

Improving Women's Mental Health through tele-based Wellbeing Centres in Bangladesh: An Efficacy Trial

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List of Abbreviation

Abbreviation	Full Form
CBT	Cognitive Behavioural Therapy
CBT-TF	Cognitive Behavioural Therapy with a Trauma Focus
CONSORT	Consolidated Standards of Reporting Trials
DGHS	Directorate General of Health Services
DH	District Hospital
DMHI	Digital Mental Health Interventions
DSMB	Data Safety Monitoring Board
DID	Difference-in-Difference
eCRF	Electronic Case Report Form
WHOQOL-BREF	World Health Organization Quality-of-Life Scale
ERC	Ethical Review Committee
FACT-L	Functional Assessment of Cancer Therapy-Lung
FIML	Full Information Maximum Likelihood
GAD-7	Generalized Anxiety Disorder-7
GoB	Government of Bangladesh
icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh
IDI	In-Depth Interview
IRB	Institutional Review Board
IT	Information Technology
ITT	Intention-To-Treat
KII	Key Informant Interview
LMIC	Low- and Middle-Income Countries
MCHD	Maternal and Child Health Division
mhGAP	Mental Health Gap Action Programme
NCDC	Noncommunicable Disease Control
NGO	Non-Governmental Organization
NIMH	National Institute of Mental Health
PHQ-9	Patient Health Questionnaire-9
PMF	Performance Measurement Framework
PP	Per-Protocol
PTSD	Posttraumatic Stress Disorder
R&LA	Regulatory and Legal Affairs
RA	Research Administration
RCT	Randomized Controlled Trial
RRC	Research Review Committee
SAE	Severe Adverse Events
SDG	Sustainable Development Goal
TMH	Tele-Mental Health
TUQ	Telehealth Usability Questionnaire
WAI	Working Alliance Inventory
WBC	Wellbeing Centre

Project Summary

[The summary, within a word limit of 300, should be stand alone and be fully understandable.]

Principal Investigator: Anika Tasnim Hossain
Research Protocol Title: Improving Women's Mental Health through tele-based Wellbeing Centres in Bangladesh: An Efficacy Trial
Background (brief): a. Burden: Women in Bangladesh face a high mental health burden, with 22% experiencing mental disorders compared to 16% of men. Access to face to face psychological care is limited by stigma, financial barriers, restricted mobility, and shortage of trained professionals, resulting in a major treatment gap. b. Knowledge gap: Evidence on tele mental health effectiveness mainly comes from high income countries. In Bangladesh, evidence is limited to observational studies, and it remains unclear whether tele counselling is as effective as in person care for women. c. Relevance: This randomized non-inferiority trial will evaluate whether tele counselling can achieve comparable outcomes to face to face care. Findings will support policy decisions and scale up of accessible mental health services for women in Bangladesh, aligned national, global and institutional goals. Hypothesis (if any): 1. Tele based counselling through WBC is hypothesised to be non-inferior to in person counselling in improving women's mental health outcomes, quality of life, and overall wellbeing, with comparable acceptability, accessibility, and usefulness. Objectives: This study aims to evaluate whether tele based counselling through Wellbeing Centres is a clinically non-inferior and feasible alternative to in person counselling for improving women's mental health and quality of life in Bangladesh. Methods: The investigators propose a two-arm randomized controlled non-inferiority trial among 1200 women with moderate to severe depression or anxiety. Participants will be randomized to tele counselling through Wellbeing Centres or standard face to face counselling using identical protocols. Outcomes including PHQ-9, GAD-7, WHOQOL-BREF, WHO-5, and GHQ-12 will be assessed at baseline and 2, 4, and 6 months. Quantitative and qualitative analyses will evaluate clinical effectiveness, feasibility, acceptability, accessibility, usability and treatment experiences. Outcome measures/variables: Primary outcomes are changes in depression (PHQ-9) and anxiety (GAD-7) scores. Secondary outcomes include quality of life (WHOQOL-BREF), psychological distress (GHQ-12), mhGAP conditions, wellbeing (WHO-5), and service acceptability, accessibility, and usefulness. All measures will be assessed at baseline and at 2, 4, and 6 months.

Description of the Research Project

This research project, titled "Improving Women's Mental Health through tele-based Wellbeing Centres in Bangladesh: An Efficacy Trial," is a two-arm, randomized controlled non-inferiority trial designed to evaluate the clinical effectiveness of remote psychological care. The primary objective is to determine whether structured tele-counselling delivered via government-introduced Wellbeing Centres (WBCs) is non-inferior to standard face-to-face counselling in reducing symptoms of depression and anxiety, and in improving the overall quality of life for women in Bangladesh. A total of 1200 adult women presenting with moderate or severe symptoms (screened using validated PHQ-9 and GAD-7 tools) across two selected healthcare facilities will be randomized in a 1:1 ratio to receive either remote tele-counselling or in-person counselling from a site-appointed psychologist. To isolate the true effect of the delivery modality, both intervention arms will strictly utilise the exact same counselling manual, number of sessions, duration, and supervision structure. Quantitative clinical outcomes-specifically symptom reduction and quality of life improvements (measured via WHOQOL-BREF)-will be assessed during follow-ups at 2, 4, and 6 months post-intervention. Furthermore, the trial incorporates a qualitative component that utilises in-depth and key informant interviews with service users, their families, psychologists, and hospital authorities to comparatively explore treatment experiences, socio-cultural dimensions, and technological mediation of Cognitive Behavioural Therapy (CBT) models. Ultimately, this project seeks to fill a critical evidence gap by providing high-quality, comparative data to inform national health policy and to determine whether tele-mental health model is an effective alternative for expanding mental health access for vulnerable women in low-resource settings.

Hypothesis to be tested:

Does this research proposal involve testing of hypothesis: ☐ No ☒ Yes (describe below)

Tele based counselling through WBC is hypothesised to be non-inferior to in person counselling in improving women's mental health outcomes, quality of life, and overall wellbeing, with comparable acceptability, accessibility, and usefulness.

Specific Objectives:

Primary Objectives

- i. To assess whether tele based counselling through the Wellbeing Centre (WBC) is as effective as standard in person counselling in reducing depressive symptoms among women, measured using the PHQ-9.
- ii. To assess whether tele based counselling through the Wellbeing Centre (WBC) is as effective as standard in person counselling in reducing anxiety symptoms among women, measured using the GAD-7.

Secondary Objectives

- i. To compare improvements in quality of life (WHOQOL-BREF) and overall wellbeing (WHO-5) between women receiving tele counselling and in person counselling.
- ii. To compare reductions in psychological distress (GHQ-12) and monitor mhGAP guided conditions and diagnoses across both counselling approaches.
- iii. To assess and compare the acceptability, accessibility, and usefulness of tele counselling and in person counselling from participants' perspectives during follow up.
- iv. To explore participants' and providers' experiences, perceptions, and social and cultural factors related to receiving and delivering technology based mental health services.
- v. To evaluate if exposure to gender-based violence serves as a moderator of clinical recovery, and to assess whether mental health improvements yield a positive spillover effect on maternal immunisation and preventative healthcare uptake.
- vi. To evaluate and compare the direct implementation and operational costs of the Wellbeing Centre tele-counselling model with standard in-person counselling.

Background of the Project including Preliminary Observations:

Global and Regional Mental Health Disorders Burden

Mental health conditions like depressive and anxiety disorders, represent one of the leading causes of disability and morbidity around the world (1). Globally, 1 in 7 people live with mental disorders, especially, 359 million people were living with anxiety disorders and 280 million people were living with depression (2), which are characterized by a distinctly diminished interest in usual activities, reduced energy, and persistent feelings of worthlessness (1). These conditions can result in substantially diminished quality of life, lost economic productivity, and increased risk of suicidal (1). This global burden is disproportionately concentrated in Low- and Middle-Income Countries (LMICs), where systemic resource limitations, poverty, environmental degradation, and chronic psychosocial stress significantly intensify population vulnerabilities (3). In Bangladesh, the burden of mental health reveals a substantial and persistent gender disparity, where women experience a substantial and unmet burden of mental health conditions. According to the National Institute of Mental Health 2019 survey, 22% of women were living with a mental disorder compared with 16% of men, highlighting a persistent gender gap in mental health needs and service utilisation in Bangladesh (4). This disparity stems from a complex

matrix of structural determinants exclusively affecting women, including restricted autonomy (5, 6), high rates of intimate partner violence (7), and limited access to supportive healthcare environments (5, 6).

Mental Health Service Gap

Despite the proven clinical efficacy of face-to-face psychotherapeutic interventions, such as Cognitive Behavioural Therapy (CBT), the global mental health treatment gap remains evident (8). Traditional face-to-face psychological counselling is tremendously resource-intensive, requiring highly trained clinicians, dedicated clinical infrastructure, and substantial time commitments from patients (8). This restricts the coverage of face-to-face psychological counselling even in high-income contexts, whereas, in LMICs shortage of mental health workforce worsen the condition where majority of the people did not receive required care (3). Those who actively seek help often face prolonged waiting times for both psychiatric or psychological services, whereas, studies shows that waiting times for psychotherapy can elevate the risk for symptom deterioration among individuals (9). In Bangladesh context, women faces significant challenges in accessing in-person mental health services, where mental health services are severely constrained with only 0.16 psychiatrists, 0.34 psychologists, and 0.4 nurses per 100,000 population in urban areas, where only 0.49% of the healthcare providers trained to deliver mental health services (10). According to the National Mental Health Survey 2018-2019, nationwide the treatment gap for adult was 91.0% and for children it was 94.3% for different mental disorders (11). However, the government is spending very little for getting mental health treatments illustrating merely 0.44% of the total health budget in Bangladesh (12). Besides, mental healthcare services are exceedingly inaccessible throughout Bangladesh particularly in rural areas (13, 14) due to the absence of mental health professionals, lack of mental health services in primary level facilities, asymmetrical formation of health facilities in urban areas and big cities, and unstructured national policies (14-16).

The Emergence of Tele-Mental Health

To overcome these systematic and structural barriers, health systems have increasingly adopted digital psychiatry and tele-mental health solutions, whose adoption exponentially accelerated following the COVID-19 pandemic (3). Tele-mental health (TMH) leverages videoconferencing technology and internet platforms to connect patients directly with remote providers, effectively bypassing barriers related to geography, logistics, and stigma (17). Besides, tele mental health has been found to be efficient for diagnosing and lessening common mental disorders and enhancing quality of life in different ambience over mass population (18, 19). Many logistical obstacles like delayed time to appointment, transportation, financial obligations, stigma related to traditional in-person consultancy are seemed to be

minimized in video-conference based tele-consultation (20-25). Patients are further intended to tele-consultation as a more convenient alternative to traditional in-person care (26-29) due to compatible high satisfaction level in TMH services (18, 25, 30, 31). Participatory research studies highlight that integrating digital mental health interventions (DMHIs) into routine clinical practice requires careful alignment with the needs of both patients and mental health professionals (32). Moreover, trials in primary care settings have demonstrated the practical effectiveness of guided internet-based treatments, emphasizing that, with adequate support, digital platforms can seamlessly integrate into routine care to manage depression and anxiety on a large scale (33).

Efficacy of Tele-counselling vs Face-to-face Interventions

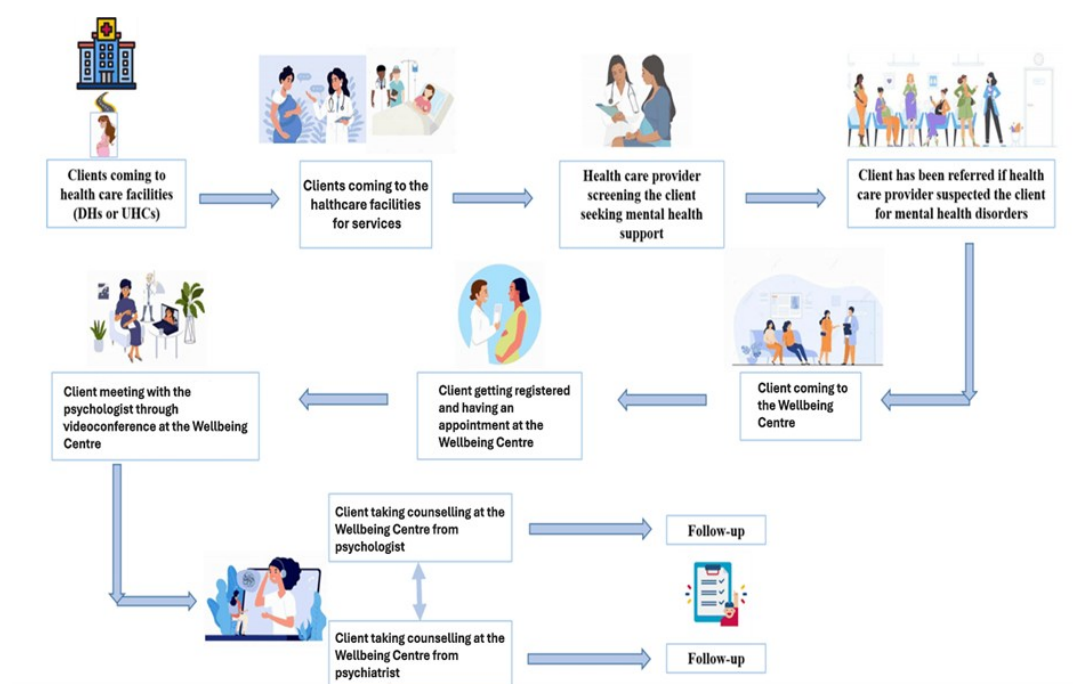
A robust and expanding body of literatures demonstrates compelling evidence supporting the effectiveness of tele-counselling and usually non-inferior to traditional face-to-face treatment. For example, one meta-analysis evaluating 54 randomized controlled trials (RCTs) comprising over 5,400 participants, finding no significant difference in primary patient-important outcomes between therapist-guided remote CBT and in-person CBT (34). Similarly, a comprehensive meta-analysis by synthesizing 57 studies, evaluating videoconference mental health services using a Hierarchical Linear Model, concluding that tele-interventions produced symptom reductions statistically identical to in-person services (17). These findings are corroborated by another systematic review study which analysed trials focusing on PTSD, mood, and anxiety disorders, finding an overall standard mean difference effect size near zero (-0.01) (35). Furthermore, for PTSD, the RAPID trial demonstrated that a guided internet-based CBT program with a trauma focus (CBT-TF) was non-inferior to, and significantly cheaper to deliver than, individual face-to-face CBT-TF at 16 weeks (36). In early palliative care, a multisite RCT of 1,250 patients with advanced lung cancer found that care delivered via secure video produced quality-of-life scores (measured by FACT-L) clinically equivalent to in-person visits (37). Moreover, therapeutic alliance, comprising the bond, agreement on goals and tasks, can be successfully established in digital settings as well, as one RCT Trial study comparing online and face-to-face CBT for depression found highly comparable Working Alliance Inventory (WAI) scores across both formats (38). In recent times, another study evaluated therapeutic alliance and client satisfaction across tele-counselling, in-person, and hybrid modalities in Saudi Arabia and found a moderate to strong positive relationship between WAI scores and client satisfaction across all delivery modes (39).

Preliminary Observations: Wellbeing Centres in Bangladesh

In response to these unmet mental health needs of women, the Government of Bangladesh, alongside implementation partners, introduced Wellbeing Centres.

These Centres provide a tele based mental health platform designed to provide structured counselling services within primary and secondary level facilities (i.e., District Hospitals and Upazila health Complexes). The model aims to overcome known barriers to care, including stigma, financial hardship, household responsibilities and mobility restrictions that often prevent women from seeking in-person services. Early implementation evidence indicates that Wellbeing Centres are feasible to operate within constrained health system settings, acceptable to both clients and providers, and associated with indicative reductions in standardised symptom scores for depression and anxiety (40).

Figure 1: Mental Health Service Delivery Mechanism of Wellbeing Centre



However, the existing evidence on Wellbeing Centres comes primarily from observational implementation research, which, although useful for assessing feasibility and acceptability, cannot establish causal effects on clinical outcomes. Observational studies are inherently limited by selection bias, unmeasured confounding, and variability in how services are delivered. These factors make it difficult to determine whether the observed improvements in symptom scores can truly be attributed to the tele-based intervention. As a result, the current evidence base does not clarify whether tele-counselling provides clinical benefits comparable to those achieved through standard in-person psychological care. Without a rigorous comparative design that controls for baseline differences and isolates the intervention effect, it is not possible to accurately assess the clinical effectiveness of a tele only model or determine whether it is suitable for broader system level adoption.

Rationale for the Proposed Project

High quality evidence is essential before policymakers can rely on tele based counselling as a trusted, scalable approach for meeting the mental health needs of women in low resource settings, especially when decisions about integration and national scale up depend on robust evidence of comparable clinical impact. As shown above, existing international evidence suggests that tele-mental health interventions are clinically equivalent to face-to-face treatment. Besides, systematic reviews and meta-analysis provide evidence that remote delivery of cognitive behavioural and psychiatric interventions similarly yields non-inferior reductions on symptom severity across a range of mental health conditions (17, 34, 35). However, majority of the findings are based on high-income country context and no rigorous efficacy studies have yet been conducted in Bangladesh, where available evidence predominantly limited to observational implementation research. Hence, without a rigorous comparative design, it is not possible to determine whether a tele only model can be trusted as an alternative for scaling mental health support for women in low resource settings like Bangladesh. A recent multisite randomized clinical trial validated this approach, illustrating that telehealth delivery is similar to in-person care in improving quality of life, suggesting the suitability of this metric for measuring remote care models (37). But, this evidence is lacking in Bangladesh context.

Therefore, this project proposes a rigorous Non-Inferiority Randomized Controlled Trial to directly compare structured tele-counselling delivered through Wellbeing Centres with standard in-person counselling for women in Bangladesh. The trial will assess reductions in depression and anxiety, and improvement in quality of life to determine whether the tele model can achieve non-inferior results suitable for national scale up. The investigators will recruit approximately 1200 women presenting with moderate or severe symptoms across two hospitals (600 at Dinajpur District Hospital and 600 at Matlab Dakshin Upazila Health Complex), randomizing them (1:1) to receive either tele-counselling via a secure video platform or face-to-face counselling. To ensure robust methodological fidelity and isolate the delivery modality's effect, both arms will use the exact same counselling manual, session duration, and supervision structure.

The research question is highly relevant to both the global Sustainable Development Goals and icddr's strategic priorities. It directly supports SDG 3, which emphasizes ensuring healthy lives and promoting wellbeing for all, with a specific focus on improving mental health and expanding access to quality, equitable services. In Bangladesh, women face substantial barriers to seeking mental health care because of stigma, mobility limitations, financial constraints and the scarcity of trained professionals. By examining whether tele based counselling delivered through Wellbeing Centres can achieve outcomes comparable to standard in-person counselling, the study addresses a critical evidence gap in designing accessible,

scalable and effective mental health services for women. The research question is also closely aligned with Goal 2.6, Priority 7 of icddr,b's strategic priority, which highlights the need to identify major health conditions affecting women, understand their determinants and support nationwide implementation of comprehensive mental health support systems through Wellbeing Centres within primary healthcare. Evidence from a rigorous comparative evaluation is essential to guide quality improvement, inform national policy, and strengthen the case for scaling tele based mental health models. The study therefore contributes directly to the institution's goal of improving maternal and child health outcomes through innovations that address neglected health issues affecting women.

Description of the Intervention

The proposed efficacy trial study evaluates Wellbeing Centres (WBCs), dedicated, private rooms set up inside local government hospitals (i.e., District Hospitals and Upazila Health Complexes). This digital model is designed to help women in rural and semi-urban Bangladesh overcome barriers like distance, cost, and stigma. By using these Centres, women can easily access specialized mental health care, which is especially critical during pregnancy and after childbirth.

Figure 2: Patient Getting Tele-counselling Services at WBC



To rigorously evaluate this model, enrolled women will be divided into two groups (arms) that receive the same structured counselling, for the same duration, but delivered in different ways:

- **Arm 1 (Tele-counselling Intervention):** Women will visit the Wellbeing Centre at their local hospital and receive counselling service via a secure video call with a highly qualified, remotely located psychologist.
- **Arm 2 (In-person Control):** Women will visit a similar private room at the hospital and receive traditional face-to-face counselling service from a psychologist working on-site.

By comparing these two arms, the investigators can accurately determine if the tele-counselling sessions are just as effective at reducing symptoms as standard in-person care. To provide a comprehensive overview before detailing the trial methodology, the intervention is broken down into four core operational components:

1. Demand Generation and Patient Identification: Before initiating clinical counselling, the project will implement targeted Social and Behavioural Change Communication (SBCC) strategies. Culturally appropriate communication materials, including posters and informative leaflets, will be actively distributed throughout the hospital's outpatient departments. These materials are designed to raise awareness among women and their families about maternal mental health, destigmatize psychological distress, and inform them about the free services available at the facility.

The patient pathway begins in the outpatient wards, specifically during routine Antenatal Care (ANC) and Postnatal Care (PNC) visits, or general visits for women seeking care. The attending healthcare providers will conduct a brief initial mental health needs assessment. If a woman exhibits signs of psychological distress, she will be introduced to a trained Field Assistant (FA) who will formally screen her using validated psychometric tools (the PHQ-9 for depression and GAD-7 for anxiety). Women meeting the threshold for moderate or severe symptoms will be invited to enrol in the trial.

2. Physical Setup and Technological Infrastructure: A cornerstone of the WBC model is ensuring that remote care feels as personal, safe, and confidential as traditional psychological counselling. A dedicated room within the facility will be allocated and refurbished to serve as the Wellbeing Centre. To ensure strict audio and visual privacy, the room will be sound-secured, windows will be covered with veils, and appropriate lighting will be installed.

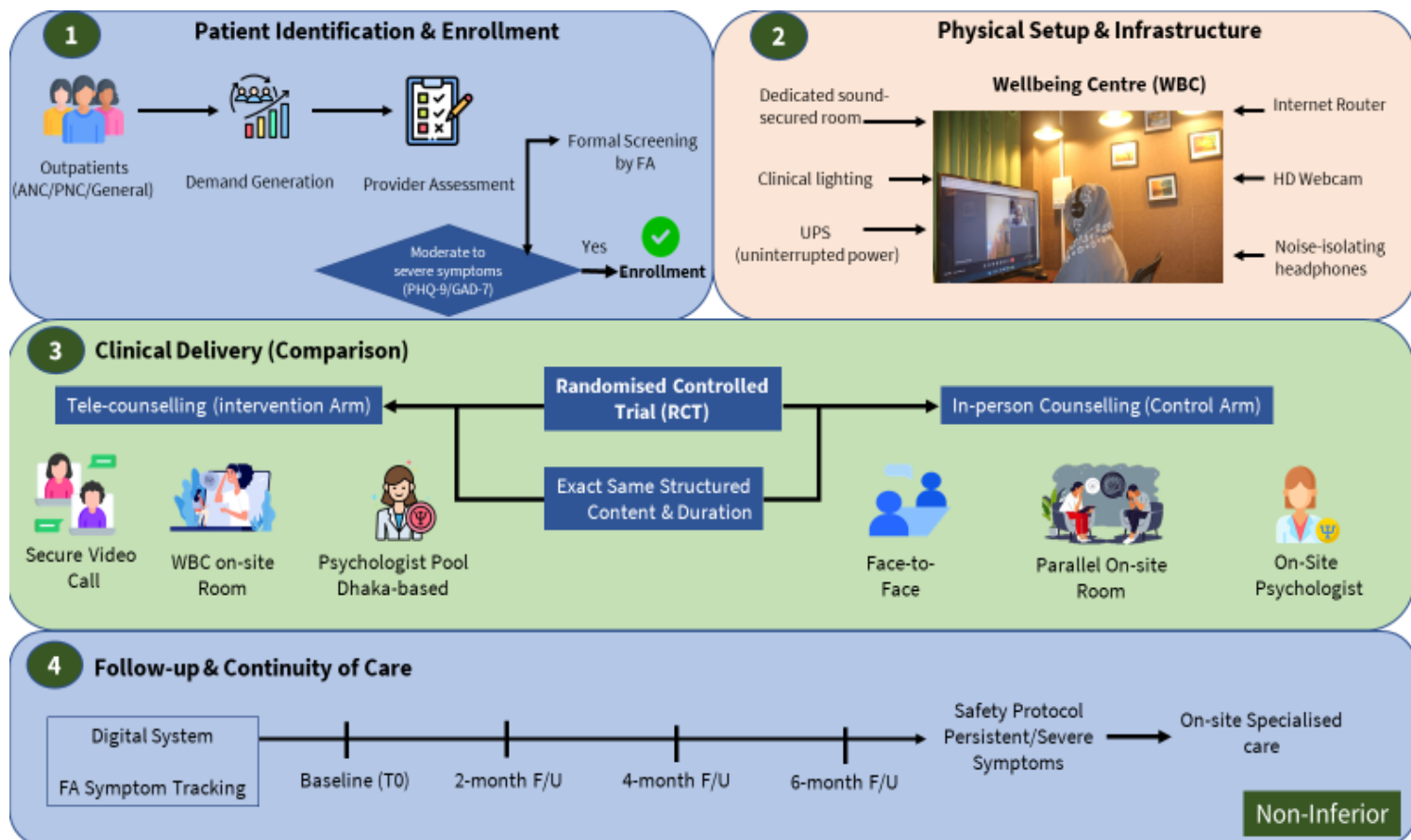
Technologically, the room will be equipped with a computer, a high-speed internet router, and a high-definition webcam. To mitigate infrastructure challenges common in resource-poor settings, an Uninterrupted Power Supply (UPS) will be installed to prevent session disruption during electricity failures. Furthermore, to cancel ambient hospital noise and ensure absolute confidentiality, both the patient and the remote psychologist will use noise-isolating headphones. The webcam will be strategically positioned at the client's eye level to closely approximate natural, face-to-face eye contact, and prior to the first session, "test calls" will be conducted to evaluate video, audio, and connection quality. The overall setup adheres strictly to the tele-mental health Standard Operating Procedures (SOPs).

3. The Provider Pool and Clinical Delivery: The tele-counselling services will be delivered via a secure, password-protected videoconferencing platform by a centralized pool of highly qualified clinical psychologists operating remotely (i.e., from Dhaka).

Participants randomized into the intervention arm will receive structured, evidence-based psychological counselling through this tele-platform. Conversely, participants randomized to the control arm will receive the exact same structured counselling, for the same duration and frequency, but delivered in-person by a site-appointed psychologist in a parallel private room at the facility. This guarantees that the therapeutic content remains identical across both arms, isolating the delivery modality (tele-video vs. face-to-face) as the sole variable being tested in the non-inferiority trial.

4. Follow-up and Continuity of Care: Each arm will utilise a digital registration and appointment-keeping system to manage patient schedules and ensure continuity of care. As established in the trial timeline, participants will receive their baseline assessment and first session (T_0), followed by scheduled counselling sessions. Follow-up assessments to measure the reduction in symptom severity will be rigorously tracked by the FAs at 2, 4, and 6-month intervals. If severe symptoms persist or deteriorate, strict safety protocols will be triggered to refer the patient to specialized psychiatric care.

Figure 3: Overview of the Proposed Non-Inferior RCT for WBC Model



Research Design and Methods:

Study Design and Methodological Approach

This proposed study will be conducted as a two-arm parallel-group, randomized controlled non-inferiority trial. The primary objective is to evaluate whether structured tele-counselling delivered through Wellbeing Centres is clinically non-inferior to standard face-to-face (in-person) counselling for women experiencing symptoms of depression and anxiety in Bangladesh.

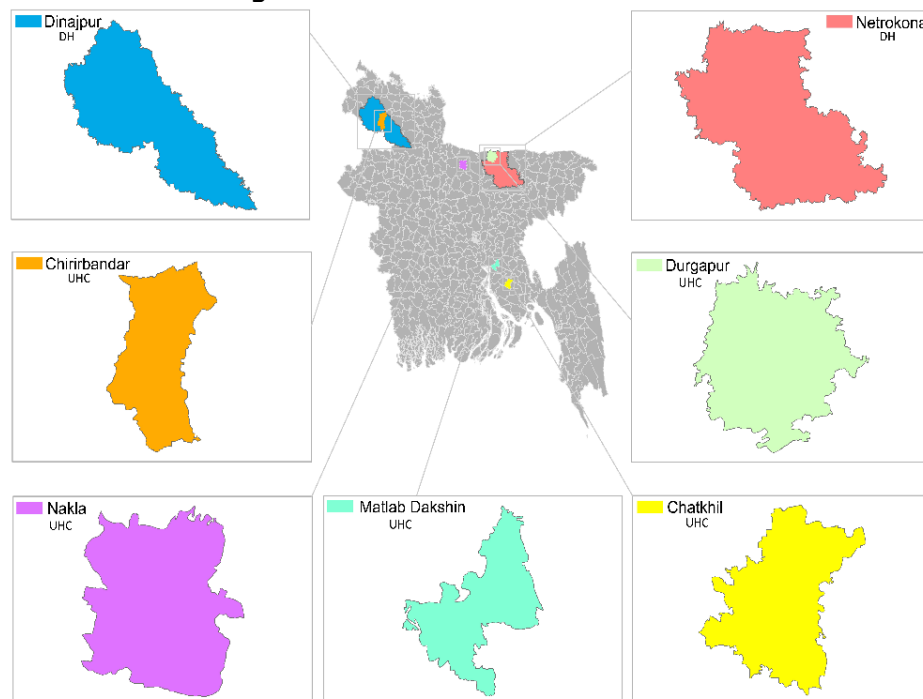
The choice of a non-inferiority design is scientifically and methodologically imperative in this context. The primary research objective in a non-inferiority trial is not to prove that the proposed methods (tele-counselling) is superior in reducing clinical symptoms, when transitioning from an established evidence-based delivery platform (i.e., face-to-face counselling) to an innovative and novel delivery platform (i.e., tele-counselling) (41). Rather, according to the Consolidated Standards of Reporting Trials (CONSORT) extension for non-inferiority trials, the goal is to demonstrate that the new delivery method is not unacceptably worse (i.e., non-inferior) to the standard treatment, while simultaneously providing critical benefits (41). In this study context, tele-counselling service delivery offers profound systemic advantages, including increased geographic accessibility, reduced patient travel burden, lower out-of-pocket costs, and greater potential for nationwide scalability. Furthermore, to eliminate psychologist variability concern, two appointed psychologists will be involved in delivering counselling services for both treatment conditions. Especially, the psychologists will conduct both tele-counselling and in-person counselling, swapping roles halfway through the six-month intervention delivery period. This method avoids confounding the effects of the treatment modality with the therapists' individual qualifications, therapeutic skills, or allegiance effects, ensuring that any differences in clinical outcomes between the intervention and control arms are strictly attributable to the delivery platform itself rather than the practitioner.

Study Setting

Currently Wellbeing Centre (WBC) implementation is ongoing in 2 district hospitals (i.e., Dinajpur DH & Netrokona DH) and 5 Upazila Health Complexes (i.e., Durgapur UHC, Chirirbandar UHC, Nakla UHC, Chatkhil UHC, & Matlab UHC). Among active Wellbeing Centres, Dinajpur District Hospital (DH) and Matlab Dakshin Upazila Health Complex (UHC) have been finalized as the two study sites based on feasibility assessments and discussions with hospital authorities. Dinajpur DH represents a high-volume regional urban catchment area in northern Bangladesh, whereas Matlab Dakshin UHC represents a peri-urban/rural demographic in Chandpur district with a long history of maternal and child health surveillance through icddr,b. This dual-site

setting significantly improves the external validity of our trial findings. A dedicated room will be allocated for the in-person psychologist control arm, while the intervention arm utilises existing Wellbeing Centre model.

Figure 4: Study Sites of Wellbeing Centres



Target Population and Eligibility Criteria

The target population comprises adult women actively seeking healthcare services at the two selected study facilities. To strictly maintain the high internal validity of the 'One Facility' approach and successfully control for population-level confounders, the investigators will execute the within-facility 1:1 randomization independently within each hospital (Dinajpur DH and Matlab Dakshin UHC). Recruitment will not be extended to other healthcare facilities. Within the selected hospital, participants will be proactively recruited from general outpatient wards, as well as routine Antenatal Care (ANC) and Postnatal Care (PNC) clinics. To ensure the study sample is well-defined and appropriate for the non-inferiority trial design, participants must meet all of the following inclusion and exclusion criteria -

Inclusion Criteria

1. **Demographics:** Female, aged 18 years and above at the time of enrolment.
2. **Clinical Threshold:** Presenting with moderate to severe symptoms of depression or anxiety. This will be objectively defined and confirmed by a score of ≥ 10 on the Patient Health Questionnaire-9 (PHQ-9) and/or the Generalised Anxiety Disorder-7 (GAD-7) scale during the formal baseline

assessment. Specifically, moderate, moderately severe, and severe depression are defined by PHQ-9 cut-off scores of 10, 15, and 20, respectively. Moderate and severe anxiety are defined by GAD-7 cut-off scores of 10 and 15, respectively.

3. **Trial Compliance:** Demonstrated willingness to be randomly assigned (1:1 ratio) to either the tele-counselling intervention arm or the in-person active control arm.
4. **Informed Consent:** Provision of voluntary, written informed consent prior to any baseline data collection or clinical intervention.

Exclusion Criteria

1. **Severe Psychiatric Comorbidity:** Presence of acute or severe psychiatric disorders that require immediate, specialised psychiatric hospitalisation or intensive management (e.g., active psychosis, severe bipolar affective disorder, or severe substance dependence).
2. **Imminent Safety Risk:** Demonstration of a high risk of suicide or self-harm, as identified during the initial screening (e.g., via a high score on PHQ-9 Item 9), which requires immediate crisis management rather than standard outpatient counselling. To ensure these vulnerable individuals are not left without support, any woman excluded under this criterion will trigger an immediate emergency pathway: the Field Assistant will immediately escort her to the on-site Study Physician for an urgent clinical evaluation. Following this assessment, the Study Physician will facilitate a direct referral to the hospital's emergency department or psychiatric unit for crisis stabilisation, or to the National Institute of Mental Health (NIMH) for specialised care.
3. **Concurrent Treatment:** Currently receiving ongoing structured psychological counselling or formal psychological treatment from another provider, to prevent confounding the treatment effects of the trial.
4. **Medical or Cognitive Impairment:** Presence of severe cognitive impairment, intellectual disability, or acute medical instability that would preclude the participant from comprehending the therapeutic material or safely engaging in weekly counselling sessions.

Concurrent Care and Management of Comorbidities: To accurately isolate the specific effects of the counselling interventions from other treatments, strict protocols regarding concurrent care will be implemented. As established in the eligibility criteria, patients presenting with severe psychiatric comorbidities requiring immediate hospitalisation, or those currently receiving structured psychological counselling elsewhere, are excluded. For participants with stable, non-exclusionary comorbidities

(e.g., chronic physical health conditions), standard routine medical care will continue uninterrupted. However, participants will be requested to maintain stable dosages of any existing psychiatric medications and to refrain from initiating new formal psychological therapies during the six-month trial period.

To rigorously investigate whether clinical improvements are attributable to the trial interventions rather than external treatments, any changes to a participant's medication or additional care sought will be systematically documented at each follow-up assessment (T₁, T₂, and T₃). During the statistical evaluation, any reported changes in concurrent treatments or medication will be incorporated and controlled for as covariates within the linear mixed-effects models. This statistical adjustment ensures that the specific efficacy of the tele-counselling delivery platform is accurately evaluated, independent of external treatment effects.

Interventions and Exposure Variables

The primary exposure variable is the modality of psychological service delivery.

1. **Arm 1 (Intervention):** Women will attend a private room at the facility's Wellbeing Centre and receive live counselling from a qualified psychologist through a secure video call platform.
2. **Arm 2 (Control):** Women will receive face to face counselling from a facility-based psychologist in a private room at the health facility.

To rigorously isolate the effect of the delivery modality and prevent confounding, both intervention arm will use the same counselling manual, same number, and duration of sessions, and the same training and supervision structure to ensure assay sensitivity and isolate the effect of delivery modality. The only difference will be mode of service delivery. This aligns with recommended non-inferiority trial protocols, where maintaining constant intervention fidelity between arms is essential for determining clinical equivalence (42).

Procedure of Participant Enrolment

Step 1-Participant Identification and Approach: The enrolment process will take place at the selected healthcare facilities over a two-month period. To prevent any feeling of coercion or obligation among the women, a strict separation between routine healthcare provision and research recruitment will be enforced. Attending healthcare providers (e.g., doctors and nurses at the ANC, PNC, and general outpatient wards) will only conduct routine care and brief initial mental health needs assessments. If psychological distress is suspected, the provider will merely inform the patient about the availability of the Wellbeing Centre and introduce her to an independent, non-clinical Field Research Assistant (FA). The hospital's healthcare

providers will have absolutely no role in trial recruitment, formal psychometric screening, or the informed consent process.

Step 2-Initial Screening for Eligibility: During this screening, field assistants will administer the contextually validated Patient Health Questionnaire-9 (PHQ-9) and Generalised Anxiety Disorder-7 (GAD-7) tool (43, 44) to assess for the presence of moderate (≥ 10) or severe symptoms of depression and anxiety. Crucially, if a woman demonstrates severe suicidal ideation or imminent risk of self-harm during this screening step, the assessment for trial eligibility will be immediately terminated. The Field Assistant will enact the study's emergency referral arrangement, ensuring the woman is not sent home but is directly linked to the on-site Study Physician to receive immediate, appropriate psychiatric and medical support

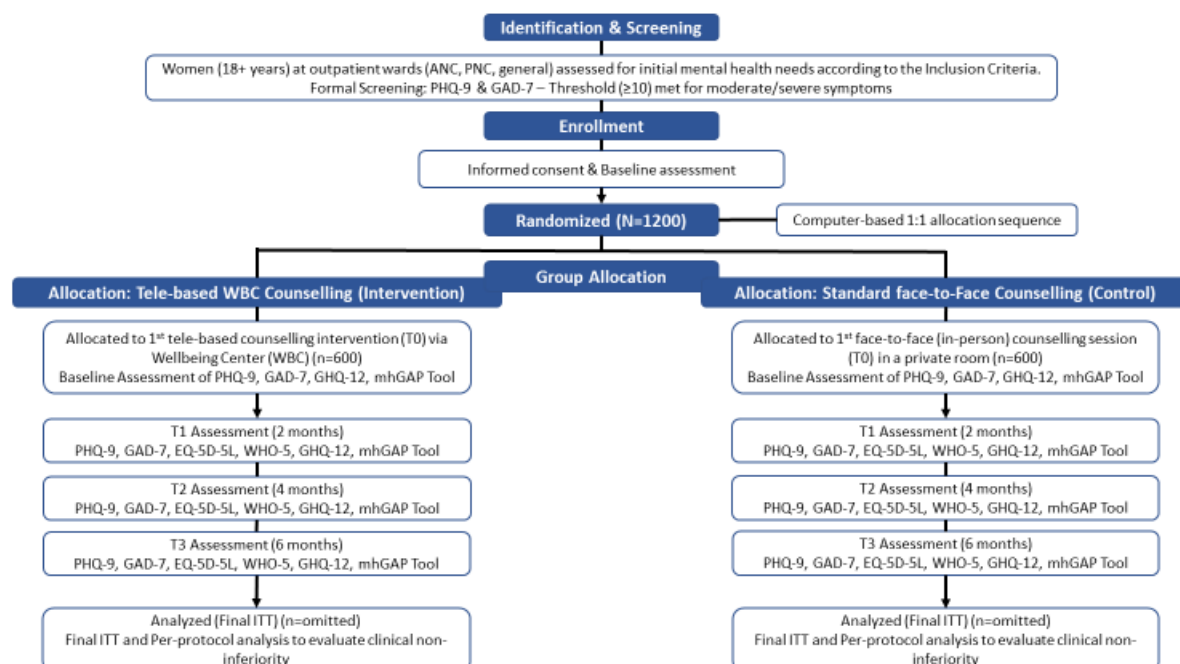
Step 3-Informed Consent: Eligible women will receive detailed verbal and written information regarding the study's objectives, the randomized nature of the trial, and the two modalities of service delivery (tele-counselling via Wellbeing Centres versus in-person counselling). Researchers will clearly explain the potential risks, benefits, and data privacy measures. Participants will also be informed about their voluntary participation and their right to withdraw from the study at any time before obtaining written informed consent.

Step 4-Baseline Assessment: Following the obtained written informed consent, participants will undergo a comprehensive baseline assessment of socio-demographic data (e.g., age, marital status, education, employment) and current mental health medications. Furthermore, baseline data for all primary and secondary outcome measures, including health-related quality of life (WHOQOL-BREF), will be recorded through electronic surveys.

Step 5-Randomisation and Allocation: Following the completion of the baseline assessment, participants will be officially enrolled and randomized in a 1:1 ratio to either: (A) Tele-counselling at Wellbeing Centre intervention arm, or (B) In-person counselling with a site-appointed psychologist control arm. To prevent selection bias and guarantee strict allocation concealment, a computer-based randomisation process will be utilised centrally (i.e., like a digital coin toss). The allocation sequence will be hidden within an electronic Case Report Form (eCRF) system, such as REDCap, and will only be revealed to the site therapist or researcher at the exact moment they trigger the randomisation assignment in the system¹ (45).

¹ This approach aligns with standard practices for computer-based randomisations using systems like REDCap, where the assignment is kept hidden until the moment the therapist clicks the "randomize" icon.

Figure 5: Flow Diagram of the Study Design & Randomisation



Follow-up Assessment

Baseline (T₀): At the enrolment day all women will undergo a baseline assessment strictly before receiving their first counselling session (either in tele-counselling or in-person counselling, depending on their randomized arm). During this time, baseline data and outcome data (i.e., PHQ-9, GAD-7, GHQ-12, EG-5D-5L) will be collected and this strict sequencing ensures that baseline measurements are captured completely uninfluenced by the intervention.

Subsequent Follow-ups (T₁, T₂, T₃): Over the 6-month trial period, the investigators will conduct three follow-up assessment visits spaced at two-month intervals:

- **T₁:** 2 months post-baseline
- **T₂:** 4 months post-baseline
- **T₃:** 6 months post-baseline

Because the structured counselling intervention is delivered acutely over an 8 to 12 week period, evaluations at 2, 4, and 6 months post-randomisation are methodologically sufficient to capture both immediate symptom reduction and medium-term clinical maintenance (46). This duration aligns with established non-

inferiority trials evaluating tele-psychological counselling (1, 45), carefully balancing the need for robust longitudinal data with the pragmatic constraints of participant attrition and the 12-month trial timeline.

Between these assessment points, the number of counselling services each patient receives will be entirely need-based. The frequency of sessions will be determined by the patient's individual clinical condition and the appointed psychologist's clinical judgement and suggestions (maximum four sessions per patient). At each follow-up point, participants will be reassessed on the primary and secondary outcomes of this study. Furthermore, in strict adherence to the intention-to-treat (ITT) principle, all patients who receive the baseline counselling session will be included in the follow-up assessments, irrespective of the total number of counselling sessions they attend or whether they drop out of active treatment.

Inclusion and Intention-to-Treat (ITT) Protocol: Every woman who completes the baseline assessment and receives her first treatment session at Day 1 (T_0) will be actively included in the T_1 , T_2 , and T_3 follow-up assessments. Accordingly, follow-up data will be assessed irrespective of the number of counselling sessions the participant has attended or whether she has completed the full intervention program.

This approach strictly adheres to the intention-to-treat (ITT) principle, ensuring that all randomized women are included in the final data analysis regardless of their level of participation or treatment adherence. This minimizes bias and provides a highly rigorous, real-world evaluation of whether the tele-counselling model is non-inferior to in-person care.

Strategies for Participant Retention

To minimize attrition and ensure a high retention rate throughout the trial, the investigators will employ a rigorous, multi-layered tracking and follow-up protocol. Follow-up will be completed in 3-steps:

1. **Participant Enrolment and System Entry:** Upon enrolment, all participant contact details and locator information will be immediately entered and securely tracked in our electronic data management system.
2. **Phone Call Reminders:** To ensure follow-up, our research assistants will initiate phone calls prior to scheduled assessments and psychological counselling sessions to encourage attendance and identify any immediate barriers.
3. **Home Visits for Loss to Follow-up:** If a participant becomes inactive or cannot be reached via phone, a third layer of follow-up will be initiated. Field staff will visit the patient's house to find out the actual cause of absence and,

if safely possible, resolve the barrier to ensure their continued retention in the trial. All home visits will be conducted discreetly to maintain participant confidentiality and minimize potential stigma related to mental health care.

Additionally, other established methods will be used to promote retention and ensure outcome data is captured:

- **Flexible Assessment Collection:** All questionnaires and follow-up assessments will be designed to provide a high level of flexibility and convenience for the patients, reducing the burden of participation.
- **Incentives for Follow-up:** To improve retention and data quality, participants may be provided with fair compensation or incentives for completing subsequent follow-up assessments.
- **Continued Monitoring Regardless of Adherence:** If a participant decides to discontinue the actual intervention (tele-counselling or in-person sessions), the investigators will still actively invite them to complete the post-intervention and follow-up assessments, ensuring outcome data is collected regardless of their adherence to the treatment protocol.

Qualitative Data Collection

An ethnographic implementation research component will be incorporated to gain an in-depth, real-time understanding of how the intervention is delivered and enacted in routine practice. This will involve a nested qualitative design conducted to during and after the intervention, including In-Depth Interviews (IDIs) and day-long observation to explore participants' experiences of receiving and delivering mental health care. The study component will include health service professionals, project staff, mental health service recipients, and their companions (such as- husband, family members and peers) from the intervention and control arms. The qualitative component will explore two distinct pillars of the project: 1) the promotion of mental health services based on biomedical models that draw extensively from Eurocentric mental health traditions (such as CBT), and 2) the delivery of these services in formats mediated (or not) by technologies. These two pillars will be explored from the perspectives of both mental health service recipients and health service professionals (project staff, psychologists and health service provider). Within these pillars, the investigators will investigate treatment experiences and the social and cultural dimensions of mental health services. The investigators will include research participants from both the intervention and control arms of the study, enabling a comparative exploration of the technological mediation of mental health services. Furthermore, to comprehensively explore the socio-cultural dimensions and technological mediation of the mental health services, the sample will include diverse participant types, comprising in-depth

interviews with service recipients and their family members, as well as key informant interviews with mental health professionals and facility managers.

All interviews will be audio-recorded, strictly subject to the participant providing separate, explicit informed consent for the recording. Prior to the interview, participants will be clearly informed that they have the right to refuse the audio recording while still participating in the interview. If a participant declines the audio recording, the interview will proceed unrecorded, and the interviewer will rely exclusively on detailed handwritten notes. Refusing the audio recording will not affect their participation in the overarching clinical trial or the standard of care they receive in any way.

The investigators will rely primarily on In-Depth Interviews (IDIs) to generate qualitative data. To select the service users, the investigators will collect the list of enrolled patients from the selected site and purposively select the service users and their companions from both the intervention and control arms of the study. The investigators will also conduct IDIs with health service professionals (such as- Civil surgeon (CS), Upazilla health and family planning officer (UH&FPO), Residential medical officer (RMO), Medical officer (MOs), psychologist and project staff involved in service delivery. The qualitative sample size has been proclaimed in an endeavour to attain the data saturation. With this objective the probable sample size for the qualitative part has been discussed in the following paragraph and summarized in the next table.

1. In-Depth Interviews (IDI) with Service Receivers and Companions

The investigators will conduct in-depth interviews with a purposively selected sub-sample of women enrolled in the trial, representing both the tele-counselling and in-person control arms. Selection criteria will explicitly include study arm allocation (tele-counselling versus in-person), baseline symptom severity (moderate versus severe), and treatment completion status (capturing both those who successfully completed the sessions and those who dropped out or missed appointments). These interviews will thoroughly explore the treatment experiences and the social and cultural dimensions of mental health services.

2. In-Depth Interviews (IDI) with health service professionals

The investigators will also conduct IDIs with health service professionals, including Civil surgeon (CS), Upazilla health and family planning officer (UH&FPO), Residential medical officer (RMO), Medical officer (MOs), psychologist and project staff involved in service delivery. These interviews will explore their direct experiences and perceptions regarding the delivery of care via video-conferencing, the effectiveness of building a therapeutic alliance remotely, managing patient safety and risk, handling technological challenges,

and their expectations or recommendations for improving the tele-mental health delivery model.

During the intervention phase, the investigators plan to conduct interviews during the recipient's 2nd follow-up visit (approximately two months after the first visit) to explore how service recipients' experiences, perceptions and engagement with the counselling service evolve over time. rather than relying only on initial impression. Particular attention will be given to participants' experiences of biomedical mental health approaches, socio-cultural understandings of distress, and the role of technology in shaping therapeutic interactions and access to care.

In the endline phase, interviews will be conducted immediately after completion of the intervention phase to capture participants' comprehensive reflections on the overall intervention experience, including perceived impacts, challenges, cultural relevance, and recommendations for future improvement. The qualitative component will also comparatively explore experiences of technology-mediated and non-technology-mediated mental health service delivery across the intervention and control arms, with particular attention to participants' lived experiences and the social and cultural dimensions of care.

The investigators will conduct interviews at the service users' homes to ensure a comfortable environment that enables participants to openly share their experiences. However, as participants may come from locations beyond the study site, it may not always be feasible for data collectors to travel long distances. In such cases, an alternative option will be to conduct interviews at the hospital premises, while ensuring participants' privacy and confidentiality. The numbers represent an initial target, and data collection will continue until thematic saturation is reached, where no new themes or insights emerge from additional interviews.

In addition, participant observation will be conducted during the trial implementation to understand how the project is being implemented (such as- Screening, recruitment, post counselling recruitment) intervention is delivered in practice and to document implementation processes and challenges encountered.

Table 1: Qualitative Sample Size

Research method	Participants		Number
In-Depth Interviews (IDIs)	Service recipient	Intervention phase	15
		Endline phase	15
		Total	30
	Companion	Intervention phase	7
		Endline phase	8
		Total	15
	Psychologist		4
	Health manager & Health service providers (CS, UH&FPO, RMO, medical officer)		8
	Intervention support staff		4
Observation	Study implementation		2

*Data collection tool or number may change based on data saturation and study criteria

A total 20 IDIs with service recipient (10 in intervention phase and 10 in endline phase), 10 IDIs with companions (5 in intervention phase and 5 in endline phase), 4 IDIs with psychologists, 6 IDIs with health service professionals, and 2 IDIs with intervention support staff will be conducted. However, these numbers represent an initial target, and data collection will continue until thematic saturation is reached, where no new themes or insights emerge from additional interviews.

Internal Validity

This non-inferiority trial study will implement several rigorous methodological controls to ensure internal validity and minimize potential biases:

- **Eliminating Selection Bias:** A computer-based randomisation (as mentioned above) will be implemented to allocate participants in a 1:1 ratio

in either in-person and tele-counselling arm. This will ensure the equal distribution of confounding variables in both arms and facilitate the comparison at baseline in terms on their socio-demographic characteristics and symptom severity.

- **Intervention Fidelity:** Both the in-person and tele-counselling arm will be standardised in terms of counselling manual, number and duration of the sessions, and training and supervision structure to accurately isolate the effect of the delivery modality.
- **Mitigating Attrition Bias:** Following the intention-to-treat (ITT) analysis principle, the investigators will include all randomized women in the final data analysis regardless of their level of participation or whether they dropped out of the treatment. This will prevent biases from skewing the result if drop-out rates differ between the intervention arm.
- **Blinding of Outcome Assessors:** Due to the physical nature of the interventions, participants and treating psychologists cannot be blinded to the assigned delivery modality. However, the independent Field Assistants responsible for conducting all follow-up psychometric assessments will remain strictly blinded to the participants' group allocation. To maintain this blinding, participants will be explicitly instructed prior to all follow-ups not to disclose whether they received tele-counselling or in-person counselling.
- **Preventing Contamination:** Because both study arms are hosted within the same healthcare facility, strict measures will be implemented to prevent intervention contamination. The two modalities will be physically segregated; one dedicated private room will be equipped exclusively for tele-counselling (the Wellbeing Centre), and a separate parallel room will be used exclusively for in-person counselling. Furthermore, the digital registration and appointment-keeping system will strictly control patient flow, ensuring that participants only enter the room corresponding to their randomised assignment.

Management of Treatment Failure and Adverse Events

Monitoring and Identification: Throughout the trial period, participants wellbeing and symptom trajectories will be continuously monitored and assessed by the counsellors during their scheduled sessions and follow-up (during T₁, T₂, and T₃) assessments. The structured tele-counselling and in-person interventions are acute psychological treatments typically delivered over an 8 to 12-week period; thus, a 6-month timeframe is clinically sufficient to achieve and measure symptom alleviation. However, participants demonstrating no clinical improvement or persistent severe symptoms at the final 6-month follow-up will be formally classified as non-responders. To ensure continuity of care, a strict post-trial referral chain will be activated: the treating psychologist will refer the non-responding participant to the

on-site Study Physician for a comprehensive clinical evaluation. Treatment failure or clinical deterioration during the intervention period will be flagged immediately and will trigger established risk assessment protocols, if a participant shows severe decline in mental health condition (i.e., severe exacerbation of depressive or anxiety symptoms or show acute suicidal ideation or self-harm).

Immediate Management and Referral: Study counsellors are authorized to provide brief supportive counselling, guided by risk assessment protocols to manage acute distress of participants by ensuring their safety and continued trial eligibility. Additionally, all enrolled women will be provided with 24-hour emergency contact number so they can reach the responsible person (i.e., study coordinator/therapist) at any time in case of crisis.

To ensure patient safety, a strict emergency escalation protocol is established for acute suicidal ideation. Participant well-being and suicidal ideation will be continuously monitored by the psychologists during every scheduled counselling session, and by the Field Assistants and Study Physician during all follow-up assessments (at 2, 4, and 6 months). Following the formal assessment, if a participant is considered to ineligible to continue the trial intervention (either in-person or tele-counselling sessions are not sufficient or safe), they will not be referred to an external facility. Instead, the patient will be immediately managed within the study area with more intensive, specialised psychiatric or medical treatment directly within the hospital setting, under the direct clinical oversight of the Study Physician. Similarly, if a remote psychologist identifies acute suicide risk, they will maintain video contact with the participant while simultaneously alerting the on-site Study Physician. The physician will immediately intervene to conduct a face-to-face clinical risk assessment. If acute risk identified, the participant will be safely accompanied to the hospital's emergency department or a specialised psychiatric treatment for urgent care.

While structured counselling aims to reduce symptoms of depression and anxiety, the investigators acknowledge that an incidence of suicide may be influenced by complex, multifactorial variables outside the direct scope of the counselling outcomes. Therefore, a singular event of suicide will be classified and formally reported as a Serious Adverse Event (SAE). However, the study will be considered to have failed its safety parameters if the independent Data Safety Monitoring Board (DSMB) identifies a disproportionate rate of suicide, suicide attempts, or severe suicidal ideation in the tele-counselling arm compared to the in-person active control arm, indicating that the delivery modality poses an unacceptable clinical risk. To ensure rigorous safety monitoring, these adverse events will be systematically captured through multiple data sources (i.e., follow-ups, item 9 of the PHQ-9, reports from family members or companions).

Documentation and Impact on Data Analysis: Any treatment failure, severe clinical deterioration, or need for referral will be formally recorded as an adverse event and reported for case management. In case of treatment failure for any participants or seeks outside psychological counselling, their trial intervention may be discontinued, but their data will be captured for ITT analysis to prevent biases.

Crisis Management Pathway and Emergency Contact Process: Given that suicide risk can fluctuate rapidly, continuous safety monitoring will extend beyond the scheduled counselling sessions. All enrolled participants will be provided with a 24-hour emergency contact number at baseline. This dedicated hotline will be continuously monitored by a trained on-call study coordinator or Field Assistant. If a participant experiences acute emotional distress or suicidal ideation between visits and contacts the hotline, an immediate phone triage will occur. If acute risk is suspected, the participant will be instructed to visit the study facility immediately, triggering an urgent face-to-face clinical evaluation by the on-site Study Physician.

Between-Visit Follow-up Plan: For participants who report elevated distress between visits but are assessed by the Study Physician as not requiring immediate psychiatric referral or hospitalisation, a proactive follow-up safety plan will be initiated. The treating psychologist or study coordinator will conduct an ad-hoc safety check-in call within 24 to 48 hours of the crisis contact. Furthermore, Field Assistants will be assigned to conduct increased routine monitoring calls for these flagged individuals during the gaps between the standard 2, 4, and 6-month longitudinal assessments to ensure ongoing stability.

Psychologist Qualification

This non-inferiority trial study will utilise two highly qualified clinical psychologists for both arm service delivery, in-person and tele-counselling services, to ensure high-quality care and maintain strict intervention fidelity. Both of the proposed psychologists possess advanced educational qualification (Masters in Psychology – MS) in psychology and have accumulated long, robust professional experience in both tele mental service and face to face service. Before joining icddr,b, they build a strong foundation in clinical practice by providing evidence-based psychological interventions and counselling across various reputed institutions. Moreover, they bring direct, hands-on expertise in remote service delivery, having actively provided tele-counselling services at icddr,b (Wellbeing Centre Project) continuously from 2023 to present. Their extensive background in both traditional face-to-face psychological counselling and digital mental health platforms ensures they are uniquely equipped to deliver standardised, empathetic, and highly effective care across both arms of the trial.

All psychologists involved in the trial will receive standardised training on both tele-counselling and in-person counselling delivery modalities before trial initiation. The

psychologists will be competent to provide counselling in both arms using the same counselling manual, supervision structure, and session protocol to ensure intervention fidelity and minimize therapist-related variability between study arms.

Justification of Scientific Validity

- **Gender Validity:** Women in Bangladesh face acute structural determinants of poor mental health, compounded by patriarchal norms that restrict independent mobility and financial autonomy. By embedding tele-counselling within localized general health facilities (Wellbeing Centres), this research specifically targets these gendered vulnerabilities. It assesses a model that eliminates the need for women to travel long distances to urban psychiatric hospitals, thereby maximizing equitable access to care.
- **Social Validity:** Traditional mental health treatment carries immense societal stigma in South Asia. By evaluating a service delivered within primary and secondary general health complexes rather than dedicated psychiatric institutions, the study leverages a socially valid, stigma-reducing environment, protecting the social standing of the participants.

Study Timeline

Table 2: Proposed Timeline of the Study

Description	Project Time Period (months)											
	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12
Stakeholder Engagement												
IRB approval												
Site Preparation												
Staff Training, Recruitment												
Enrolment and Randomisation												
Baseline Assessment												
Conduct Efficacy Trial												
Follow-up Assessment												
Data Analysis and Report												
Dissemination												

Sample Size Calculation and Outcome (Primary and Secondary) Variable(s)

Sample Design and Randomisation

The proposed non-inferiority trial aims to recruit a total of 1,200 women, with 600 participants in each treatment arm (300 per arm at Dinajpur District Hospital and 300 per arm at Matlab Dakshin Upazila Health Complex). Because the co-primary outcomes (PHQ-9 depression and GAD-7 anxiety) are continuous variables, the sample size was derived using the standard non-inferiority formula for comparing two independent continuous means:

$$N_{\text{per arm}} = \frac{2 \cdot (z_{\alpha} + z_{\beta})^2 \cdot \sigma^2}{(\delta - \Delta)^2}$$

Assuming a true mean difference $\delta = 0$, an anticipated standard deviation $\sigma = 4.8$ for PHQ-9 and 4.2 for GAD-7 (based on published psychological intervention trials in low-resource settings), (47) a one-sided significance level $\alpha = 0.025$ ($z_{\alpha} = 1.96$), and 85% statistical power ($z_{\beta} = 1.04$) to jointly test both co-primary outcomes, the non-inferiority margin was set at $\Delta = 1.5$ points for both PHQ-9 and GAD-7 (representing less than 50% of the Minimal Clinically Important Difference of 4.0–5.0 points). Under these parameters, the minimum required sample size is 324 participants (162 per arm). To account for an anticipated 20% longitudinal attrition rate, therapist clustering, and ensure sufficient statistical power (>90%) for secondary site-specific subgroup evaluations, the sample is expanded to a target of $N = 1,200$ adult women (600 per site). Primary non-inferiority will be evaluated overall across the pooled trial population ($N = 1,200$), providing >95% statistical power.

Following baseline assessment and written informed consent, participants will be randomly assigned in a 1:1 ratio to either tele-based counselling or standard in-person counselling within each facility. Randomisation will be conducted centrally using a computer-generated stratified block randomisation sequence prepared by an independent statistician. Stratification will be based on three factors: (1) study site (Dinajpur District Hospital versus Matlab Dakshin Upazila Health Complex), (2) maternal status (antepartum/postpartum versus general outpatient), and (3) baseline symptom severity (moderate versus severe, based on formal PHQ-9 and GAD-7 screening scores). Allocation concealment will be strictly maintained using an electronic Case Report Form (eCRF) system, ensuring field researchers cannot predict allocation.

The target recruitment of 1,200 women (600 per site) over a two-month enrolment period is supported by high patient turnover across outpatient departments. Dinajpur District Hospital records an average daily female outpatient footfall of 270 adult women. Matlab Dakshin Upazila Health Complex records a daily outpatient throughput of 200 to 250 adult women across Antenatal Care (ANC), Postnatal Care (PNC), and general outpatient wards (around 5,000 female visits monthly). Screening approximately 20–25% of attendees (~1,000–1,200 women per month per site) with an estimated 30% eligibility yield (PHQ-9/GAD-7 ≥ 10) and 80–85% consent rate yields 300 enrolled women per month at each site (600 total enrolled per month across both facilities). This footfall fully supports achieving the required 1,200 participants (600 in Dinajpur and 600 in Matlab) within the planned two-month recruitment window. Additionally, substantial national prevalence of common mental disorders among women in Bangladesh (notably 20% for anxiety and 5% for depression among women aged 15-49, according to BDHS 2022) - ensures a more than sufficient sampling pool to achieve the required target sample size within the planned recruitment period.

The Facility Selection Approach

Although the trial is conducted across two hospitals, it strictly preserves the methodological strength of the 'One Facility' approach by executing within-facility randomization independently at each site. Rather than assigning tele-counselling to Site A and in-person care to Site B (which would introduce cluster design effects and systemic demographic bias), the investigators hold all hospital-level, environmental, and travel-time confounders substantially constant within each hospital.

Strengths of One Facility Approach:

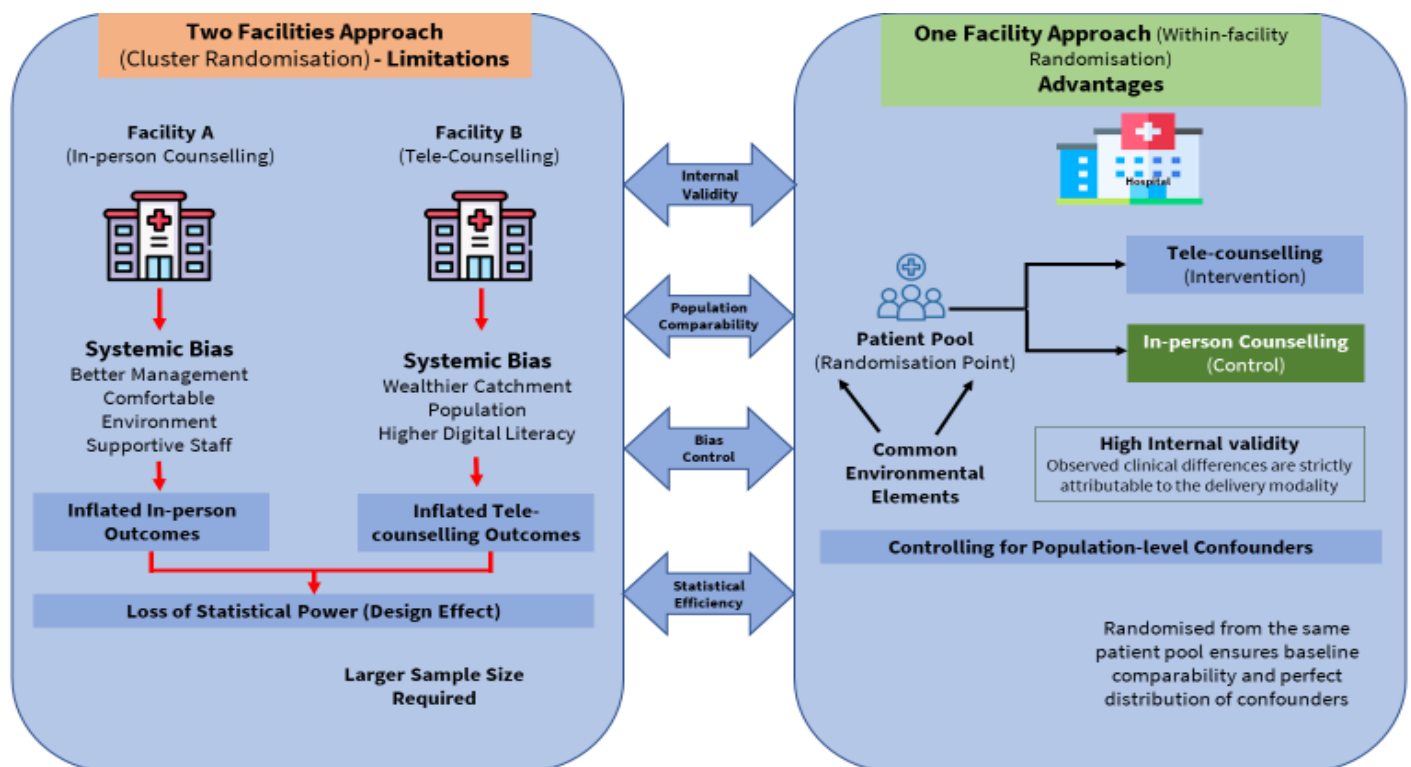
- **Isolating the Delivery Modality (High internal Validity):** The primary objective of this efficacy trial is to determine if the *delivery modality* (tele-counselling vs in-person counselling) affects clinical outcomes. By hosting both arms in the exact same facility, the investigators hold the environmental and systemic variables constant. Both the intervention and control groups experience the same hospital travel time, the same waiting room environment, and the same facility administration, which guarantees that any observed clinical differences, are strictly attributable to the intervention modality, not the hospital environment.
- **Controlling for Population-Level Confounders:** In case of selecting different hospitals, which can serve distinct catchment areas with varying socio-economic status, cultural dynamics, and baseline mental health severity. On the other hand, randomizing women from same patient pool of one facility ensure substantial distribution of these confounding variables across both arms, ensuring baseline comparability.

- **Avoiding Systemic Bias and Design Effects:** A multi-facility design would introduce systemic biases (e.g., varying facility management or digitally literate demographics) and could turn this study into a cluster-randomized trial. This design effect would demand a significantly larger sample size to achieve the same statistical power as our proposed efficacy trial.

Limitations of a Two-Facilities Approach:

- **Systemic Bias:** In case of selecting two facilities, for example Facility A (in-person counselling) and Facility B (tele-counselling), systemic biases would inevitably skew the result. For instance, if Facility A has better management, comfortable environment, supportive staff, the in-person arm might show inflated result. Similarly, if Facility B has wealthier, digitally literate catchment population, tele-counselling might appear more effective solely due to patient demographics.
- **Loss of Statistical Power (Design Effect):** A two-facility choice can turn this study into a cluster-randomized trial, instead of our proposed efficacy trial. Because patients within the same facility tend to share similar characteristics, statistical analysis requires accounting for intra-cluster correlation. This design effect would demand a significantly larger sample size to achieve the same statistical power as our proposed efficacy trial.

Figure 6: Methodological Justification for One Facility Approach



By implementing the trial within the same facility, the investigators successfully eliminate institutional and geographic confounders, yielding highly rigorous, unbiased data on the true efficacy of tele-mental health delivery.

Due to the nature of this trial, conducting within a single district hospital, the findings may not be fully generalisable to the broader population of Bangladesh, which encompasses diverse socio-economic, cultural, and geographical contexts. To establish nationwide generalisability and definitively confirm the non-inferiority of tele-counselling compared to in-person counselling across the country, a larger, multi-centre non-inferiority trial will be required in the future.

Outcome Variables and Data Collection Tools

Data collection will occur at four main time points, Baseline, Post-treatment (2 and 4 months), and a 6-month follow-up.

Primary Outcome Variables

- Depressive Symptom:** Will be measured using the validated Patient Health Questionnaire-9 (PHQ-9) in Bangladesh context (43), a widely 9-item scale evaluating the severity of depressive symptoms over the past two weeks. The scale consists of 9 items, each scored from 0 (not at all) to 3 (nearly every day), yielding a total score range of 0 to 27. Symptom severity is categorised

using established clinical cut-off values: 0-4 (mild), 5-9 (moderate), 10-14 (moderately severe), and 15-19 (moderately severe), 20-27 (severe) depression.

- **Anxiety Symptom:** Will be measured using the validated Generalised Anxiety Disorder-7 (GAD-7) scale in Bangladesh context (44), a 7-item instrument that reliably captures symptoms of clinical anxiety. The scale consists of 7 items, each scored from 0 (not at all) to 3 (nearly every day), yielding a total score range of 0 to 21. Anxiety severity is categorized using the following cut-off values: 0-4 (mild), 5-9 (moderate), 10-14 (moderate), and 15-21 (severe) anxiety.

Secondary Outcome Variable

- **Health-Related Quality of Life:** Will be measured via the WHOQOL-BREF, validated in the Bangladesh context (48), a standardised and globally recognised instrument developed by World Health Organisation (WHO)-WHOQOL Group, comprising four dimensions (physical health, psychological, social relationships, and environment). This instrument consists of 26 items rated on a 1 to 5 scale, which includes two independent items assessing overall perception of quality of life and general health, the remaining 24 items compute the four domain scores (49). The raw domain scores are derived from the mean score of items within each domain and will be transformed to either a 4-20 scale (to be comparable with the full WHOQOL-100) or a 0-100 scale to facilitate interpretation and statistical analysis.
- **Common Presentation of Conditions:** mhGAP common presentation of conditions and diagnosis developed and validated by World Health Organization in Bangladesh context (50) will be utilised by psychologist (during first and follow-up visits) of both arms for identifying usual conditions of depression, psychosis, bipolar disorder, epilepsy, mental health disorders, dementia, substance use disorders, and suicidal/self-harm ideation.
- **Wellbeing Index:** Will be measured via the validated World Health Organization-Five Well-Being Index (WHO-5) in Bangladesh context (51), designed to measure subjective psychological well-being over the past two weeks of women. This tool will be administered by psychologist of both arms during follow-up visits. The raw score of this scale ranges from zero to 25, zero representing worst possible mental well-being and 25 representing best possible mental well-being.
- **Psychological Distress:** Will be measured using the validated General Health Questionnaire (GHQ-12) in the Bangladesh context, a widely used 12-item screening tool designed to assess overall psychological distress and detect non-psychotic mental health problems among participants (52). Score

in GHQ-12 ranges from 0-12, where 0-3 refers normal psychological condition and 4-12 score refers to have potential psychological distress.

- **Gender-Based Violence (GBV) Exposure (Baseline T0 & Follow-up Period T1, T2, T3):** Exposure to gender-based violence will be measured using the standardised World Health Organization (WHO) Violence Against Women instrument. This globally recognised gold-standard tool systematically assesses partner-controlling behaviors, the frequency and severity of emotional, physical, and sexual violence, as well as the resulting impacts, injuries, and experiences of non-partner violence.
 - **Baseline Assessment (T0):** The full, comprehensive WHO instrument will be administered once at baseline (T0) only by a trained FRA. This baseline module captures controlling behaviors, lifetime physical violence, lifetime sexual violence, non-partner sexual assault, childhood sexual abuse, and 12-month recall of spousal violence.
 - **Follow-up Assessments (T1, T2, T3):** To eliminate overlapping recall periods and avoid unnecessary participant burden, all lifetime, childhood, and 12-month recall questions are omitted from follow-up visits. At T1 (2 months), T2 (4 months), and T3 (6 months), FRAs will administer a streamlined 'Since Last Visit' (Incident Violence). This tool measures only new or ongoing incidents of physical, emotional, or sexual violence occurring specifically within the 2-month interval since the previous study assessment.
- **Maternal Immunization Tracking Module (Baseline T0):** A specialized 6–8 item Maternal and Child Immunization Tracking Module will be administered once during baseline enrolment (T0) only by trained Field Research Assistants (FRAs) to track maternal vaccination history during the current or most recent pregnancy, specifically identifying the receipt of Td/tetanus, according to the DHS Mothers Health and Contextual Factors. Instead of tracking child immunization, the adopted module focuses on the mother's decision-making factors and explores her future preferences for integrating vaccinations directly into routine antenatal care (ANC) visits versus utilizing separate EPI centers. This comprehensive data allows us to evaluate whether clinical recovery from mental distress (improved PHQ-9/GAD-7) positively influences a mother's preventive healthcare uptake and her receptiveness to future maternal immunization programs.
- **Implementation and Operational Costs:** A direct cost comparison will be conducted by systematically tracking and evaluating the implementation and operational expenses associated with both intervention arms. This includes comparing the direct costs of the tele-counselling model (e.g., therapist time,

electronic equipment, internet connectivity, and dedicated room establishment) against the standard in-person counselling modality to determine the financial feasibility and budget impact of scaling the Wellbeing Centre model.

Indicators and Thematic Areas

The following table illustrates the list of indicators proposed to address the objectives of this study.

Table 3: Indicators and Thematic Areas of the Study

Study Objectives	Outcome of Interest	Indicators / Themes
To evaluate the non-inferiority of tele-counselling vs. in-person counselling in reducing the severity of depressive symptoms.	Depression severity	• Mean difference in depression symptom scores between arms. • Percentage of women achieving reliable recovery or clinically significant reduction in depressive symptoms.
To evaluate the non-inferiority of tele-counselling vs. in-person counselling in reducing the severity of anxiety symptoms.	Anxiety severity	• Mean difference in anxiety symptom scores between arms. • Percentage of women achieving reliable recovery or clinically significant reduction in anxiety symptoms.
To evaluate and compare improvements in health-related quality of life between the two modalities.	Health-related quality of life	• Mean change in quality of life index scores. • Self-reported overall health rating.
To assess and compare the reduction of general psychological distress.	Psychological distress	• Mean difference in psychological distress scores between the tele counselling and in-person arms.
To evaluate and compare improvements in the overall well-being index.	Overall well-being	• Mean change in subjective psychological well-being scores.
To monitor and compare mhGAP-guided common presentations of conditions and diagnoses.	Clinical presentation & Diagnosis	• Incidence and frequency of specific mental health/neurological/substance use conditions identified and managed following mhGAP guidelines.

Study Objectives	Outcome of Interest	Indicators / Themes
To measure and compare service acceptability, accessibility, and usefulness of the tele-counselling model vs. in-person.	Acceptability, Accessibility, and Usefulness	• Percentage of users reporting the service as acceptable, accessible, and useful. • Mean scores on usability and convenience scales. • Completion rates (adherence) of counselling sessions.
To explore and understand the experiences, perceptions, and social and cultural dimensions of receiving and delivering mental health services within a technology-mediated intervention.	User, Caregiver, and Provider Experience	• Thematic insights regarding treatment experiences, socio-cultural dimensions, and technological mediation of CBT models.
To continuously monitor participant safety and treatment failure across both arms.	Adverse Events & Treatment Failure	• Number of participants experiencing acute clinical deterioration or suicidal ideation. • Number of participants requiring referral to specialized psychiatric care.

Data Analysis

Quantitative Analysis

In superiority trials, Intention-To-Treat (ITT) analysis (analysing all patients within their randomized groups, regardless of whether they completed allocated treatment) is standard (41). However, in a non-inferiority trial, ITT analysis can conservatively bias the results toward the null (no difference), which increases the likelihood of falsely claiming non-inferiority (41, 53). Therefore, consistent with CONSORT guidelines, the investigators will strictly report both Intention-To-Treat (ITT) and Per-Protocol (PP) analyses (41, 45). The ITT population will include all randomised women regardless of their level of participation or treatment adherence. The Per-Protocol (PP) population is strictly defined as participants who complete the predefined minimum number of scheduled counselling sessions without initiating any new external psychological or psychopharmacological treatments during the trial period. Non-inferiority will only be definitively concluded if the 95% confidence intervals from both the ITT and PP analytical models consistently fall entirely within the pre-defined non-inferiority margin.

To evaluate the non-inferiority objective, the investigators will employ a difference-in-difference (DID) analysis across both the ITT and PP analysis populations. Continuous outcomes such as PHQ 9, GAD 7, EQ 5D 5L, GHQ-12, and WHO-5 will be analysed using linear mixed effects models with random intercepts for individuals and fixed effects for group, time and the group by time interaction, adjusting for baseline scores and relevant covariates. The group-by-time interaction within these models will explicitly yield the DID estimate, illustrating the mean difference in change scores from baseline to follow-up between the Arm-1 (tele-counselling) and in Arm-2 (in-person counselling). To maintain clinical precision, the PHQ-9 and GAD-7 will first be analysed in segregate manner as distinct co-primary outcomes. Following this initial segregated analysis, a composite score combining both the PHQ-9 and GAD-7 will be calculated and evaluated to assess the overall mental health treatment effect. Furthermore, the investigators will conduct a complete case analysis to complement these findings. To rigorously account for therapist effects and intra-individual data clustering, both 'therapist' and 'individual participant' will be included as random intercepts in the models. Furthermore, baseline psychiatric medication uses and any subsequent changes in dosage during the follow-up period will be systematically tracked and included as fixed-effect covariates to prevent confounding of the treatment effect. To manage missing data resulting from longitudinal attrition, the mixed-effects models will employ Full Information Maximum Likelihood (FIML) estimation. This approach permits valid statistical inferences under the Missing At Random (MAR) assumption, ensuring robust Intention-to-Treat (ITT) estimates using all available longitudinal data without resorting to listwise deletion.

Non-inferiority will only be claimed if both ITT and PP analytical models demonstrate that the 95% confidence interval for the DID (the mean difference in change scores between the tele-counselling and in-person groups) falls entirely within the pre-defined non-inferiority margin (45).

Exploratory and Moderation Analysis: Baseline scores from the WHO Domestic Violence instrument will be treated as a covariate in our mixed-effects models to evaluate if active domestic violence moderates treatment efficacy (i.e., whether treatment response differs for women experiencing high versus low baseline abuse). Additionally, the secondary objective relating to maternal immunization focuses on evaluating baseline cross-sectional associations between maternal mental health distress and preventive healthcare utilization. Using baseline (T0) data, multivariate logistic regression models will evaluate whether moderate-to-severe depression (PHQ-9 ≥ 10) or anxiety (GAD-7 ≥ 10) independently predicts:

1. Incomplete maternal TT/Td immunization during pregnancy (defined as receiving < 2 dose equivalents).
2. Incomplete age-appropriate child EPI immunization among postpartum mothers.
3. Higher reported structural or financial barriers to accessing routine clinic-based immunization services.

Covariates in these cross-sectional models will include participant age, household socio-economic status (asset index quintiles), maternal education level, study site (Dinajpur DH vs Matlab Dakshin UHC), and geographic distance to the nearest healthcare facility.

Qualitative Analysis

All interviews will be audio-recorded with field notes and transcribed verbatim. Transcripts will be randomly checked against the audio recordings to ensure quality of transcription. The qualitative data will be analysed using an inductive approach with data collection and primary data analysis occurring simultaneously until a theoretical saturation level is reached.

The qualitative data analysis will be performed through thematic approach assisted by qualitative software (i.e., Atlas.ti). Data will be analysed manually. Transcripts will be read and coded by the investigators. The investigators will look for inductive codes to address the study objectives (selective or focused coding method). A codebook will be developed and maintained for all a- inductive codes. At the beginning, a minimal set of transcripts will be coded by different researchers to check for inter coder reliability. Upon establishing the inter-coder reliability, a master code-list will be generated, based on which the rest of the transcripts will be coded. The

investigators will employ the constant comparative analysis method to compare the new data with the earlier data to identify possible similarities and differences.

Table 4: Description of the Process of Thematic Analysis

Phases of analysis	Description of the process	Result
Data Familiarization	Researchers will listen to the audio recordings of the IDIs (service users and caregivers) and KIIs (psychologists and health managers). They will read and re-read the verbatim transcripts (and English translations) to become completely immersed in the data, noting down initial ideas regarding participant experiences, privacy concerns, and operational challenges of the Wellbeing Centres.	Preliminary "start" codes and detailed reflective notes specific to the tele-counselling and in-person care experiences.
Generation of initial codes	Researchers will systematically code the dataset using Atlas.ti software. Using an a priori codebook based on the interview guides, alongside an inductive approach, they will collapse data into labels capturing specific concepts (e.g., service acceptability, societal stigma, technological barriers, therapeutic alliance, and facility readiness).	A comprehensive set of codes capturing how the IDI and KII data answer the research questions on the feasibility and acceptability of the two treatment arms.
Searching for themes among codes	Codes will be collated into broader, meaningful themes that capture the core narratives across the different participant groups. For example, grouping codes about 'internet issues' and 'lack of power supply' under a candidate theme of "Technological Barriers to Tele-Psychiatry."	A list of candidate themes reflecting care-seeking behaviours, operational feasibility, and user satisfaction for further refinement.
Reviewing themes	The research team will review the candidate themes against the coded extracts and the entire dataset to ensure they accurately reflect the views of the women, caregivers, and health professionals. They will check if the themes adequately capture the comparative context (tele-counselling vs. face-to-face) and generate a thematic "map" of the analysis.	A coherent recognition of how themes are patterned to tell an accurate, overarching story about the implementation of the Wellbeing Centres.
Defining and	Researchers will refine the specifics of	A comprehensive analysis of

Phases of analysis	Description of the process	Result
naming themes	each theme, generating clear, descriptive names (e.g., "Overcoming Stigma through Remote Care"). They will define exactly what aspects of the intervention (demand generation, physical setup, clinical delivery) are captured in each theme and why it is critical for understanding the intervention's success or failure.	what the themes contribute to understanding the tele-mental health model's implementation in government hospitals.
Producing the final report	The final report will weave together the thematic findings, supported by vivid, de-identified quotes from the IDIs and KIIs. This qualitative narrative will provide a deep contextual understanding of the trial's quantitative results, explaining why tele-counselling was acceptable or what specific operational barriers must be addressed for national scale-up.	A final qualitative description of the findings, ready to be integrated into the trial's overall efficacy and feasibility report.

Cost Comparison Analysis

To assess the financial feasibility and resource requirements of the Wellbeing Centre model, a direct cost comparison analysis will be conducted from a healthcare provider perspective and between the two delivery modalities. This analysis is strictly limited to a direct cost comparison and will not include a formal cost-effectiveness evaluation. The investigators will systematically track and compare the direct implementation and operational costs associated with each arm. For the tele-counselling intervention, this includes tracking expenses such as therapist time, electronic equipment, internet connectivity, and the establishment of the dedicated counselling room. These will be compared against the equivalent operational costs and facility requirements for the standard in-person counselling arm. By evaluating these direct cost differences, the study will provide policymakers with concrete evidence regarding the financial viability and budget impact of scaling the tele-counselling intervention across the healthcare system.

Data Safety Monitoring Plan (DSMP)

Investigators and institutions involved in the study will permit trial-related monitoring and audits and regulatory inspection(s). In the event of audit or monitoring, the investigator agrees to allow the sponsor representatives direct access to all study records and source documentation in regulatory inspection. The principal investigator is responsible for the quality of the data. The principal investigator will ensure that the required documentation is available in local investigator site files.

Additionally, to ensure the safety of participants and the integrity of the data in this non-inferiority trial comparing tele-based and in-person counselling for women, a comprehensive Data and Safety Monitoring Board (DSMB) by icddr,b. Before commencing, the study will seek ethical approval from the icddr,b IRB and will be officially registered on the U.S. government website, clinicaltrials.gov. The DSMB will oversee trial progress, engaging in periodic assessments with the principal investigators to evaluate data quality, participant accrual, retention, and the performance of the trial site (including Wellbeing Centre and hospital setting). Because the trial involves women presenting with moderate to severe depression and anxiety, clinical safety monitoring is highly prioritized. Though, the investigators are not suspecting any adverse event from the trial, however, if any event observed that considered to be adverse, DSMB will be reported within 24 hours and the further procedures will be decided as per their guidance.

Safety review plan and monitoring

Because this trial involves a psychological intervention, the parameters for reviewing participant safety will focus strictly on the women's mental health and emotional well-being. Key safety parameters include the potential exacerbation of depressive or anxiety symptoms, severe psychological distress, or the emergence of acute suicidal ideation.

The Principal Investigator and the designated Study Physician will be responsible for the validation and oversight of the study's safety monitoring. The trial's counsellors (trained psychologist) will continuously monitor the participants' well-being during all tele-counselling and in-person sessions, while Field Research Assistants will monitor safety during follow-up assessments. The Study Physician will provide dedicated clinical oversight to manage any safeguarding concerns, track adverse events, and ensure strict adherence to clinical safety guidelines. Furthermore, the study team will conduct regular reviews of the overall study progress and check for any negative psychological side effects, that may arise during the counselling process.

Upon completion of the 6-month trial, a final report will be generated to document the study's overall findings. This report will provide a comprehensive summary of the participant recruitment process, including the total number of women screened,

enrolled, and the specific reasons for any exclusions. It will detail the overall treatment success rates (e.g., non-inferiority in reducing PHQ-9 and GAD-7 symptom severity) and failure rates (e.g., severe clinical deterioration requiring specialized referral) across both treatment arms. The report will also formally document any adverse events or psychological side effects, such as transient distress or the exacerbation of symptoms - and evaluate whether the frequency of these events is consistent with expected parameters for standard psychological interventions. Furthermore, it will include an analysis of treatment adherence, describing how many enrolled women fulfilled the study purpose by completing the trial protocol and specifying the number of tele-counselling or in-person sessions they attended prior to the final follow-up.

Data Management and Confidentiality

All collected research data, classified as risk-bearing data under the icddr,b Data Protection Policy, will be securely stored and shared exclusively with the authorized data management and analysis team. Electronic data will be stored on password-protected, restricted-access computers equipped with updated anti-virus, anti-malware software, and firewall configurations maintained by the icddr,b IT Department. Access to these digital platforms will follow strictly defined user roles approved by the Principal Investigator.

Data Security and Protection of Recorded Interviews: To prevent any accidental disclosure of sensitive mental health information, all tele-counselling sessions will be conducted exclusively via a secure, password-protected videoconferencing platform equipped with end-to-end encryption. For the qualitative component, all audio-recorded interviews will be transferred immediately from portable recording devices to the encrypted icddr,b Secure Server, after which the original files will be permanently deleted from the devices. Recognising that pseudonymised data remains risk-bearing, all audio recordings will be transcribed verbatim and rigorously stripped of names, locations, and any other personal identifiers prior to thematic analysis.

Any physical records, such as paper questionnaires or written informed consent forms, will be kept in locked filing cabinets within restricted-access offices. To safeguard participant privacy, all information will be de-identified (pseudonymised) prior to analysis and the publication of any final reports or manuscripts. The dataset will be used solely for the agreed purposes of this efficacy trial and will not be disclosed to third-party organizations without explicit authorization from the Research Administration (RA) and Regulatory and Legal Affairs (R&LA) departments of icddr,b. Furthermore, any identified gaps in security, unauthorized access, or suspected data breaches will be communicated immediately to the Principal

Investigator and formally reported to the Chair of the icddr,b Data Protection Management Team (DPMT) for prompt incident response.

Data Storage, Access Control, and Retention: All digital research data, including electronic Case Report Forms (eCRFs) and pseudonymised transcripts, will be stored on the institution's Secure Server, which is automatically backed up to an off-site location each night. Strict access control measures will be enforced; access to this risk-bearing data will be governed by defined user roles. The server will be heavily encrypted, and the encryption keys and password access will be restricted exclusively to immediate, authorised research team members directly involved in data analysis. In compliance with institutional guidelines, all anonymised data and records will be securely retained for a minimum of 10 years following project completion. Following this retention period, the data will be permanently and securely disposed of in accordance with the icddr,b Data Protection Policy.

Ethical Assurance for Protection of Human rights

Ethical approval will be obtained from the Institutional Review Board (Research Review and Ethics Review Committee) of icddr,b. Besides, permission for field implementation will be obtained from the implementing facility.

Informed Consent Process: Written informed consent will be obtained directly from each eligible woman (aged 18 and over) at entry into this trial study, following the initial screening for depression and anxiety. First, Field Research Assistants will identify women suitable for the trial based on the study's inclusion criteria. According to the ethical guidelines of icddr,b's IRB and the Declaration of Helsinki, the investigators will strictly safeguard the human rights and privacy of all participants, with special consideration for those who may be economically or educationally disadvantaged. In all situations, it is duly vested in the research team to thoroughly explain the research goals, objectives, randomisation process, and expected activities in a clear, culturally appropriate manner that will be easily comprehended by the participants. The women will be informed about the intervention (tele-counselling via the Wellbeing Centre or standard in-person counselling) aimed at reducing depression and anxiety. The investigators will clearly explain any potential psychological consequences, such as transient emotional distress or temporary symptom exacerbation that may arise during psychological counselling. Moreover, they will be informed about the study's safety protocols, including the provision of 24-hour emergency contact numbers, the referral procedures in case of severe clinical deterioration or treatment failure, and their absolute right to withdraw from the study at any time without it affecting their access to standard medical care.

For the qualitative components (IDIs and KIIs), a dual-consent process will be employed. Participants will first consent to participate in the interview, and

subsequently be asked for separate, specific consent to allow audio recording. Participants will be explicitly counselled that consenting to the interview does not mandate consenting to the audio recording, and they may refuse the recording without withdrawing from the study or facing any consequences. To prevent any perceived pressure or undue influence stemming from the provision of free psychological counselling, the informed consent procedure will place a paramount emphasis on voluntariness. Field Research Assistants will be specifically trained to clearly explain to every eligible woman that she is under no obligation to join the trial. Crucially, participants will be explicitly assured verbally and in writing that refusing to participate, or choosing to withdraw at a later time, will not result in any consequence, nor will it negatively affect their ongoing access to standard medical care, routine outpatient psychiatric consultations, or any other health services available at the facility.

Perceived risks and benefits: Although there are no more than minimal risks to participate in this study and there are no physical risks associated with this study, there is a recognised and anticipated psychological risk. Because the study involves participants presenting with moderate to severe depression and anxiety, discussing personal trauma, life challenges, and sensitive mental health issues during screening, counselling, or interviews carries a substantial risk of inducing emotional distress, sadness, fatigue, or temporary symptom exacerbation.

Safeguards to protect any recognised vulnerability of the study: Confidentiality of the data will be ensured at all steps of the study including data collection, data management, access to data and use of the information. All personal identifiers will be removed from the data prior to analysis.

To ensure participant safety and well-being, emotional distress will be proactively monitored and managed across every phase of the study:

- **During Screening and Quantitative Assessments:** All Field Assistants will undergo specialised training in empathetic, trauma-informed communication and distress identification. If a participant exhibits signs of acute emotional distress or discomfort during data collection, the Field Assistant will immediately pause the session. The participant will be offered a break and explicitly reminded of their right to skip any questions or withdraw entirely. If the distress persists, the assessment will be terminated, and the participant will be immediately linked to the on-site Study Physician or an available clinical psychologist for supportive care.
- **During Tele-counselling and In-person Counselling:** Both remote and on-site psychologists are highly trained to monitor emotional responses continuously. Should a participant become overwhelmed while discussing trauma, the psychologist will utilise evidence-based grounding and de-

escalation techniques within the session. If the distress indicates a severe clinical deterioration or acute suicidal ideation, the established risk assessment and immediate escalation protocol to the Study Physician will be triggered.

- **During Qualitative Interviews (IDIs and KIIs):** Qualitative interviewers will maintain a highly supportive, unhurried environment, allowing the participant to completely control the pace of the conversation. Participants will be reminded beforehand that they do not have to discuss any trauma they are uncomfortable sharing. The same 'pause, terminate, and refer' mechanism used by Field Assistants will apply here.
- **Post-Session and Between Visits:** Because emotional distress can sometimes manifest after a discussion, all enrolled women are provided with a 24-hour emergency contact number. This ensures they have continuous access to the study coordinator or therapist for immediate support and crisis management between scheduled study activities.

Ethical Protocols for Administering Partner, Non-Partner, and Childhood Violence Questions: The inclusion of questions addressing partner-controlling behaviours, physical and sexual intimate partner violence, non-partner sexual assault, and childhood sexual abuse necessitates specialized ethical precautions. To protect participant welfare, the study team enforces the following protocol:

1. **Qualified Researcher & Absolute Privacy:** Violence modules are administered exclusively by trained field research assistant in dedicated private rooms. Only one eligible woman per household is interviewed to prevent domestic collusion or suspicion.
2. **Interruption Safeguard:** If any third party (family member, healthcare worker, or patient) enters the assessment room, the researcher will immediately pause the module and switch to non-sensitive general health questions.
3. **Voluntariness and Refusal Codes:** Participants are explicitly informed that answering violence-related questions is entirely optional. Field assistants and psychologists will never press for responses, and every item in the survey instrument includes an explicit **Code 9 = Refused / Prefer not to answer** option to record non-response without stigma.
4. **Confidentiality Limits and Non-Liability:** All collected data are encrypted and pseudonymised using unique study identification numbers. The study team operates under strict research confidentiality; data will not be shared

with law enforcement, hospital authorities, or family members, ensuring disclosures carry zero civil, criminal, or marital liability for the participant.

5. **Site-Specific Risk Assessment, Safety Planning, and Referral Pathway:** If a participant discloses active abuse, severe distress, or immediate safety concerns, the researcher will administer immediate first-line emotional support. A confidential, site-specific risk assessment and safety plan will be initiated. At the conclusion of the session, the participant will be discreetly offered a compact, easily concealable safety card containing emergency helpline numbers and pre-mapped local support pathways in Dinajpur (Dinajpur District Hospital catchment) and Matlab (Matlab Dakshin UHC catchment), including government social service officers, legal aid NGOs, and secure women's shelters.

Ethical issues to consider for enrolment of study participants: Ensuring patient safety and human rights are primacy for this project. The investigators brainstormed few of the ethical consideration the investigators need to focus on during the study period those the investigators notted down in the table below.

Table 5: Ethical Issues to Consider During Trial Implementation

No.	Ethical Issue	Approach
1	Will the study team seek permission from the participants before every data collection event?	The study team must seek permission from the enrolled women before collecting data at the baseline (T_0) and each subsequent follow-up assessment (T_1 , T_2 , T_3) over the 6-month trial.
2	Does the participant hold the right to withdraw from the study at any moment?	Without the fear of any further consequences (such as losing access to standard medical care at the facility), the women will be given the full authority to withdraw from the trial at any moment, including before, during, or after any counselling session or data collection event.
3	Does the participant have the right to withdraw the consent to use any data collected from them even after data collection?	Participants will have the full right to withdraw their consent to use any personal or clinical data collected from them at any moment.

No.	Ethical Issue	Approach
4	Who will be responsible for managing care if a participant experiences severe psychological side effects or treatment failure?	The study team, under the supervision of the designated Study Physician, will take responsibility to manage acute distress (via brief supportive care) and formally refer the participant to more intensive, specialized psychiatric or medical treatment facilities if their mental health severely deteriorates.
5	Will participants be forced to continue counselling sessions if they become reluctant?	If a woman becomes reluctant to continue her tele-counselling or in-person sessions, she will be counselled on the benefits of continuing, but will not be forced. If she stops attending, her decision will be respected. Under the intention-to-treat (ITT) protocol, she may be invited to continue providing follow-up data, or she can be completely withdrawn from the study if she chooses.
6	How will unpredictable adverse events (e.g., acute suicidal ideation) be managed during the trial?	As outlined in the safety monitoring plan, if an adverse event occurs, participants will have access to 24-hour emergency contact numbers. The trial counsellors and Study Physician will conduct formal clinical assessments to manage the crisis, refer the patient for proper psychiatric treatment if necessary, and formally record the incident for the Data Safety Monitoring Board (DSMB) review.

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Annex 1: Informed Consent Form (English)

Information Sheet for Participant (Adult Women)

Name of participants' group for whom Consent Form is written

Protocol No. PR-26-043	Version No. 2.00	Date: 14-09-2026
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Protocol Title: Improving Women's Mental Health through tele-based Wellbeing Centres in Bangladesh: An Efficacy Trial

Investigator's name: Aniqa Tasnim Hossain

Organization: International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b)

Protocol No. PR-26-043	Version No. 2.0	Date: 14-09-2026
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Purpose of the research

You are being invited to participate in a research study. The purpose of this study is to compare two ways of providing mental health counselling: tele-counselling (via secure video calls at a Wellbeing Centre) and standard in-person (face-to-face) counselling. We want to find out if tele-counselling is just as effective as in-person counselling in reducing symptoms of depression and anxiety, and improving the overall quality of life for women in Bangladesh. The findings from this study will help us understand if the tele-counselling model can be trusted as a reliable alternative for scaling up mental health support across the country.

In addition to questions regarding your general health and emotional well-being, the survey includes questions on maternal and child immunization (such as Tetanus doses during pregnancy, routine child EPI vaccination records, and structural access barriers), as well as sensitive questions concerning personal relationships, household conflict, and experiences of physical, sexual, or emotional violence by intimate partners or non-partners, including experiences during childhood. Completing these additional modules will add approximately 5 to 10 minutes to your total assessment time. To safeguard your privacy, these sensitive topics will be discussed in a private room by a trained female researcher. You have the absolute right to skip any question or refuse any topic without giving a reason and without losing access to your healthcare or counselling services.

Background (brief introduction of the issue and the need for/ importance of the research)

Many women in Bangladesh experience mental health conditions like depression and anxiety, but face barriers such as social stigma, financial constraints, or travel restrictions that make it hard to seek in-person support. Tele-counselling (counselling through secure video calls) has been introduced at Wellbeing Centres to overcome these barriers and make it easier to receive help. However, we do not yet know for sure if tele-counselling provides the exact same clinical benefits as traditional face-to-face counselling for women in

Bangladesh. To determine this, we are conducting a research study that requires the enrolment of approximately 1200 women experiencing symptoms of depression or anxiety. The results of this study will improve our understanding of remote mental health care and help decide if this tele-counselling model should be scaled up nationally to support more women.

Why invited to participate in the study?

As we are trying to understand the most effective ways to provide mental health support, we need to conduct this study with women who are experiencing symptoms of mental distress. We are inviting you to participate in this study because you have recently sought care at this facility and our initial screening indicates that you may be experiencing symptoms of depression or anxiety. By participating in this study, you can help us discover if tele-counselling can be as helpful for women like you as traditional in-person counselling.

Methods and procedures [What is expected from the participants of the research study?]

If you agree to our proposal of including you in the study, you might expect the following:

- First, we will ask you some questions about your current mood, feelings of anxiety or depression, and some general background information (such as your age and education).
- You will then be randomly assigned by a computer (like flipping a coin) to one of two groups: you will either receive standard in-person counselling with a psychologist in a private room, OR you will receive tele-counselling through secure video calls at the hospital's Wellbeing Centre.
- Regardless of the group you are in, you will receive the same number of counselling sessions from a trained professional using the exact same counselling manual.
- We will ask you to participate in follow-up assessments at 2, 4, and 6 months after you start the study. During these follow-ups, we will ask you similar questions to understand how you have been doing and if your quality of life has improved.
- We may also invite a small number of participants for an interview to hear more about your personal experience, privacy concerns, and any barriers you faced while using the counselling services.

We assure you that all the information and answers you share with us will be kept strictly confidential and will only be used for this research study.

Risk and benefits

Potential Benefits: By participating in this study, you will receive free, evidence-based mental health counselling (either face-to-face or via tele-counselling) from a trained psychologist. The direct, potential benefit to you is a reduction in your symptoms of depression and anxiety and an improvement in your overall quality of life. Additionally, your participation will provide an indirect, long-term benefit to society by helping us understand if

tele-based Wellbeing Centre can be a reliable and scalable way to provide mental health services to other women across Bangladesh.

Potential Risks and Precautions: There are no physical risks associated with this study. However, because counselling involves discussing your personal feelings, life challenges, and difficult experiences, there is a small chance you may experience moderate, temporary emotional distress, sadness, or fatigue during or immediately after the sessions. If you are in the tele-counselling group, you may also experience minor frustration from occasional technical issues, such as poor internet connectivity.

Discussing personal relationships, household conflict, or past experiences of physical or sexual violence may evoke emotional distress, sadness, uncomfortable memories, or privacy concerns. To safeguard your privacy, these questions will be asked in a private room by a trained female researcher. If anyone enters the room, the discussion will be paused immediately. You have the absolute right to skip any question, refuse to answer any specific topic, or stop the survey at any point without giving any reason and without any penalty. Refusing or skipping questions will not affect your access to psychological counselling, routine medical care, or any healthcare services at this facility.

Management of Risks: We will take all necessary precautions to minimize these problems. All counselling sessions will be conducted in a private, confidential room by highly trained psychologists who are experienced in managing emotional distress safely, and secure video platforms will be used to protect your privacy. In the event that you develop severe psychological distress, or experience suicidal thoughts during your participation in the study despite our preventive efforts, your psychologist will provide immediate support. We will also arrange for appropriate advanced psychiatric care or medical treatment or refer you to a specialized facility, ensuring your safety is prioritized at all times.

Your responses will remain strictly confidential. If you disclose active abuse, emotional distress, or safety concerns during the session, our team will provide immediate, compassionate emotional support and offer you a small, easily concealable information card containing free helpline numbers for local legal aid, medical care, social protection, and safe shelter services in Dinajpur and Matlab.

Privacy, anonymity and confidentiality

We assure you that the privacy, anonymity, and confidentiality of the data and information identifying you will be strictly maintained. We will keep all your personal information, mental health screening results, counselling descriptions, and interview audio recordings strictly confidential. Hard copies of records will be kept securely under lock and key, and electronic data will be password-protected and stored securely in accordance with the icddr,b Data Protection Policy. None other than the investigators of this research; possible study monitors; the Research Review Committee (RRC) and Ethical Review Committee (ERC) of icddr,b; and any law-enforcing agency in the event of necessity would have access to the information. We want to inform you that anonymized data related to the study may be sent outside the country for analysis or publication, where applicable; however, any personal identifiable information will be held and processed under secured conditions, with access limited to pre-identified staff of that organization.

Future use of information

In the future, the data and information collected from this study may be used to answer new research questions or combined with other datasets to advance our understanding of mental health treatments. In such cases, anonymous or abstracted information and data may be supplied to other researchers or independent research institutions exclusively for scientific purposes. The decision to share any research data will be strictly overseen by the Research Administration (RA) and Regulatory and Legal Affairs (R&LA) departments of icddr,b. We assure you that this process will not conflict with or violate the maintenance of your privacy, anonymity, and confidentiality in any way, as all personal identifying information will be completely removed prior to sharing.

Right not to participate and withdraw

Your participation in this study is entirely voluntary. We understand that the offer of free counselling might make you feel pressured to join, but you have the absolute right to decide whether or not to participate without any fear of negative consequences. You are also able to withdraw your participation at any time during the study, without showing any cause or giving a reason. Refusal to take part in or withdrawal from the study will involve no penalty or loss of care, benefits, or attention. If you do not enrol, or if you choose to withdraw from the study later, your decision will be fully respected, and you will continue to receive the usual standard medical care and routine mental health services available at this hospital for your condition without any interruption or prejudice.

Principle of compensation

There is no cost to you for participating in this study; all mental health counselling sessions and assessments will be provided completely free of charge. You will not receive financial payment for loss of earnings, as this study involves routine outpatient counselling sessions and does not require extended hospitalization or confinement. However, you may be reimbursed for the actual cost of transportation required to attend the follow-up assessment visits at the hospital, ensuring the amount covers your expenses without influencing your decision to participate. Furthermore, while the risk of physical injury is essentially non-existent in a psychological counselling study, in the unlikely event that you experience any research-related harm or severe psychological distress, you will be provided with the best possible, free medical and psychiatric treatment at this facility.

Consent Form for Participants

Name of participants' group for whom Consent Form is written

Protocol No. PR-26-043	Version No. 2.00	Date: 14-09-2026
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Protocol Title: Improving Women's Mental Health through tele-based Wellbeing Centres in Bangladesh: An Efficacy Trial

Investigator's name: Aniqa Tasnim Hossain

Organization: International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b)

If you agree to our proposal for enrolling you/your patient in our study, please put ✓ mark on appropriate box(es) of the following and finally sign on the specified place for you:

- I have read the participant's information sheet version 21-05-2026 and have had the opportunity to ask question, discuss the study, and received satisfactory answers. Yes ☐
No ☐
- I understand that I am free to leave the study without giving any reason. Yes ☐
No ☐
- I agree to participate in this qualitative interview. Yes ☐
No ☐
- I understand that the information I give is confidential. Yes ☐
No ☐
- I agree to my identifiable data being used for future ethically approved studies. Yes ☐
No ☐
- I agree to being contacted in the future for studies related to this research. Yes ☐
No ☐
- I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the sponsor and by regulatory authorities, where it is relevant to my taking part in this research. I give my permission for those individuals to have access to my records. Yes ☐
No ☐
- I give my separate and specific consent to allow this interview to be audio-recorded. Yes ☐
No ☐
- I understand that I can refuse to be audio-recorded without it affecting my participation in the study or my medical care. Yes ☐
No ☐

- I understand that the survey contains sensitive questions regarding personal relationships and violence, and I have the absolute right to skip any question or refuse to answer without losing my healthcare or counselling services
Yes ☐
No ☐
- I give my consent to take part in the study.
Yes ☐
No ☐

Signature or left thumb impression of participant

Date

Signature or left thumb impression of
Parent/ Guardian/ Attendant

Date

Signature or left thumb impression of the witness

Date

Signature of the PI or his/her representative

Date

Communication:

If you have any question you can ask me right now or at any time later to the below mentioned personnel:

Purpose of contact	Name and address	Address for communication
For any question related to the study, or any problem	 (local coordinator or representative)	Address: _____ _____ Mobile No. (to be open 7/24 hours)
	Aniqa Tasnim Hossain	Address: <u>68, Shaheed Tajuddin Ahmed</u>

	Associate Scientist Maternal and Child Health Division Icddr,b (Name of PI)	<u>Sarani, Mohakhali, Dhaka-1212</u> Mobile: <u>+880 1716-543128</u> (9:00 am to 5:00 pm)
To know the rights or benefits or to log any complain or dissatisfaction	Sabina Shahnaz (IRB Coordinator)	IRB Secretariat, Research Administration, icddr,b, Mohakhali, Dhaka-1212 Phone: 02-222277084 or Mobile: 01716599329

Thank you for your cooperation.