and may result in reduced feelings of social connection or therapeutic alliance, which some participants may find challenging.

IT-related

- Data security risks: The online format of iCBT could present data security risks and breaches. These concerns persist with any online intervention.
- Technological difficulties: Participants might experience difficulty understanding the materials without real-time support.
- Lower adherence and completion rates: Adherence to online programmes may be lower compared to scheduled in-person sessions.

4. STUDY POPULATION

4.1. List the number and nature of subjects to be enrolled.

A multi-agency collaborative approach for participant recruitment will be adopted, partnering with the Agency of Integrated Care (AIC), selected Community Intervention Teams (COMIT), primary care networks (PCN), Institute of Mental Health (IMH) and identified general practitioner (GP) partners. **390 participants** will be recruited from the primary care and community setting and randomised 1:1 to intervention or control groups using stratified block randomisation, with stratification based on symptom severity and primary care clinic.

The generalisability of the iCBT programme may be limited across different demographic groups. To enhance its generalisability across:

- Quantitative studies – A representative participant sample will be actively sought.
- Qualitative studies – A diverse participant sample that reflects a range of ages, ethnicities, socioeconomic backgrounds, and mental health experiences will be actively sought.

There will be no restrictions based on race or ethnicity. Individuals under the age of 21 will be excluded from participation due to the need for parental or guardian consent as well as differences in clinical presentation and treatment response in younger populations.

4.2. Criteria for Recruitment and Recruitment Process

Pre-screening using PHQ-9 and GAD-7 will be conducted by COMIT Admin via phone call upon receiving referrals from GPs or other sources. Individuals who score between 5 and 19 on the PHQ-9 and between 5 and 14 on the GAD-7 will be considered eligible and invited to participate in the study. Those who are interested will be directed to the research assistant (RA) for assessment of eligibility and informed consent taking. Individuals who declined participation will continue usual care as per COMIT protocol.

4.3. Inclusion Criteria

Participants must meet the following inclusion criteria to participate in this study:

- Age ≥21 years
- Tier 2 – 3 depression and/or anxiety based on PHQ-9 and GAD-7 scores
    - PHQ-9 score of 5 to 19
    - GAD-7 score of 5 to 14
- Able to provide informed consent

4.4. Exclusion Criteria

Participants meeting any of the following exclusion criteria at baseline will be excluded from the study:

- Unable to read or understand English (Primary 6 level)
- Unable to use the internet (e.g. due to lack of internet access or insufficient digital literacy)
- Does not possess a mobile device or is not able to access the iCBT application
- Actively experiencing psychosis
- Suspected with personality disorder
- Primary concern is obsessive compulsive disorder (OCD)
- Tier 4 patients with severe depression or anxiety
    - PHQ-9 score of 20 and above
    - GAD-7 score of 15 and above
- Any suicidal risk or ideation
    - PHQ-9 Question 9 score of more than 2

5. STUDY DESIGN AND PROCEDURES/METHODOLOGY

This study comprises of two components: (1) quantitative and (2) qualitative research.

Quantitative Study Design: Clinical and Cost-Effectiveness

The proposed study design will be a two-arm (intervention-control), single-blind (evaluator-blind) randomised controlled trial to evaluate the clinical effectiveness of iCBT for anxiety and depression in Singapore's primary care setting. The trial will compare an iCBT intervention group (N = 195) with a usual care control group (N = 195). Please refer to appendix A for the trial workflow diagram.

The guided iCBT intervention will consist of 8 weeks of online modules covering core CBT techniques, including interactive exercises and homework assignments delivered via the iCBT programme on a mobile application. COMIT counsellors will schedule regular check-ins with the participants at Week 3, 5, and end of Week 8 via face-to-face or video sessions to introduce the treatment rationale, practise skills, and assess

the participants' progress. The control group will continue usual care, including but not limited to care from GP consultations, standard CBT, and/or referral to other mental health services.

The primary outcome measures include changes in the PHQ-9 and GAD-7 scores from baseline to 6 months: (1) Pre-treatment - baseline, (2) mid-treatment, (3) post-treatment, (4) 3 months from baseline, and (5) 6 months from baseline. The secondary outcome measures include WHO Disability Assessment Schedule (WHODAS), patient satisfaction, healthcare utilisation, and cost-effectiveness.

An economic evaluation will be conducted alongside the randomised controlled trial using a cost–utility analysis framework from the healthcare system perspective. Health outcomes will be measured in quality-adjusted life years (QALYs), derived from EQ-5D-5L utility weights collected at baseline and follow-up time points, with area-under-the-curve methods used to estimate QALY gains over the study horizon. Resource utilisation data will be captured using the Client Service Receipt Inventory (CSRI), including primary care visits, specialist consultations, emergency attendances, hospitalisations, medication use, and relevant community mental health services. Unit costs will be applied using standard national costing sources to estimate total costs per participant. An incremental cost-effectiveness ratio (ICER) will be calculated to compare iCBT with usual care, expressed as cost per QALY gained. Uncertainty will be explored through bootstrapping and probabilistic sensitivity analyses, with results presented using cost-effectiveness planes and acceptability curves against relevant willingness-to-pay thresholds.

Qualitative Study Design

Qualitative components will also be incorporated into the project to explore patients' and healthcare providers' experiences, perceptions, and preferences regarding iCBT for depression and anxiety disorders. The qualitative study will provide deeper insights into the factors that influence treatment engagement, adherence, and satisfaction, which are not fully captured by quantitative measures alone.

A semi-structured interview guide will be developed to explore participants' experiences with iCBT. The guide will include open-ended questions to allow participants to share their perspectives in their own words. Please refer to Appendix B for the questionnaires. Key topics to be covered in the interviews include:

- Treatment Experience: Participants' overall experience with iCBT.
- Support from Therapists: The value of guidance from therapists (if applicable) in their treatment journey, including the quality and frequency of support received.
- Adherence and Engagement: Factors that influenced their adherence to the program, including motivation, barriers, and facilitators.
- Suggestions for Improvement: Recommendations for improving the iCBT program based on their experience.

6. SAFETY MEASUREMENTS

6.1. Definitions

In accordance with Section 2 of the HBRA, the following untoward medical occurrences as a result of the human biomedical research are construed as "serious adverse events (SAE)"::

- results in or contributes to death
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in or contributes to persistent or significant disability/incapacity or

- results in or contributes to a congenital anomaly/birth defect
- results in such other events as may be prescribed

6.2. Collecting, Recording and Reporting of Serious Adverse Events (SAEs) to NUS-IRB

The reporting requirements will be in accordance with the reporting requirements published on NUS-IRB website at the time when the event took place.

Only related SAEs will be reported to NUS-IRB. Related means there is a reasonable possibility that the event may have been caused by participation in the research.

The investigator is responsible for informing NUS-IRB after first knowledge that the case qualifies for reporting. Follow-up information will be actively sought and submitted as it becomes available.

Related AEs will not be reported to NUS-IRB. However, the investigator is responsible to keep record of such AEs cases at the Study Site File.

6.3. Safety Monitoring Plan

The study will incorporate a safety protocol to identify and respond to participants who may be at elevated risk of harm based on their responses to the PHQ-9 and GAD-7 questionnaires.

Trigger Criteria for Escalation:

- Tier 4 severity, defined as:
    - PHQ-9 total score ≥ 20 (severe depression), and/or
    - GAD-7 total score ≥ 15 (severe anxiety), and/or
    - A positive response to Item 9 of the PHQ-9 (indicating thoughts of self-harm or suicidal ideation, scored as 1 or above).
- All participants, both in the control and iCBT intervention groups, will be provided with a safety plan by their COMIT Admin or Counsellor to use if they feel unsafe, distressed, or experience a mental health crisis. The safety plan may include specific action steps and relevant emergency contact details. The guidance will align with the COMIT counsellor's existing organisational protocols for escalating high-risk cases.

Response Actions:

1. Immediate In-app Notification

- Participants who meet the above criteria will receive an automated in-app message urging them to seek urgent support.
- The message will include contact details for the Institute of Mental Health (IMH) Emergency Helpline (6389 2222) and Samaritans of Singapore (SOS 1767) and advise them to present to the nearest emergency department if in immediate danger.

2. Follow-Up by Study Team

- The COMIT counsellor will be automatically alerted when a high-risk response is submitted. Participants may also contact the COMIT team through the usual channels provided by their COMIT team.

- The COMIT Counsellor will attempt to contact the participant within 24 to 48 hours via their preferred contact method (phone or email) to check on their safety and provide guidance on accessing further help. The guidance provided will align with the COMIT counsellor's existing organisational protocols for escalating high-risk cases.
- The COMIT team will also inform the RA and PI of any participant triggers, along with the response actions or follow-up measures taken.
- If the participant is uncontactable, and there is sufficient concern based on their responses, the RA will be notified and may consider further action as appropriate under institutional guidelines.

3. Documentation and Risk Reporting
- All escalation events will be logged in a secure, access-controlled database.
- The research team will review risk alerts during weekly safety monitoring meetings.
- Any serious adverse events (e.g., confirmed suicide attempt or psychiatric hospitalization) will be reported to the IRB and sponsor in accordance with regulatory requirements.

4. Participant Education:
- Participants will be informed during onboarding and in the consent form that their questionnaire responses are monitored for safety, and that they may be contacted by the study team if concerning responses are detected.

6.4. Complaint Handling

Participants will be informed of their rights to raise concerns or complaints about any aspect of the study, including conduct by study personnel, privacy issues, or the intervention itself.

1. Communication of Rights
- Participants will be notified of their rights during the consent process and provided with clear instructions on how to submit a complaint.
- Contact information for the Principal Investigator, COMIT Organisations, and the Institutional Review Board (IRB) will be provided in the Participant Information Sheet and Consent Form.

2. Submission of Complaints
- Complaints may be submitted directly to the Research Coordinator or COMIT team via phone or email.

3. Acknowledgment and Initial Response
- All complaints received by the study team will be acknowledged within 2-3 working days.
- The Principal Investigator (or a delegated team member) will review the complaint and provide an initial response or resolution plan within 7 working days.

4. Escalation
- If a complaint cannot be resolved by the study team or involves serious allegations (e.g. safety concerns, misconduct), it will be escalated to the IRB and/or sponsoring institution for further review and investigation.
- All escalated complaints will be documented and managed in accordance with institutional and IRB policies.

5. Documentation
- A log of all complaints, actions taken, and outcomes will be maintained securely and reviewed as part of regular study oversight activities.
- Serious complaints and related actions will be reported in study progress reports to the IRB.

6. Participant Protection
- Participants will be assured that submitting a complaint will not affect their rights to continue in the study or receive care, and that their confidentiality will be maintained throughout the process.

7. DATA ANALYSIS

7.1. Data Quality Assurance

1. **Standardised Data Collection Procedures**
   All data collection tools (e.g., study questionnaires, digital assessments of PHQ-9, GAD-7, WHODAS 2.0) will be standardised and pre-tested to ensure clarity and consistency. RAs will be trained thoroughly on study protocols to minimise variability in data capture.

2. **Training and Quality Assurance for Staff**
   All study team members, including RAs and Investigators, will undergo comprehensive training on data collection procedures for the study, ethical considerations, and handling of sensitive information. Regular supervision will be provided to ensure continued adherence to protocols.

3. **Regular Data Monitoring and Entry Checks**
   Data will be entered into platforms used by the RAs and COMIT providers/counsellors for their daily work. Staff can access data monitoring dashboards to identify abnormal readings, which will be followed up promptly.

7.2. Data Entry and Storage

The data will be entered electronically onto the COMIT provider's client records system and the counsellor dashboard for the iCBT programme. No paper-based data collection will be used. All entries will be made directly by authorised personnel using secure, password-protected systems to ensure data integrity and confidentiality.

Data will be stored on secure, encrypted servers managed by the COMIT team, with access restricted to designated RAs and counsellors based on their roles.

All data handling procedures will comply with relevant data protection regulations and institutional policies, including anonymisation or pseudonymisation where appropriate to safeguard participant privacy.

8. SAMPLE SIZE AND STATISTICAL METHODS

8.1. Determination of Sample Size

Quantitative Study Design

The RCT sample size was determined a priori using a statistical power analysis to ensure adequate power to detect clinically meaningful differences between iCBT and usual care. The calculation was based on the co-primary outcomes of symptom reduction in depression (PHQ-9) and anxiety (GAD-7). Expected effect sizes and outcome variability were informed by prior studies reporting moderate-to-large effects in favour of iCBT. A superiority framework was adopted with equal allocation (1:1) between arms, using a two-sided significance level of $\alpha = 0.05$ and 90% power ($\beta = 0.10$). Under these assumptions, the required sample size for the joint primary endpoint was N = 300 (150 iCBT, 150 usual care). To mitigate loss of power due to anticipated attrition, the sample size was inflated by 30%, yielding a final recruitment target of N = 390 (to preserve the effective analysable sample of ~300 participants at the primary endpoint).

Qualitative Study Design

Data saturation will be used to determine the sample size for the qualitative study. Saturation occurs when no new themes or insights emerge from the data, indicating that sufficient data have been collected to fully understand the phenomenon under study. To achieve saturation, interviews will be conducted iteratively, with ongoing analysis of the data after each interview. Recruitment will continue until saturation is reached.

8.2. Statistical and Analytical Plans

a. General Consideration

This study adopts a mixed-methods design to evaluate the effectiveness and user experience of internet-based cognitive behavioural therapy (iCBT) compared to usual care provided by mental health counsellors. Both quantitative (e.g. symptom scales) and qualitative (e.g. user interviews) data will be systematically collected and analysed to generate a comprehensive understanding of intervention outcomes.

The study is underpinned by the following conceptual frameworks:

- Behavioural Theories
    - Health Belief Model – to understand perceived benefits and barriers that influence iCBT adoption.
    - Transdiagnostic Psychotherapy Approach – to support intervention design targeting common psychological processes across disorders.
- Health Economics Models
    - Cost-Effectiveness Analysis – to compare cost per unit of clinical improvement (e.g. PHQ-9/GAD-7 score changes).
    - Cost-Utility Analysis – to evaluate outcomes in terms of quality-adjusted life years (QALYs).
- Technology Evaluation Models
    - Technology Acceptance Model – to assess users' perceived ease of use and usefulness of the iCBT platform.
    - Technology Readiness Levels – to gauge the platform's maturity and suitability for deployment in real-world settings.

These frameworks collectively inform the study design, implementation, and interpretation of findings, ensuring both clinical and real-world relevance.

b. Safety Analyses

Safety monitoring in this study will focus on identifying and responding to adverse psychological outcomes associated with both the iCBT and usual care arms. The interventions are non-invasive and low-risk but proactive risk monitoring will be adopted for the study.

Primary safety signals will include:

- Clinically significant worsening of symptoms (e.g., PHQ-9 or GAD-7 scores reaching severe levels),
- Reports of suicidal ideation (positive response to PHQ-9 Item 9),
- Participant distress or dropout due to emotional discomfort from the intervention.

Safety data collection will include:

- Weekly review of high-risk PHQ-9/GAD-7 scores flagged through the digital platform,
- Logs of adverse events and complaints maintained by the study team,
- Escalation events handled as per the predefined risk protocol.

Safety outcomes will be summarised using descriptive statistics (e.g., frequency and proportion of high-risk cases, dropout reasons) and reviewed regularly by the study team. Any serious adverse events (SAEs) or protocol violations related to participant safety will be reported to the IRB within the required timelines.

c. Interim Analyses

An interim analysis will be conducted at the midpoint of the recruitment period or when approximately 50% of the total sample size has completed both baseline and post-intervention assessments.

The primary purposes of the interim analysis are to:

- Monitor emerging trends in effectiveness (e.g., change in PHQ-9 and GAD-7 scores),
- Evaluate safety data, particularly adverse psychological outcomes,
- Assess retention rates, dropouts, and adherence to both interventions.

All interim analyses will be reviewed internally by the study team. If necessary, consultation with an independent clinical advisor or ethics representative may be sought.

d. Types and Timing of Statistical Interim Analyses

Descriptive analyses of demographic and baseline characteristics by group allocation to ensure balance between arms which include:

- Paired t-tests or non-parametric equivalents (e.g., Wilcoxon signed-rank test) to assess pre-post changes in mental health scores within each arm.
- Independent t-tests or ANOVA to detect early between-group differences in outcomes.
- Dropout and adherence rates analysed using proportions and compared between arms using chi-square tests.

9. DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

The investigator(s) and participating institution(s) agree to provide direct access to source data and documents as necessary for the purposes of study-related monitoring, quality assurance audits, Institutional Review Board (IRB)/Ethics Committee review, and inspections by applicable regulatory authorities.

10. QUALITY CONTROL AND QUALITY ASSURANCE

All study data will be regularly evaluated to ensure adherence to the protocol. This process will involve cross-checking data entries in the electronic data capture (EDC) system against original source documents if available (e.g., COMIT assessment forms). The review will focus on the consistency, completeness, and accuracy of recorded information, as well as timely documentation of protocol-specified procedures and outcomes.

Trained study monitors will conduct on-site or remote monitoring visits at regular intervals to assess data quality and compliance with the approved protocol and Good Clinical Practice (GCP) standards. Any discrepancies or missing data identified during monitoring will be documented and addressed through data queries, with resolution tracked and verified.

11. ETHICAL CONSIDERATIONS

This study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with the Good Clinical Practice and the applicable regulatory requirements.

This final Study Protocol, including the final version of the Participant Information and Consent Form, must be approved in writing by the NUS-IRB, prior to enrolment of any patient into the study.

The principal investigator is responsible for informing the NUS-IRB of any amendments to the protocol or other study-related documents, as per local requirement.

11.1. Informed Consent

NUS-IRB approved study team members who are delegated for obtaining of informed consent will be appropriately trained in the informed consent process and have a thorough understanding of the study. The informed consent shall be taken in a private and comfortable setting, free from coercion or undue influence, in the presence of a witness either virtually via secure videoconferencing platforms or in-person. Study information will be explained to the potential participant and ample time will be allocated for discussion to ensure that all questions are answered satisfactorily. A copy of the signed and dated informed consent form (ICF) will be provided to the participant. All original signed ICFs, along with a documentation of the informed consent process, will be maintained in the study files in a secure location.

11.2. Confidentiality of Data and Patient Records

All data collected in this study will be handled with strict adherence to confidentiality and data protection standards. Subject confidentiality will be maintained throughout the study and in all resulting publications or

reports. Participants will be assigned unique client IDs, and all data will be stored and analysed using these identifiers to ensure anonymity. No identifiable personal information will be included in datasets used for analysis.

Electronic data will be stored on secure, encrypted servers with access restricted to authorised study personnel only. The systems used (including the COMIT provider's client records platform and counsellor dashboard) are protected by role-based access controls and strong password protocols to secure data access and modification.

12. PUBLICATIONS

All study findings will be disseminated through peer-reviewed scientific journals, conference presentations, and other appropriate academic channels in accordance with ethical standards for research publication. Authorship will follow the International Committee of Medical Journal Editors (ICMJE) criteria, based on significant contributions to the study. Individuals who contribute but do not meet authorship criteria will be acknowledged appropriately.

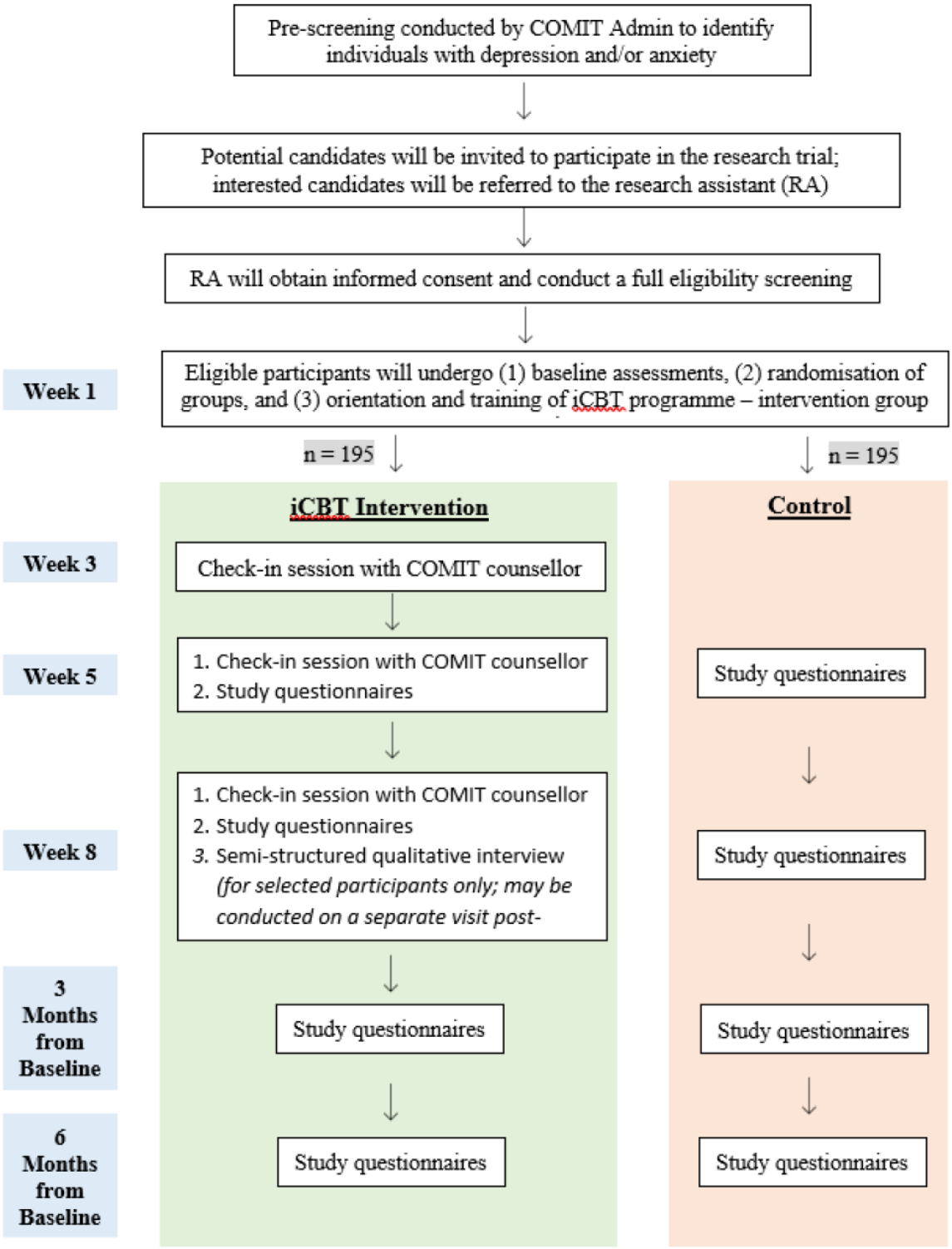
All publications must be reviewed and approved by the Principal Investigator and relevant co-investigators. Where applicable, institutional or departmental publication policies (e.g., [insert institution name]) will be followed.

13. RETENTION OF STUDY DOCUMENTS

All study documents, including CRFs, all source documentation, as well as IRB records and other regulatory documentation will be securely retained electronically by the Principal Investigator in a controlled-access location. Study documents that contain personally identifiable information will be securely retained by the respective COMIT providers in a controlled-access location for a minimum of 7 years following study completion.

List of Attachments

Appendix A- Participant Trial Workflow



Appendix B- Study Questionnaires

1. **Initial Data Collection Form**

- Name:
- Date of Birth:
- Sex: Male/ Female
- Race:
- Past Medical History:
- Past Psychiatric History:
- Current Medications:

2. **Patient Health Questionnaire-9 (PHQ-9)[16]**

Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

- PHQ-9 Total Score:

3. **Generalised Anxiety Disorder-7 (GAD-7)[17]**

Over the last two weeks, how often have you been bothered by the following problems?

	Not at all	Several days	More than half the days	Nearly every day

1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid, as if something awful might happen	0	1	2	3

- GAD-7 Total Score:

4. WHODAS 2.0 12-item version[18,19]

When scoring WHODAS, the following numbers are assigned to responses:
0 = No Difficulty
1 = Mild Difficulty
2 = Moderate Difficulty
3 = Severe Difficulty
4 = Extreme Difficulty
or Cannot Do

In the past 30 days, how much difficulty did you have in:		Score
S1	Standing for long periods such as 30 minutes?	0
S2	Taking care of your household responsibilities?	0
S3	Learning a new task, for example, learning how to get to a new place?	0
S4	How much of a problem did you have in joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	0
S5	How much have you been emotionally affected by your health problems?	0
S6	Concentrating on doing something for ten minutes?	0
S7	Walking a long distance such as a kilometre [or equivalent]?	0
S8	Washing your whole body?	0
S9	Getting dressed?	0
S10	Dealing with people you do not know?	0
S11	Maintaining a friendship?	0
S12	Your day-to-day work/school?	0
	Overall Score	

H1	Overall, in the past 30 days, how many days were these difficulties present?	
H2	In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition?	
H3	In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?	

5. Qualitative Data Form

A. User Experience & Engagement

i. How would you describe your overall experience with the iCBT app?
ii. What features of the app did you find most helpful? Why?
iii. Were there any aspects of the app that were difficult to use or understand?

B. Perceived Clinical Effectiveness

iv. Do you feel the app helped improve your mental health symptoms (e.g., anxiety, depression)? How?
v. Can you share any specific changes you noticed in your thoughts, behaviors, or emotions after using the app?
vi. Were there any exercises or modules that stood out as particularly effective or ineffective?

C. Barriers & Challenges

vii. Did you face any challenges while using the app? (e.g., technical issues, lack of motivation)
viii. What would have improved your experience with the app?

D. Comparison to Traditional Therapy (if applicable)

ix. If you've had face-to-face therapy before, how did this app compare?

E. Suggestions for Improvement

x. What changes would you recommend to make the app more effective for users like you?

Appendix C – References

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