



**The NUR study: A pilot randomised controlled trial and Nested
process evaluation stUdy of acceptance and commitment
theRapy for pregnant women with antenatal depression and/or
anxiety in Pakistan**

Chief Investigators: Dr Cerith S. Waters, Dr Samina Naeem Khalid & Dr Jennifer Berrett

Co-investigator: Dr Shaeer Ellahi

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Protocol Revision History

Protocol Version with Summary of Changes	Version Date
Version 1 – Draft shared with HSA partners for review	23.10.2025
Version 2 – Reviewed Protocols returned from HSA	24.11.2025
Version 3 – Integrated feedback from HSA and revised protocol	19.12.2025
Version 4 – Final protocol discussed and further revisions agreed	09.01.2026
Version 5 – Final protocol agreed	30.01.2026

List of Abbreviations

ACT – Acceptance and Commitment Therapy
ACT-for-PNMH – Acceptance and Commitment Therapy for Perinatal Mental Health
MEDR ODA – MEDR Official Development Assistance
HSA – Health Services Academy
SAP - Statistical Analysis Plan
LMICS - Low-to-middle income countries
WHO - World Health Organisation
CBT – Cognitive Behavioural Therapy
RCT – Randomised Control Trial
GAD – Generalised Anxiety Disorder
CI – Confidence Interval
SOP - Standard Operating Procedure
ACT-FM – ACT Fidelity Measure
CORE-10 – Clinical Outcomes in Routine Evaluation-10
PHQ-9 – Patient Health Questionnaire
PAI – Prenatal bonding
PBQ – Postpartum Bonding Questionnaire
BSS – Birth Satisfaction Scale
EuroQol-5d-3L – EuroQol 5 Dimension 3 Level Health Questionnaire
MPFI – Multidimensional Psychological Flexibility Inventory
PPI - Patient and Public Involvement
GDPR – General Data Protection Regulation
IRB – Institutional Review Board
TSC – Trial Steering Committee
DMEC – Data Monitoring and Ethics Committee
TMC – Trial Management Committee
PI – Principle Investigator

1. ADMINISTRATIVE INFORMATION

Trial Title: The NUR study: A pilot randomised controlled trial and Nested process evaluation study of acceptance and commitment therapy for pregnant women with antenatal depression and/or anxiety in Pakistan

Trial Registration: No.7-82/IERC-HAS/2022-241.

Funding: MEDR, ODA funding.

Sponsor: Health Services Academy Islamabad, Ministry of National Health Services. No role in study design or reporting

Chief Investigator: Dr Cerith Waters (Cardiff University)

Collaborators: Dr Jennifer Berrett, co-Chief Investigator (Cardiff University); Professor Samina Naeem Khalid, co-Chief Investigator (Health Services Academy); Dr Shaheer Ellahi, co-Investigator (Health Services Academy)

Conflicts of Interest: None declared

Patient and Public Involvement: Service user representatives contributed to intervention design, participant materials, and outcome measure selection.

Open Science and Transparency: The protocol, Statistical Analysis Plan (SAP), and de-identified data will be made available by request following publication.

Study Period: October 2025 – January 2027

2. BACKGROUND AND RATIONALE

Mental health conditions are highly prevalent in low-to-middle income countries (LMICs), and this is particularly the case during the perinatal period [1, 2]. In Pakistan prevalence rates of perinatal depression and anxiety have been cited at 37% and 49% (Khan et al., 2021; Mahendrun et al., 2019; Parsons et al., 2012; Sikander et al., 2019a), with the treatment gap estimated at 76-85% (Atif et al., 2023). Risk factors include lack of social and economic support, gender-based violence, being unemployed, lower educational attainment, and/or having a psychiatric history (Fisher et al., 2012; Ghaffar et al., 2017; Humayun et al., 2013). With Pakistan having one of the highest childbirth rates in the world, the economic costs of perinatal mental health conditions in Pakistan have been estimated to cost approximately £16.6 billion, with the largest proportion of the costs related to the adverse impact on the mother's quality of life (Bauer et al., 2024). In terms of impact on the child, antenatal depression has been linked with an increased risk of pediatric physical health conditions (Rahman et al., 2004). Further, post-partum depression and anxiety have been linked to various adverse child developmental outcomes in LMICs, including Pakistan (see Sridhar et al., 2025 systematic review). There is evidently a need to focus on enhancing the treatment of perinatal mental health conditions, including perinatal anxiety and depression, in Pakistan.

Over the last decades, there have been some advancements in the treatment of perinatal mental health in Pakistan. The development and implementation of the 'Thinking Healthy Programme' (WHO, 2015) as a community-level intervention, for example, has reduced rates of perinatal depression through engaging women in Cognitive Behavioural Therapy (CBT) techniques to promote social support, reduce unhelpful thinking, and engage in behavioural activation (Sikander et al., 2019b;

Vanobberghen et al., 2021). Although this has been a feasible, acceptable, and cost-effective development within a stepped care model, allowing non-specialist roles to deliver lower-level psychological skills to mothers (Atif et al., 2023), there remains a gap in the psychological evidence base for supporting women with moderate-to-severe mental health conditions, increased risk, and/or complex needs. Perinatal mental health services do not meet the needs of the population in Pakistan, with societal stigma, lack of trained staff, and poor infrastructure being identified as barriers to service provision (Gul et al., 2019; Jawed et al., 2021; Sajjad et al., 2024; Shahzad et al., 2025). Developing culturally adapted psychological interventions for perinatal women presenting with moderate-to-severe mental health conditions in Pakistan is therefore vital.

To date, culturally adapted CBT is effective in reducing post-partum depression symptomology and enhancing quality of life for perinatal women in Pakistan (Aslam & Athar, 2025; Khan et al., 2019). However, CBT may contribute to the accessibility challenges to perinatal mental health support, as it often focuses on a specific condition, such as depression, does not treat co-morbidity, and often relies on specialist training to adapt to other presentations. Acceptance and Commitment Therapy (ACT), a third-wave CBT model, may be a promising alternative due to its transdiagnostic nature, which can widen accessibility and increase timely access to intervention (Bonacquisti et al., 2017).

ACT focuses on supporting individuals to fully and consciously engage with their thoughts, sensations, and emotions (psychological flexibility), without trying to suppress or alter them (experiential avoidance), whilst connecting with values or what is most meaningful to them (Hayes et al., 2006; Hayes et al., 2012). The model focuses on six interrelated core processes: Contact with the present moment, Observer Self, Cognitive Defusion, Acceptance, Values, and Committed Action (Fang & Ding, 2020; Hayes et al., 2011). Research into its effectiveness is growing; for example, in higher income countries, ACT is an effective intervention for perinatal mental health conditions (Bonaquisti et al., 2017; Waters et al., 2020). Although limited in nature, early evidence indicates that culturally adapted ACT is a feasible, safe, and potentially effective intervention for antenatal depression and anxiety in Pakistan (Maqsood et al., 2025).

The current study will use a pilot RCT design with nested process evaluation to examine the feasibility, acceptability, and preliminary effectiveness of group-delivered ACT-PNMH for the treatment of antenatal depressive and anxiety disorders for pregnant women in Pakistan.

3. OBJECTIVES

3.1. Primary Objectives (Feasibility & Acceptability). The primary objective is to evaluate the feasibility and acceptability of the pilot RCT design and of the culturally adapted ACT-PNMH intervention.

- a) **Feasibility of Recruitment and Retention:** Determine whether eligible pregnant women can be successfully identified, approached, recruited, randomised, and retained throughout the study.

- b) **Feasibility of Intervention Delivery:** Assess whether participants can attend the ACT-PNMH sessions as planned, including session attendance, completion, and reasons for non-attendance.
 - c) **Data Feasibility:** Evaluate whether outcome measures and process measures can be completed reliably, with acceptable levels of data completeness and minimal missing data.
 - d) **Intervention Fidelity and Adherence:** Assess whether the ACT-PNMH intervention can be delivered as intended, including adherence to the intervention manual and facilitator fidelity.
 - e) **Acceptability to Participants and Facilitators:** Explore the acceptability of the intervention, study procedures, and research processes from the perspectives of participants and facilitators.
- 3.2. Secondary Objectives (Preliminary Efficacy).** To explore potential signals of clinical improvement and estimate variability to inform future sample size calculations.
- a) **Psychological Symptom Change:** Explore initial trends and variability in psychological distress, depression, and anxiety symptoms e.g., psychological distress (CORE-10; Barkham et al., 2012), depression (PHQ-9; Kroenke et al., 2001), and anxiety (GAD-7; Spitzer et al., 2006).
 - b) **Functional Outcomes:** Explore trends and variability in maternal functioning, e.g., quality of life (EUROQoL; EuroQol Group, 1990) and functioning (CORE-10; Barkham et al., 2012).
 - c) **Intervention Mechanisms:** Explore trends and variability in ACT-PNMH intervention mechanisms psychological flexibility (MPFI; Rolffs et al., 2018) and the therapeutic alliance (WAI-SF; Hatcher & Gillaspay, 2006).
 - d) **Impact on Childbirth, Infant and Mother-Infant Relationship:** Explore trends and variability in outcomes on childbirth (BSS; Hollins Martin & Martin, 2014), infant (WHO-GSED; McCray et al., 2023) and mother-infant relationship outcomes (PBQ; Brockington et al., 2006; audio-visual recording of mother-infant interaction).
- 3.3. Process Evaluation Objectives.** To understand how the intervention and the RCT procedures operate within real-world antenatal care settings and identify factors that may support or hinder scalability.
- a) **Implementation in Routine Care:** Examine how the ACT-PNMH intervention is delivered within existing healthcare systems and identify organisational, structural, and contextual factors affecting implementation.
 - b) **Mechanisms of Impact:** Explore how participants engage with ACT-PNMH components and how these may contribute to changes in psychological or functional outcomes.
 - c) **Contextual Influences:** Identify barriers and facilitators to delivery, including cultural, logistical, and system-level factors that may influence future scalability and sustainability.

4. TRIAL DESIGN

A two-arm, parallel-group, pilot randomised controlled trial with 1:1 allocation comparing group-delivered ACT-for-PNMH plus usual care versus usual care alone. A mixed methods process evaluation will be nested within the trial, following the MRC Process Evaluation Framework.

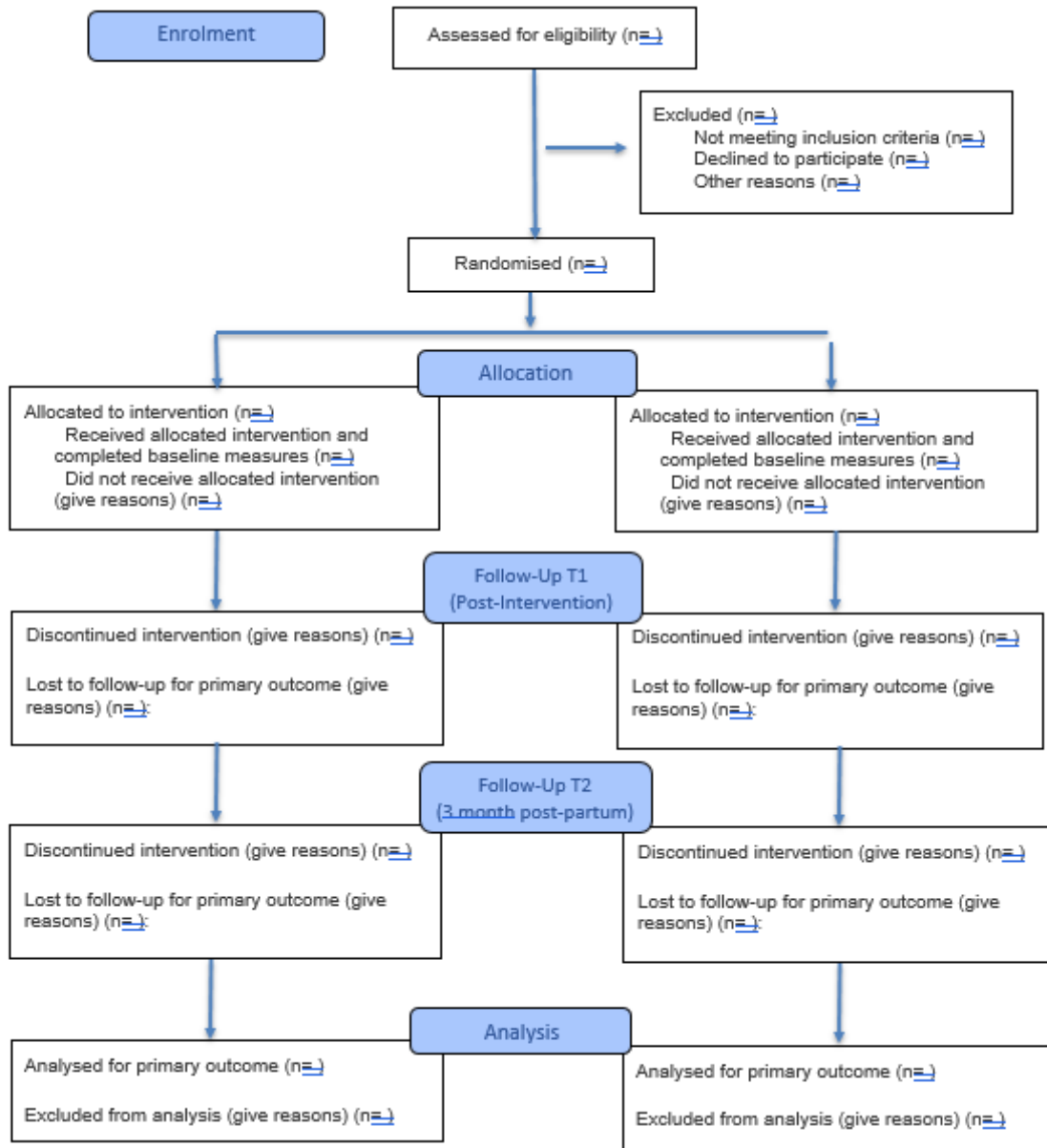


Figure 1: CONSORT Flow Diagram for the ACT-PNMH Pilot Randomised Controlled trial (ACT-NUR)

5. METHODS: PARTICIPANTS, INTERVENTIONS, AND OUTCOMES

5.1. Setting:

Community and hospital antenatal settings.

5.2. Participants:

Pregnant women experiencing antenatal depression and/or anxiety in the second trimester of pregnancy and scoring in the clinical range for depression and/or anxiety.

5.3. Recruitment:

Participants will be recruited through community outpatient antenatal clinics in the Rawalpindi region of the Punjab, Pakistan. All women attending the clinics will be provided with information about the study and will be invited to take part in the screening process. Women will be screened for antenatal distress, anxiety and depression against the inclusion/exclusion criteria specified below. Once the potential participant has had the participant information sheet (PIS) for 24 hours, and contact has been made to confirm if they would like to take part in the study, a meeting (T1) should be arranged to complete informed consent and the baseline measures.

5.4. Inclusion Criteria:

Participants are eligible if they meet the following:

- a) **Age:** 18 years or older.
- b) **Gestation:** 16–28 weeks at the start of the intervention.
- c) **Consent:** Able to provide informed consent.
- d) **Psychological Distress:** Clinical range on the CORE-10 (Barkham et al., 2012) score ≥ 11 **and** either the PHQ-9 (Kroenke et al., 2001) score ≥ 10 (depression) **and/or** GAD-7 (Spitzer et al., 2006) score ≥ 8 (anxiety).
- e) **Intervention Attendance:** Able to attend the intervention sessions.

5.5. Exclusion criteria:

Participants will be excluded if they met any of the following:

- a) **Severe psychiatric conditions:** Current psychosis or bipolar disorder.
- b) **Substance use:** Current substance dependence.
- c) **Concurrent psychological treatment:** Receiving another structured psychological intervention at baseline.
- d) **Medication changes:** Change in psychotropic medication within one month prior to randomisation.
- e) **Suicidal risk:** Suicidal intent or high risk at baseline assessment.
- f) **Other conditions:** Any medical or obstetric condition that would prevent participation in the intervention or compromise safety (e.g., severe pregnancy complications).

5.6. Sample Size:

To estimate a consent rate of 50% with a precision of $\pm 11\%$ using a two-sided 95% confidence interval (CI), we planned to approach **144 eligible participants**, aiming to achieve the required sample of **N = 72**, with **36 participants in each trial arm**. This

sample size is sufficient to assess key feasibility parameters, including **recruitment, retention, adherence to the intervention, and completion of outcome measures**, and to provide preliminary data to inform the design of a future definitive randomised controlled trial (RCT).

5.7. Randomisation:

Computer-generated, 1:1 allocation to ACT-PNMH plus usual care or usual care alone, stratified by site and baseline severity. See SOP for randomisation procedure.

5.7.1. Allocation Concealment: Centralised web-based system.

5.7.2. Blinding: Participants, therapists and research assistants unblinded.

5.8. Intervention Group Assessments:

Baseline (1 week pre-intervention), following session 3 and session 5 during intervention delivery, post-treatment (9 weeks post-randomisation and following session 8), and 3 months postpartum.

5.8.1. Control Group Assessments: Baseline (1 week pre-intervention), post-treatment (9 weeks post-randomisation) and 3 months postpartum.

5.9. Intervention:

Eight weekly sessions (90-minute duration) of group-delivered ACT-for-PNMH by trained therapists, plus usual care. The original ACT-PNMH manual (Waters et al., 2020) has been translated and culturally adapted for the Urdu speaking population of Pakistan. Intervention sessions will be delivered in person or remotely (e.g. via videoconferencing) if a participant cannot attend an in-person delivered group session.

5.9.1. Comparator: Usual care provided by standard antenatal mental health or primary care services. There is no standard model of care for antenatal depression and anxiety in Pakistan, but could include support provided by general practitioners, midwives and/or referrals to mental health services provided by psychologists and/or psychiatrists.

5.10. Primary Outcome Measures:

Primary feasibility and acceptability metrics include:

- a) Recruitment rates (no. approached/no. declined/no. consented)
- b) Reasons for declining RCT and/or intervention (see checklist)
- c) Intervention completion rates, defined as attending 4+ sessions
- d) Mean, median and modal number of sessions attended
- e) Reasons for missing a session (see checklist)
- f) Reasons for dropping out of intervention before completion (see checklist)
- g) The completeness of outcome measures and data collection
- h) ACT-PNMH adherence (checklist), ACT fidelity (ACT-FM: O'Neill et al, 2019) and participant homework completion (homework log).
- i) The acceptability of the ACT-PNMH intervention and weekly session content (acceptability questionnaire)
- j) The acceptability of the RCT design (acceptability questionnaire)

- k) Adverse events defined as a clinically significant deterioration on the CORE-10 (Barkham et al., 2012), suicidal intent, referral to crisis and/or inpatient services.

5.11. Clinical Outcome Measures:

A range of standardised questionnaires that assess maternal mental health and functioning, prenatal and postnatal bonding, childbirth, infant, and relational outcomes will be used to examine the preliminary effectiveness of the intervention. Core ACT process measures will also be assessed. Specifically, the following outcomes will be collected:

- a) Clinical Outcomes in Routine Evaluation-10 (CORE-10; Barkham et al., 2012)
- b) Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001)
- c) Generalized Anxiety Scale (GAD-7; Spitzer et al., 2006)
- d) Health Related Quality of Life (EuroQol-5D-3L; EuroQol Group, 1990)
- e) Prenatal Attachment Inventory (PAI; Muller, 1989)
- f) Postpartum Bonding Questionnaire (PBQ; Brockington et al., 2006)
- g) WHO Global Scales of Early Development (3–6-month version; McCray et al., 2023)
- h) Birth Satisfaction Scale – Revised (BSS; Hollins Martin & Martin, 2014)
- i) Multidimensional Psychological Flexibility Inventory (MPFI; Rolffs et al., 2018)
- j) Working Alliance Inventory-Short Form (WAI-SF; Hatcher & Gillaspie, 2006)
- k) Consent to complete an audio-visual recording of mother-infant interaction at 3 months postpartum.

6. NESTED PROCESS EVALUATION

The mixed-methods process evaluation will assess implementation (reach, fidelity, acceptability, adaptations), mechanisms of impact, and contextual factors that impact the delivery of both the ACT-PNMH intervention and the RCT design. The process evaluation will include semi-structured interviews with ACT-PNMH trial participants, therapists, and healthcare managers/service leads. The interviews will explore the feasibility, acceptability and implementation of the RCT design and of the ACT-PNMH intervention in healthcare settings in Pakistan. Mechanisms of impact and contextual factors that influence the delivery and uptake of the ACT-PNMH intervention and RCT design will be explored. Interviews with trial participants will also have an additional focus on ACT-PNMH intervention mechanisms (e.g. ACT specific and non-specific therapeutic factors) that facilitated improvements in mental health and functional outcomes. Interviews will be analysed using Reflective Thematic Analysis (Braun and Clark, 2016, 2019). Specifically, we aim to:

1. Interview N = 15 trial participants at post-treatment
2. Interview N = 5 trial therapists at trial completion
3. Interview N = 5 healthcare leaders/managers where ACT-PNMH is being delivered at trial completion.
4. Refine the intervention logic model for the culturally adapted ACT-PNMH manual in line with the study findings.

Quantitative data (session logs, adherence and fidelity ratings, checklists) and qualitative interviews with participants and therapists will be integrated using framework analysis.

Domain	Objectives	Data Source / Method	Analysis Approach	Outputs / Notes
Implementation	Assess reach, fidelity, adherence, acceptability and adaptations	-Session attendance logs -Facilitator adherence checklists -Fidelity ratings (ACT-FM)	Quantitative analysis (descriptive statistics)	Identify adherence rates, session completion, adherence, fidelity ratings and any adaptations
Mechanisms of Impact	Explore how ACT processes influence outcomes	- Participant interviews - Therapist interviews - Session logs (skills practice, engagement)	Qualitative Thematic Analysis	Insights into which components of ACT-PNMH are most effective and why
Contextual Factors	Identify organizational, cultural, logistical factors affecting delivery and uptake	- Healthcare managers/service lead interviews - Therapist/Lady Healthcare worker interviews	Qualitative Thematic Analysis	Barriers and facilitators to implementation; guidance for scalability
Integration	Combine quantitative and qualitative findings to understand implementation and impact	Mixed-methods triangulation	Thematic Analysis/ Narrative synthesis	Comprehensive understanding of how, for whom, and under what conditions the intervention works
Outputs	Refine intervention logic model and trial procedures	All above data	Synthesis of findings	Recommendations for manual refinement, implementation strategies, and future RCT design

Table 1: Nested Process Evaluation – ACT-for-PNMH Pilot RCT

7. SCHEDULE OF ASSESSMENTS

Outcome Measure	Screening (T0)	Baseline 1 week prior to session 1 (T1)	End of ACT Session 3 (T2)	End of ACT Session 5 (T3)	Post- treatment 9 weeks post- randomisation (End of session 8) (T4)	Follow-up 3 months post-partum (T5)
1. Clinical Outcomes in Routine Evaluation-10 (CORE-10; Barkham et al., 2012)	✓	✓	✓	✓	✓	✓
2. Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001)	✓	✓			✓	✓
3. Generalized Anxiety Scale (GAD-7; Spitzer et al., 2006)	✓	✓			✓	✓
4. Health Related Quality of Life (EuroQol-5D-3L; EuroQol Group, 1990)		✓			✓	✓
5. Prenatal Bonding Inventory (PAI; Muller, 1989)		✓			✓	
6. Psychological Flexibility (MPFI; Rolffs et al. 2018)		✓		✓	✓	✓
7. Working Alliance Inventory-SF (WAI-SF; Hatcher & Gillaspy, 2006)			✓	✓	✓	✓
8. Postpartum Bonding Questionnaire (PBQ; Brockington et al., 2006)						✓
9. WHO Global Scales of Early Development-SF (McCray et al., 2023)						✓

10. Birth Satisfaction Scale (BSS; Hollins Martin & Martin, 2014)						✓
11. Audio-visual recording of mother-infant interaction						✓
12. Acceptability of ACT-for-PNMH session content			✓	✓	✓	
13. Acceptability of ACT-for-PNMH intervention					✓	
14. Acceptability of RCT design					✓	✓
15. Feasibility of ACT-for-PNMH intervention			✓	✓	✓	
16. Feasibility of RCT design			✓	✓	✓	✓
17. Adherence and Fidelity to ACT-for-PNMH manual			✓	✓	✓	
18. Semi-structured interviews with trial participants					✓	✓
19. Semi-structured interviews with trial therapists					✓	✓
20. Semi-structured interviews with service managers/leads					✓	✓
21. Adverse event monitoring		✓	✓	✓	✓	✓

Table 2. Timing of Assessments

8. PROGRESSION CRITERIA

1. Recruitment $\geq 70\%$ of target (Green), 50–69% (Amber), $< 50\%$ (Red).
2. Retention $\geq 70\%$ at post-treatment (Green), 50–69% (Amber), $< 50\%$ (Red).
3. Adherence $\geq 70\%$ attend $\geq 50\%$ sessions (Green), 50–69% (Amber), $< 50\%$ (Red).

9. DATA COLLECTION AND MANAGEMENT

Data will be collected via the traditional paper and pen method by researchers working on the trial. The data will be anonymised and entered into SPSS or EXCEL on the day of collection. Data will be stored in line with institutional and GDPR requirements.

Identifiable data will be stored separately. Quality control will include double data entry and periodic audits. Data will be retained in accordance with institutional and GDPR requirements.

10. STATISTICAL ANALYSIS PLAN

Feasibility and acceptability data will be summarised descriptively with 95% confidence intervals. Preliminary clinical outcomes will be analysed using linear mixed models to estimate mean differences and confidence intervals. Missing data will be described, and no formal hypothesis testing will be performed.

11. ETHICS AND DISSEMINATION

Ethical approval will be sought from the Institutional Review Board (IRB) of Health Services Academy, Islamabad, Pakistan. Participants will provide written informed consent. All adverse events will be reported in accordance with sponsor procedures. Results will be disseminated through peer-reviewed journals, conferences, and participant summaries. De-identified data and analysis code will be made available following request.

12. TRIAL GOVERNANCE

A Trial Steering Committee (TSC) with independent and PPI members will oversee trial conduct. A Data Monitoring and Ethics Committee (DMEC) will review safety and feasibility data following the baseline assessment, at mid-point, following intervention delivery, and following the Time 5 (three months postpartum) assessment. The Trial Management Committee (TMC) will meet fortnightly to monitor progress.

13. SCHEDULE AND TIMELINE

Start-up and training: Months 0–3 (October–December 2025)

Recruitment: Months 4–8 (January–May 2026)

Baseline assessment and intervention delivery: Months 6–10 (March–July 2026)

Follow-up 1 (post-treatment): Months 8–10 (May–July 2026)

Follow-up 2 (three-months postpartum): Months 10–14 (August–November 2026)

Analysis and reporting: Months 13–16 (December 2026–January 2027)

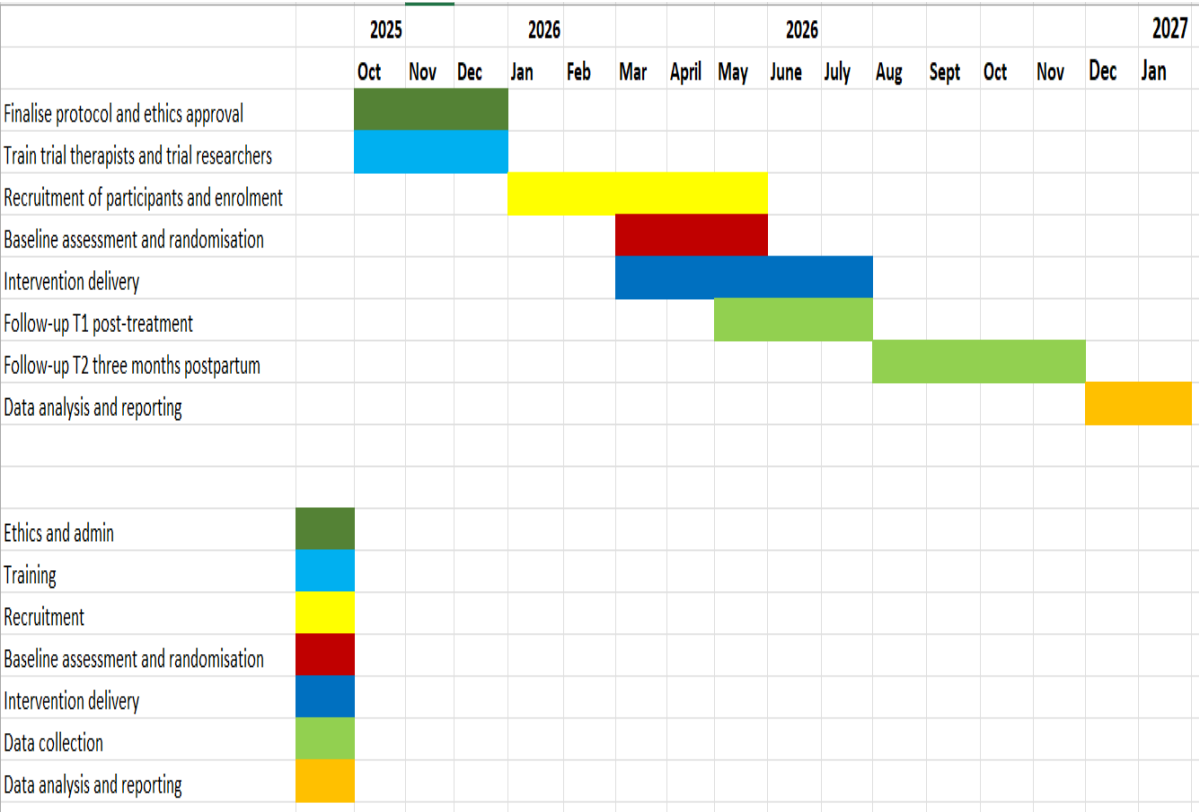


Table 3: Gantt Chart

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APPENDICES

Appendix A: SPIRIT 2025 Checklist

The following table maps each section of this protocol to the corresponding SPIRIT 2025 item. Items marked with *New (2025)* indicate newly introduced or substantially revised requirements.

SPIRIT 2025 Item	Section in Protocol	Notes / Status
Administrative information	Section 1	Includes PPI, open science, conflicts of interest (*New 2025*)
Background and rationale	Section 2	Expanded on condition, rationale, and comparator detail (*Revised*)
Objectives	Section 3	Includes feasibility and process objectives
Trial design	Section 4	Conforms to SPIRIT format
Eligibility criteria	Section 5	Explicit inclusion/exclusion criteria
Interventions	Section 5	Detailed per TIDieR; adherence and monitoring (*Revised 2025*)
Outcomes	Section 5	Outcome schedule table; includes harms (*Revised 2025*)
Sample size	Section 5	Feasibility-based
Allocation & blinding	Section 5	Randomisation, concealment, blinding described
Process evaluation	Section 6	Nested mixed-methods process evaluation
Statistical methods	Section 10	Descriptive feasibility analysis plan
Ethics and dissemination	Section 11	Includes data sharing plan (*New 2025*)

Trial governance	Section 12	TSC and DMC roles defined
Timeline	Section 13	Project schedule and milestones

Appendix B: TIDieR Checklist – Description of the Acceptance and Commitment Therapy-Perinatal Mental Health (ACT-PNMH) Intervention

1. Acceptance and Commitment Therapy for Perinatal Mental Health (ACT-PNMH).
2. ACT-PNMH targets thinking, emotional processing, values and behaviours that promote recovery from psychological distress, anxiety and depression.
3. Therapist manual and participant workbook that includes home-practice sheets.
4. Eight 2-hour group-delivered sessions provided over 8 consecutive weeks. ACT-PNMH is manualised and covers modules which map on to the core components of the ACT model. This includes mindfulness, observer self, acceptance and thought defusion in the first three weeks. One week focuses on the use of ACT to experience uncomfortable emotions, and another week focuses on how ACT can support with self-compassion. Weeks six and seven explore the use of values and committed action, to support people to work towards goals that are in line with what is important to them. The final week provides a recap of the seven prior sessions and explores endings and writing compassionate letters as reminders of what has been learnt.
5. Trained ACT-PNMH therapists with perinatal experience, supervised fortnightly by a senior ACT-PNMH therapist.
6. ACT-PNMH intervention sessions will be delivered face-to-face. Remote sessions can be delivered if a given session cannot be scheduled in person.
7. ACT-PNMH will be delivered in community venues or hospital outpatient clinics.
8. Weekly 2-hour sessions for pregnant women who are between 16-28 weeks' gestation at session 1
9. ACT-PNMH has been tailored to the perinatal period and has been culturally adapted for the Urdu speaking population in Pakistan.
10. Any protocol deviations or adaptations will be recorded with rationale.
11. The ACT-FM (O'Neill et al., 2019) will be used to monitor fidelity. Session audio recordings will be rated using the fidelity checklist. A minimum of 20% of fidelity ratings will be independently reviewed by a second researcher.
12. To enhance adherence therapists will attend regular supervision with a senior ACT-PNMH therapist. Participants will be sent weekly reminders to enhance attendance. If a participant misses a session, then they will be a telephone call/video-conference call will be scheduled to determine the reason for missing the session and to provide the material to the participant.

Appendix C: Current Logic Model for ACT-PNMH Individual Delivery

