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# Non-specialist-delivered psychosocial intervention for prenatal anxiety in a tertiary care setting in Pakistan: a qualitative process evaluation

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## ABSTRACT

**Objectives** A manualised cognitive–behavioural therapy-based psychosocial intervention for prenatal anxiety called Happy Mother Healthy Baby is being tested for its effectiveness through a randomised control trial in Pakistan. The aim of this study was to evaluate the intervention delivery process and the research process.

**Design** Qualitative methods were used to explore in depth the intervention delivery and research process.

**Setting** This process evaluation was embedded within a randomised control trial conducted in a tertiary care facility in Rawalpindi, Pakistan.

**Participants** Data were collected through in-depth interviews (n=35) with the trial participants and focus group discussions (n=3) with the research staff. Transcripts were analysed using a Framework Analysis.

**Results** The evaluation of the intervention delivery process indicated that it can be effectively delivered by non-specialist providers trained and supervised by a specialist. The intervention was perceived to be culturally acceptable and appropriately addressing problems related to prenatal anxiety. Lack of awareness of 'talking' therapies and poor family support were potential barriers to participant engagement. The evaluation of the research process highlighted that culturally appropriate consent procedures facilitated recruitment of participants, while incentivisation and family involvement facilitated sustained engagement and retention. Lack of women's empowerment and mental health stigma were potential barriers to implementation of the programme.

**Conclusion** We conclude that non-specialists can feasibly deliver an evidence-based intervention integrated into routine antenatal care in a tertiary hospital. Non-specialist providers are likely to be more cost effective and less stigmatising. Inclusion of family is key for participant recruitment, retention and engagement with the intervention.

**Trial registration number** NCT03880032.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Applying the Framework Analysis approach facilitated transparent and systematic analysis of the data.
⇒ Robust triangulation procedures for information retrieved from interviews of study participants increased the credibility of data collection procedures.
⇒ A few of the study participants were interviewed over a phone call, which may have limited rapport building and information sharing between the interviewer and interviewees.
⇒ Only a limited number of dropouts were approached for interviews, limiting the breadth of insights in present analyses.
⇒ The setting of the study in a tertiary hospital in a semiurban area may not allow for the transfer of findings to other segments of the population.

## INTRODUCTION

Anxiety during pregnancy is highly prevalent and adversely impacts maternal and child health outcomes. Prenatal anxiety disorders and anxiety symptoms disproportionately affect pregnant women in low/middle-income countries (LMICs)[1] especially in the South Asian region, including 49% in Pakistan,[2] 55.7% in India[3] and 29% in Bangladesh.[4] Prenatal anxiety is associated with impaired coping,[5] fear of childbirth,[6] postnatal anxiety and depression,[7 8] and risk of suicide.[9] Children of mothers with prenatal anxiety have poorer birth outcomes[10] and are at higher risk of poor developmental trajectories.[11] In LMICs where prevalence for prenatal anxiety is high (29.2%)[12] and the treatment gap for mental health disorders is large (76%–85%),[13] the long-term impact on women's mental health is likely to be substantial. For instance, a recent systematic review showed that 24.4% of women continue experiencing anxiety symptoms after delivery and that 16% were clinically diagnosed with postnatal anxiety in LMICs.[12]

There is an urgent need to address prenatal anxiety early and effectively to minimise adverse effects on maternal and child health. While recent evidence suggests that

psychosocial interventions delivered by non-specialist providers (NSPs)—health providers without specialised mental health training—can ameliorate common mental health problems, none have focused on anxiety during early pregnancy.[14–16] To address this gap, we adapted the evidence-based Thinking Healthy Programme, a cognitive–behavioural therapy (CBT)-based psychosocial intervention for perinatal depression, to target women with prenatal anxiety.[17] Our intervention called Happy Mother Healthy Baby (HMHB) consists of six core sessions and between two and six booster sessions delivered one-on-one during early to late pregnancy by NSPs trained and supervised by a mental health specialist.[18] Its core strategies include: developing an empathetic relationship, challenging unhelpful thoughts, behavioural activation, problem-solving and family engagement. The intervention targets three areas of a mother's well-being: her personal health, her relationship with significant others and bonding with her baby. HMHB employs culturally tailored illustrations and scenarios for psychosocial awareness, cognitive restructuring and setting tasks in collaboration with participants to engage in helpful activities. The intervention is currently being tested through a two-arm, single-blind, individual randomised controlled trial (RCT) at the Obstetrics Department of a tertiary care hospital in Pakistan.[19]

The UK Medical Research Council guidance for developing and evaluating complex interventions recommends process evaluations to explain discrepancies between expected and observed endpoints, to understand how context influences outcomes, and to provide insights to aid implementation.[20] In line with these recommendations, we conducted a process evaluation in parallel with the trial. Our objectives were twofold. First, we wanted to understand the factors impacting the *intervention delivery process* such as perceived benefits and acceptability as well as barriers and facilitators to successful intervention delivery. Second, we wanted to understand the *research process* such as challenges with participant recruitment and retention in a busy tertiary hospital and participants' views on the assessment procedures.

**Box 1 Areas included in the topic guide**

**Trial participants—intervention arm**
- ⇒ Experiences providing informed consent and of recruitment to the intervention arm.
- ⇒ Experiences participating in intervention and assessments.
- ⇒ Views on intervention content, tools, format and perceived impact.
- ⇒ Views on non-specialist providers/assessors.
- ⇒ Barriers and facilitators to participating in intervention and assessments.

*Participants who discontinued receiving the intervention were asked about reasons for discontinuation.*

**Trial participants—control arm**
- ⇒ Experiences providing informed consent and being recruited to the control arm.
- ⇒ Views on assessment tools and perceived impact of assessments.
- ⇒ Experience with assessments and assessors.
- ⇒ Barriers and facilitators to participating in assessments.

**Non-specialist providers**
- ⇒ Experiences receiving training and supervision.
- ⇒ Views on intervention content, tools, format and perceived impact on participants.
- ⇒ Experiences delivering the intervention.
- ⇒ Perceived impact of intervention on participants
- ⇒ Barriers and facilitators to intervention delivery.

**Assessment team**
- ⇒ Experiences obtaining informed consent.
- ⇒ Experiences conducting screenings and assessments.
- ⇒ Perceived impact of assessments on participants.
- ⇒ Facilitators and barriers to conducting assessments.

**Coordination team**
- ⇒ Experiences randomising participants.
- ⇒ Experiences facilitating prenatal check-ups/ultrasounds for participants.
- ⇒ Experiences following up with participants for assessments and intervention sessions.
- ⇒ Factors impacting participant engagement during the trial.

## METHODS

### Design, setting and participants

This process evaluation was embedded within the intervention trial conducted at the Obstetrics Department of the Holy Family Hospital, Rawalpindi, a tertiary care facility affiliated with Rawalpindi Medical University in Pakistan. The hospital has a catchment population of over 7 million, drawn from urban as well as periurban and rural areas of the district. For the process evaluation, we recruited interviewees from among RCT participants: women aged ≥18 years with a gestational age ≤22 weeks who resided within 20 km from Holy Family Hospital, understood spoken Urdu, and had at least mild anxiety on the anxiety subscale (score ≥8) of the Hospital Anxiety and Depression Scale,[21] in the absence of a depression diagnosis per the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders.[22] Interview participants for this study were drawn from the intervention arm, control arm and those who stopped receiving the intervention. To obtain maximum variation, the women were purposively sampled based on age, education and number of children. Focus group participants consisted of the research staff: the NSPs who delivered the intervention sessions, assessment team members who collected quantitative data, and coordination team members who were responsible for randomising the participants, facilitating check-ups, providing incentives, and following up with participants.

### Data collection

Qualitative methods were used to explore in depth the intervention delivery and research process. Data were collected through in-depth interviews (IDIs) with the trial participants and focus group discussions (FGDs) with the research staff from March 2020 to April 2022. Separate topic guides were developed in Urdu and pilot tested for each set of participants. Box 1 below outlines the areas

included in the topic guides. Full English versions of the topic guides are available as online supplemental file 1. Prior to data collection, written informed consent was obtained from all participants. Data were collected by inviting the trial participants (except those interviewed over the phone) and the research staff on the hospital premises, where trial was being conducted. Participants were paid travel expenses which was the equivalent of US$2.21. Data were collected by two research assistants with prior qualitative research experience who were not involved in the RCT. A note-taker took notes during FGDs. They were referred to while data were being analysed. Data were collected until saturation point was achieved. IDIs lasted 30–60 min, and FGDs were 90–120 min long. They were audio-recorded and transcribed in Urdu. During transcribing, all data were anonymised. Data were kept in locked filing cabinets in secured offices within participating sites.

### Data analysis

Data collection and analysis were carried out simultaneously using the Framework Analysis—allowing the systematic, rigours and transparent method of analysing data.[23 24] Data analysis employed all five steps of the Framework Analysis, starting with *familiarisation*, which involved reading and rereading transcripts to identify codes from the data. Codes referring to similar topics were grouped into categories and to generate subthemes and themes. The *thematic framework* was developed for each set of participants with index numbers assigned to themes and subthemes. This was followed by *indexing* and *charting*; indexing involved systematically applying the thematic framework to raw data while charting involved summarising indexed sections and placing them on thematic charts for each set of participants. All summaries included in the chart were referenced to produce an audit trail for the findings. Lastly, all themes and subthemes were critically examined to understand links and associations that facilitated *interpretation* of the data.

In order to ensure rigour, data were collected from different sets of participants (trial participants, NSPs, the assessment team and the coordination team) and compared to achieve greater understanding of the topic and more confidence in the findings. Furthermore, the results were shared with the NSPs and the assessment and coordination team members to evaluate the findings.

### Patient and public involvement

The Human Development Research Foundation, Pakistan, which implemented this research project has a long-standing patient and public involvement (PPI) group comprising of over a dozen service users and their family members. The PPI group was involved in key decisions throughout the study. For example, their feedback was sought on the research questions for this process evaluation, and they reviewed the topic guides for any areas of enquiry that might be uncomfortable or stressful for the participants. The PPI group were involved in the dissemination of the findings through their participation in community events organised for this purpose.

## RESULTS

In total, 35 IDIs were conducted (20 in person and 15 by phone) with participants from the control arm (n=10), intervention arm (n=20) and those who stopped receiving the intervention (n=5). Some interviews were conducted over telephone because during the period of data collection, hospitals as well as public transport systems were in lock-downs due to COVID-19 pandemic. All participants were 18–36 years old, had 0–14 years of formal schooling and had between one and five children. Most of them were living in joint families (78%). In addition to the IDIs, three FGDs were conducted with the HMHB research teams: five NSPs, five assessors and six coordinators. The NSPs were university graduates (with no clinical training), trained in delivering the HMHB intervention. The assessors were also university graduates trained in carrying out assessments. The coordination team members had at least 14 years of schooling. Data analysis generated three themes for the intervention delivery process and four themes for the research process with two to four subthemes grouped under each theme (see table 1).

### Intervention Delivery Process (IDP)

#### IDP theme 1: delivery of the intervention

##### *IDP1.1: intervention format*

The intervention involved delivering six core sessions and up to six booster sessions individually, lasting from 30 min to an hour. Most participants found the number and duration of sessions adequate. These sessions were delivered in a large room divided into three cubicles, allowing simultaneous delivery of sessions. The therapy room, compared with chaotic waiting areas and consultation rooms, was found to be appropriate: “The atmosphere was calm. The place was private and not crowded, there was no disturbance and we could easily talk” (IDI-IA-M07). However, a few participants mentioned a preference for a more private space: “There should be separate rooms instead of cubicles. Sometimes I could hear people talking and I became a little self-conscious about my privacy” (IDI-IA-M10).

##### *IDP1.2: intervention tools and content*

The intervention tools included the reference manual, the case file (to assist NSPs in intervention delivery and to take notes) and the take-home health file (for the participants, with illustrations and sessions’ key messages and health charts to monitor activities). The NSPs found these intervention tools essential for intervention delivery: “Case files were helpful. We can recall participants’ issues by looking at our notes. And, the health files motivated participants to do their homework and to engage their families. I think these tools were essential” (FGD-NSP). Illustrations were used throughout the intervention to help participants improve

**Table 1** Themes and subthemes generated through the data analysis

| Intervention delivery process (IDP) | | |
|---|---|---|
| **Themes** | **Subthemes** | **Categories** |
| IDP theme 1: delivery of the intervention | IDP1.1: intervention format | The number and duration of sessions were appropriate. The venue was somewhat busy but accessible and provided a safe space to talk. |
| | IDP1.2: intervention tools and content | Health files and case files were essential for intervention delivery. Intervention contents were comprehensible and informative. Illustrations were culturally acceptable and relatable. The mood chart and health charts were useful for monitoring mood and behaviour activation, respectively. Homework was easy to follow and beneficial. |
| | IDP1.3: response to intervention | Helped manage worrying thoughts.<br>Improved; overall well-being, improved mood, confidence, decision-making, problem-solving skills and anger management skills, relationship with husband and in-laws (noticed by husband/family), mother–baby bonding/baby care psychosocial awareness/ breastfeeding awareness, attending prenatal check-ups, diet and exercise, better sleep quality. |
| IDP theme 2: acceptability of NSPs to intervention delivery | IDP2.1: NSPs' adequate training and supervision | Trainers were knowledgeable and enthusiastic. Training was adequate for understanding intervention contents and its delivery mechanisms.<br>Training strategies such as role-plays and discussions were helpful, preference for increased training duration and opportunity for more role-plays. |
| | IDP2.2: NSPs' counselling skills | Good listening, interpersonal, communication and problem-solving skills. Trustworthy, approachable, polite and well mannered. Concerned about participants' and their babies' well-being. |
| IDP theme 3: barriers to intervention delivery and its acceptability | IDP3.1: lack of awareness of talking therapies | Lack of awareness of talking therapies. Initial lack of clarity about the programme. Initial difficulty in comprehending information. Difficulty in sharing problems. |
| | IDP3.2: lack of family support | Husbands not accompanying wives for hospital appointments. Husbands'/mothers-in-law's lack of empathy, lack of concern about participants' well-being.<br>No support from family to do between-session tasks. |
| **Research process (RP)** | | |
| **Themes** | **Subthemes** | **Categories** |
| RP theme 1: recruitment of the participants | RP1.1: getting informed consent | Information sheet was appropriate and easy to understand. Consent procedures were culturally appropriate. Family members involved when giving consent. Given/not given adequate time to decide with family. |
| | RP1.2: motivational factors for consenting | Research staff's good at rapport building and cultural awareness. Participants' desire to gain information about their well-being. Knowing potential benefits for both the mother and baby. Tangible benefits: travelling allowance, expedited check-ups and free ultrasound. |
| | RP1.3: screening and randomisation | Space private/not very private/at times a bit noisy. Screening questions were easy to understand. Some initial reluctance to respond to screening questions. Satisfied with being assigned to control arm (as monthly appointments were more manageable and received incentives). Unsatisfied with being assigned to control arm (as there was less opportunity to discuss problems) |
| RP theme 2: assessment of the participants | RP2.1: assessment tools and processes | Questions were culturally acceptable and comprehensible. Duration of assessments was alright/a bit long. Participants getting impatient/losing interest. Fear of breach of confidentiality during initial assessments. Struggled to respond to questions about domestic violence. Hospital setting preferred over community setting for assessments. |
| | RP2.2: response to assessments | Participants felt relieved after sharing problems. Participants felt understood. Realised other women have similar issues. |
| RP theme 3: facilitators to retention of the participants | RP3.1: appropriate incentivisation | Travel expenses being paid was crucial. Expedited check-ups were motivational. Free ultrasounds and flexible appointments were appreciated. |
| | RP3.2: family engagement | Family engagement included giving permission, escorting participants to hospital, attending sessions and motivating participants to engage in healthy activities. Family member attending sessions improved participants' engagement, motivating participants to attend appointments. Lack of family support could lead to participants' disengagement. |
| RP theme 4: barriers to retention of the participants | RP4.1: lack of empowerment | Need to seek family's permission for attending appointments, lack of permission could result in participants' disengagement. Difficulty to engage in some proposed activities, due to lack of autonomy. Lack of mobile phone ownership made it difficult to contact the participants. |
| | RP4.2: mental health stigma | Denial of mental health issues by participants and their families. Participants' fear of being stigmatised. Not disclosing their participation in the programme to husbands/in-laws. |

NSPs, non-specialist providers.

psychosocial awareness and challenge unhelpful thinking patterns. These illustrations were described as culturally appropriate and relatable. A participant with limited literacy skills reported: "There were pictures of a pregnant woman, she used to explain my problems while referring to her. I have changed due to these pictures" (IDI-IA-M03). As a behavioural activation strategy, participants were encouraged to engage in healthy activities and monitor them by noting them on their health charts. Overall, participants found the programme easy to follow and behavioural activation strategies helpful: "It was easy because the activities can be incorporated into my daily routine. I used to do all the exercises she asked me to do" (IDI-IA-M06). Participants were also encouraged to monitor their level of anxiety using the anxiety chart, which they found helpful: "The biggest benefit of doing homework was that I used to write about my feelings and it was easy to explain when she asked me about them. I used to easily take time out for my homework. […] I wanted to start a new life" (IDI-IA-M13). According to the NSPs, while most participants filled in their charts thoroughly, some failed to realise its importance: "Sometimes they are doing them [their between-session tasks] but not

ticking them off. Either it is not important for them or they simple forget" (FGD-NSP).

#### *IDP1.3: response to intervention*

Most participants found the intervention was beneficial to their overall well-being. A mother who received intervention during her first pregnancy said, "I used to feel like something would be snatched away from me and I was worrying all the time. I wasn't sure how it would be resolved. But after taking only few sessions I started feeling better" (IDI-IA-M07). This was also noticed by her family members, as she said, "Everyone at home noticed a change in my behaviour and they said 'Now you look well and think positively'" (IDI-IA-M07). Likewise, a participant with anger management issues reported improvement and positive feedback from her husband: "When I reflected and realised how harmful anger is for myself, my baby and my family I learned to control my anger and realized that I should do things in the right way and at the right time. Then my behaviour got better" (IDI-IA-M09). She added, "My husband also noticed the change in me and said now you look happy" (IDI-IA-M09). The intervention encouraged the participants to share their concerns with trusted people, which helped in releasing pent-up feelings: "The biggest improvement in me now is that I do talk. Even when they don't pay attention to me, I talk. If I keep everything inside me, my worries will increase" (IDI-IA-M10). This sentiment was also supported by an NSP who reported, "Their relationship with their husbands got better as they started to talk and discuss problems with them" (FGD-NSP). For some participants, it took longer to start feeling the benefits. One participant said, "In the beginning I was struggling to talk with her (NSP) and to do the activities she was suggesting. But then gradually I opened up with her and things started getting better" (IDI-IA-M10). Many participants reported having an improved bonding with their babies, as they realised the importance of developing feelings for the baby during pregnancy through both visualising positive images of the baby and preparing for the baby's arrival: "I felt the difference after joining this programme. I developed feelings for my baby, and did activities that were beneficial for me and my baby" (IDI-IA-M13). The NSP attributed the improvement in a majority of participants to improved awareness, decision-making and problem-solving skills and autonomy: "They used to take a stand by saying it was not up to them to determine the gender of the baby. I felt they become empowered, they understood their problems and tried problem-solving. I can't say whether they succeeded or not, but definitely they started trying" (FGD-NSP). The NSPs were also optimistic that the participants would continue benefiting from this learning: "This is a once in a life time experience for them. Nobody would have given them this information. They will never forget it" (FGD-NSP).

### IDP theme 2: facilitators to intervention delivery and its acceptance

#### IDP2.1: NSPs' adequate training and supervision

The NSPs' in-person training included a total of 42 hours of classroom instruction followed by field training that involved delivering the intervention to two expectant women with anxiety symptoms. The NSPs found their trainers to be knowledgeable and enthusiastic and felt the training strategies were helpful. They described the training as helpful for understanding the contents of the intervention and equipping them with the right skills to deliver it: "We did not have to rote learn anything as the concepts got embedded in our minds. […] We learnt how to deliver the sessions using counselling skills. It was a very good experience for me, which will be remembered forever" (FGD-NSP). The NSPs found the role-plays helpful to practise skills. These role-plays were followed by feedback sessions and discussions, about which an NSP said, "Initially I used to be defensive when receiving feedback, but later I learnt how to accept feedbacks and realised how much it contributed to my learning" (FGD-NSP). Some NSPs felt that an additional day of training would have helped them to conduct more role-plays to practise session delivery. The NSPs found field training crucial for their hands-on learning. While talking about her experience, one NSP said, "It felt like suddenly I was in the middle of the battlefield and it dawned upon me that participants will be asking me all sort of questions, it was nerve-wracking, but it turned out to be a very useful experience" (FGD-NSP).

The NSPs received weekly online group supervision sessions lasting between 90 and 120 min. These sessions helped the NSPs share their experiences, discuss ongoing challenges, consult on difficult cases and their management, and address issues impacting their own well-being. The NSPs found the supervision beneficial, as illustrated in the following quote: "The supervision played the major role in helping me to manage difficult cases and respond appropriately to difficult questions posed by the participants" (FGD-NSP). Another NSP said, "Through the supervision we learnt how to adapt information which participants can comprehend easily and retain" (FGD-NSP). Some NSPs felt that weekly supervision sessions were no longer needed later in the study since with time they gained experience and confidence: "During the third year [of intervention delivery] most of the cases we were seeing had similar issues and we could deal with them without difficulty. Therefore, fortnightly supervision rather than weekly supervision would have been sufficient" (FGD-NSP). Discussing the impact of supervisions on personal and professional growth, one NSP summed it up by saying, "Supervision helped us at both personal and professional level. On a personal level we learnt how to look after our own wellbeing and on a professional level we learnt how best to communicate and deal with the challenges posed by the participants. Overall, it was a very good experience" (FGD-NSP).

#### IDP2.2: NSPs' good counselling skills

The participants felt that NSPs were able to understand their problems, showed empathy and guided them. A participant, while appreciating her NSP's counselling skills, said, "She listened attentively to me. It felt so good

knowing someone is there to listen and understand my problems without judging me" (IDI-M10). The NSPs were able to instil hope in most of the participants and encouraged them to look after their health and well-being. A participant who feared dying in labour reported feeling better after sharing her concerns. She said, "I was constantly worrying if I would survive or die. She told me not to lose hope, and if I would look after myself, my baby and I would be happy and healthy. What she said touched my heart" (IDI-IA-M06). Most participants found their NSPs approachable and appreciated the personal attention they received from them: "When I missed my sessions once or twice, she called me to ask why I didn't come. I felt good knowing that someone remembered me and asked about me" (IDI-IA-M03). Another participant said, "She told me that she would be available anytime if I needed to discuss anything else" (IDI-IA-M11).

### IDP theme 3: barriers to intervention delivery and acceptance

#### IDP3.1: lack of awareness of talking therapies

There was a lack of familiarity with talking therapies among the target population. One participant was unsure of what they were being asked to do in attending sessions: "Initially I didn't know what they meant by attending sessions. Later I found out that it meant having conversations and nothing else" (IDI-IA-M01). This lack of awareness also created doubts about the purpose of the intervention as stated by a mother of two: "They said that we will see you every week. I wondered why would they want to call me every week? What is my problem? Some people said that they will do sterilization. I thought it can't be true, as they know that every mother need kids" (IDI-IA-M09). For some participants, it took a few sessions for the intervention to become familiar and acceptable: "For the first couple of sessions, I was neither interested in what she was saying nor could I comprehend her. I was also finding it difficult to talk about my problems. But after a few sessions it was fine" (IDI-IA-M02).

#### IDP3.2: lack of family support

Most of the participants had to be accompanied by their husbands or elders in their families to hospital appointments. At times, having no one to accompany them resulted in missed sessions: "It was difficult to come for the sessions because my husband runs his own business and has no time to accompany me" (IDI-IA-M02). The family members (mostly husbands and mothers-in-law) were invited to attend a few sessions to enhance their support for the participants. The NSPs reported that some family members would dominate the sessions by being unempathetic and criticising the participants during sessions: "Some husbands and mothers-in-law are very domineering. They were not really concerned about participants' wellbeing. They talked a lot and the poor women stayed quite throughout the session" (FGD-NSP). Similarly, restrictions on some participants' mobility created barriers for them to engage in between-session activities, as described by one participant: "She (the NSP) used to say 'Go out,' meaning outside the house, into the open air. I could not go because my husband doesn't like it. I always stayed at home" (IDI-IA-M01). Despite the lack of support, a participant reported, "At times it was difficult (for me to do the homework), so I used to do it at night after finishing my chores and when the kids were asleep" (IDI-IA-M02).

### Research Process (RP)

#### RP theme 1: recruitment of the participants

##### *RP1.1: getting informed consent*

The majority of participants found the content of the information sheet easy to understand and the consent process satisfactory. A participant from the control arm said, "The method of taking consent was alright. […] My heart agreed to it so I joined this programme" (IDI-CA-M04). As part of the consent procedures, the participants were encouraged to consult with their family members before giving their consent if they wished. While the majority of participants reported that the discussion with family was useful, a few felt they were not given enough time: "No, they did not give me time to discuss with my family. They just asked me; do you want to take part in this programme? I said yes, and that's all, nothing else" (IDI-CA-M01). Some study staff shared their difficulties responding when asked by participants exactly how many times they were expected to come to hospital before giving their consent: "They wanted to know, at the time of consenting, how many visits are expected, so that they can decide whether to take part or not. This was problematic for us because no one knew before their randomisation [assignment]" (FGD-AT).

##### *RP1.2: motivational factors for consenting*

Several factors were mentioned by participants as motivators to take part in the trial. The most commonly reported factor was research team's rapport-building skills: "I joined because I have never seen such a good team. The way they listened and understood me, made me realise that they were very concerned about me and my baby" (IDI-IA-M06). An assessor recalled a participant saying, "She said she prayed in the morning to find a nurse who will listen and understand her problem, and she felt her prayers were answered in finding us" (FGD-AT). Second, the desire to gain information about well-being during pregnancy was motivating: "It was my first pregnancy, and I didn't know much about it. So, I decided to participate in this programme for my understanding and guidance" (IDI-CA-M10). Lastly, participants found the tangible benefits offered to be attractive; this included reimbursement of travel expenses, free ultrasounds and expedited prenatal check-ups. A young primigravida woman said, "They told me that I will be given some money (travel allowance) and I will not have to wait in the long queues. Sitting in the queue is a waste of time and it is difficult as well. I was told I will be called for my check-up quickly" (IDI-IA-M01).

#### RP1.3: screening and randomisation

The screening/assessment team used a large room of the hospital that was divided into compartments to conduct assessments. Most participants found the arrangement reasonable, as stated by a participant, "Privacy was assured by the assessors. No one could hear me talk, when I was responding to her questions" (IDI-CA-M06). However, some found the arrangements unsatisfactory, "It bothered me when more than one assessor was conducting assessment and the room became a little bit noisy and I had to speak louder" (IDI-CA-M10). While, the majority of the participants found the questions easy to understand and responded without much hesitation, some felt reluctant as it was a novel experience for them: "The questions were easy to understand but I was confused and hesitant to answer because never before had I shared my problems with a stranger. So, I was a bit scared and felt unsure how to respond" (IDI-CA-M01). Most participants recruited in the control arm did not express any disappointment. Rather, they felt it would be easier to make monthly instead of weekly visits to receive the intervention. However, some felt that they were missing out on the opportunity to discuss their problems in detail: "I like to talk/discuss more and in this part (control arm), I was only facilitated for my check-ups, so I felt a little bad" (IDI-CA-M01).

### RP theme 2: assessment of the participants

#### RP2.1: assessment tools and processes

While the assessors found the assessment questions easy for the participants to comprehend, there were some concerns about the number of assessments carried out and the time required for it: "We had too many instruments, and it could take up to an hour and a quarter. At times, participants became restless and asked us to hurry up, and even when they didn't say anything, you could tell [that they were impatient] from their body language" (FGD-AT). Another assessor validated this, saying, "The postnatal assessments were even lengthier. At times they had their babies with them, which can further prolong the process" (FGD-AT). The assessors thought some tools had similar questions, which could make participants lose interest: "When they started responding without thinking, we tried to bring their focus back so that we could collect accurate data and the quality of assessments wouldn't be impacted" (FGD-AT). The assessors found that the questions in most tools were culturally acceptable and appropriate. However, they felt that participants were uncomfortable with some question in relation to domestic abuse. This was also described by a participant from the control arm, "I was hesitant to answer personal questions such as about domestic problems. I was worried that if my husband would find out, he would argue with me" (IDI-CA-M10). However, assessors felt that most participants, following their baseline assessment, knew what was expected from them and having developed rapport, they felt at ease and responded to questions openly and honestly. Most assessors had experience carrying out assessments in both hospital and community settings. They preferred the hospital setting as it increased their credibility and had fewer external distractions: "It was easier working in the hospital setting. Participants felt safe, they perceived us as medical professionals and gave us equal importance" (FGD-AT). Another said, "Unlike in community setting where we had to build rapport with the entire family, we worked only with the participants and carried out assessments, without disruptions" (FGD-AT).

#### RP2.2: participants' response to assessments

The assessors, despite asking primarily close-ended questions, felt that assessments gave participants an opportunity for catharsis. The participants perceived it as a novel experience to share their problems and be listened to without being judged: "They used to come for assessments happily knowing that there is someone who will listen to them, and they felt relieved sharing their problems" (FGD-AT). This was also validated by the coordinators who mentioned that while waiting, participants used to vent their feelings and feel relaxed afterwards: "Participants tell us, 'We have no one to share our domestic problems with, we can't even discuss with our sisters and mothers. We share with you when we come here and that makes us feel better'" (FGD-CT). Furthermore, assessors found that participants recognised during assessments that there were other expectant women who had similar emotional and physical symptoms as them and felt relieved. They also appreciated that their problems were understood and not minimised or disregarded: "They felt good that they were taken seriously as their mothers-in-law and other relatives used to believe that they are making things up to get attention" (FGD-AT).

### RP theme 3: facilitators to retention of the participants

#### RP3.1: appropriate incentivisation

Incentives included travel allowances, expedited check-ups, free ultrasounds and appointment flexibility. Many participants appreciated the travel allowance, and it was frequently mentioned that without it, they would have missed their appointments: "It was good, my family took me to hospital because of it. They would not have taken me to the hospital if you would not have paid the fare" (IDI-CA-M10). A participant with an unemployed husband expressed her gratitude, "When I was really struggling (financially) I saved the travel money and spent it on my children. I bought things for my kids with that money" (IDI-CA-M09). Likewise, given that wait times for check-ups often fall between 1 and 2 hours, facilitated check-ups were greatly appreciated. One participant said, "This programme was implemented very well. They took good care of us. I didn't have to wait in long queues, as is always the case in government hospitals" (IDI-IA-M10). For some participants, monetary incentives and assisted check-ups seemed more appealing than receiving the intervention itself. An NSP said, "The only thing some of them were mainly concerned about was their incentive. They used to come to us and say 'We had our ultrasound

done, give us money. We had our check-up done, give us money'" (FGD-NSP). The flexibility in scheduling the appointment day and time was also appreciated. A coordination team member said, "If they told us we can come only on certain days, we would arrange their appointments as per their convenience even if it meant that the NSP had to work on the weekend" (FGD-CT).

#### RP3.2: family engagement

The family's engagement ranged from giving permission and escorting participants to the hospital to attending sessions with them as well as motivating them to accomplish between-session tasks. One participant sounded pleased when she said, "Whenever I asked permission to go to hospital, my family had no objection. And since I was also given a travel allowance, I attended all my appointments" (IDI-IA-M12). On the contrary, a mother with three children who stopped after receiving few sessions explained, "I was very weak and found difficult to attend hospital appointments with my excessive domestic responsibilities. This is an issue when living in a joint family system and having no support from them" (IA-M04). Significant family members, mostly husbands and mothers-in-law, were invited for the introductory session and the session focusing on participants' social support. In the majority of cases, NSPs found family members' participation helped ensure their engagement: "One of my participants was a bit reluctant to receive her sessions. Later after her husband attended a session, he made sure that she attended all her sessions without a miss" (FGD-NSP). This was also reported by the participant who found her husband's involvement motivational. She said, "My husband fully cooperated with me. He would give me time [for myself], reminded me my appointments and helped me do the between-session tasks" (IDI-IA-M12). Likewise, another participant who was separated from her husband and living at her natal home felt her mother's involvement motivational to continue with the programme: "My mother took a session with me. She was very happy and said, 'they are right; you should look after yourself and your unborn baby and not be stressed, rather, stay positive'" (DO-M05).

### RP theme 4: barriers to retention of participants

#### RP4.1: lack of empowerment

Permission from in-laws was crucial for sustained engagement of the participants. Lack of permission was a major barrier for some participants. For instance, a participant from a conservative family who was not allowed to visit the hospital for her prenatal check-ups or trial assessments expressed her anguish by saying, "They called me to come but I couldn't as I didn't have permission from my in-laws or my husband. They are very conservative. They think that baby is safe in the womb and it would be a waste of time" (IDI-CA-M01). The majority of participants did not own a mobile phone and were contacted through their husbands or in-laws. During the FGD, the coordinators described difficulties getting in touch with participants: "At times we had multiple contact numbers for each participant and had to dial at least 6 or 7 numbers before being able to get connected with them. Some family members didn't like us calling them and either told us sternly to stop calling or blocked our numbers" (FGD-CT).

#### RP4.2: mental health stigma

The assessment and coordination teams reported that many expectant women refused to give consent either because they denied having issues out of fear of stigma or because their family refused to acknowledge they had any psychological problems. As summarised by an assessor, "When we told them it was about women's mental health, those who had strict in-laws became scared and told us that they couldn't participant as they are not 'mad' and therefore don't need this programme. And, their mothers-in-law also used to say, 'why are you asking her to take part she has no tension.'" (FGD-AT). Refusal by family members also led to a few in-laws' insistence on accompanying the participants, "During assessments, sisters-in-law refuse to leave the room and the mothers-in-law say, 'there is nothing wrong with them we treat them very well'" (FGD-AT). The fear of being stigmatised resulted in some participants hiding their participation from their in-laws, as mentioned by a mother of five living in a joint family, "I didn't tell my family. You know families become suspicious if anything is happening out of the routine, but later I was worried what if they call me (in the presence of my in-laws), what will I say?" (IDI-IA-M03). Likewise, another participant, after knowing her husband's negative views about mental health programmes, decided not to disclose her participation: "When I told him about the programme, he said 'It is nonsense' and nothing else. So, I didn't tell him that I was receiving the intervention" (IDI-IA-M10). This was also reported by the assessors, including one who said, "They used to tell their families they were going for medical check-ups, knowing that otherwise it will create problems for them" (FGD-AT).

## DISCUSSION

The evaluation of the intervention delivery process indicated that the HMHB can be effectively delivered by NSPs trained and supervised by a mental health specialist. The NSPs were perceived to be empathetic and the intervention to be culturally acceptable and appropriately addressing problems related to anxiety during pregnancy. Lack of awareness of talking therapies and poor family support were identified as potential barriers to receiving the intervention. The evaluation of the research process highlighted that culturally appropriate consent procedures such as use of non-stigmatising language and consultation with the family members before giving consent facilitated recruitment of participants, while incentivisation and family involvement facilitated sustained engagement and retention. Factors such as participants' lack of empowerment and stigma towards mental health problems were potential barriers to implementation of the programme.

Our results add to the evidence that 'task shifting' is an effective and feasible approach to address treatment gaps[25 26] and that CBT-based psychosocial interventions can be delivered by NSPs.[15 16] Systematic reviews of qualitative studies from LMICs have indicated high levels of acceptance of CBT-based maternal mental health interventions.[2 27] However, for non-specialist-delivered interventions to be successful, effective training and supervision structures are essential.[14 28] In our trial, before NSPs delivered the intervention to mothers with prenatal anxiety, they received 42 hours of classroom instruction followed by supervised field training and weekly ongoing supervision by mental health specialists.[19] The supervision sessions helped to improve the quality of intervention delivery and the competency of NSPs. The participants perceived them as competent in their role and the intervention as culturally acceptable and relevant to their needs. Similar findings have been reported in the systematic review of process evaluations of task sharing perinatal interventions, where acceptability of the intervention and its delivery agent was identified by the participants as a crucial implementation factor.[29]

Participant recruitment and retention are critical to the success of public health interventions as well as to the RCTs evaluating their effectiveness.[30 31] Understanding the features unique to the target population and the study setting, including contextual factors external to the intervention or trial that act as facilitators or barriers,[32] can help in devising strategies for overcoming potential challenges to recruitment and retention.[31] Most of our participants were living in joint families, or patriarchally extended households in which a married couple resides with the husbands' parents and family.[33] Such patriarchal and hierarchical family structures place women in subordinate and disempowered positions.[34] In this context, women's decisions about their healthcare[35] and/or visiting their natal home require permission by elders in the family.[36] Taking this into consideration, our study participants were advised to discuss participation with their families before giving consent, a procedure followed by the majority. However, some participants made their decisions independently and a few did not disclose their participation to their families due to fear of stigma or in anticipation of their disapproval. Overall, our findings suggest that strong family support was crucial for continuous engagement of the participants. This is consistent with the findings from our previous community-based studies in Pakistan, where lack of family support for female participants and fear of being stigmatised were the most frequently reported reasons for refusal or disengagement.[18 37 38] Similarly, a process evaluation study from India also reported high levels of stigma related to mental health issues as a barrier to the implementation of mental health interventions.[39]

Our participants were recruited from a government-run tertiary care hospital. Generally, these hospitals tend to lack adequate health specialists and face significant challenges in quality of care.[11 40] Their waiting times are long, consultation times are very brief and mistreatment by the hospital staff is not uncommon.[41] Mostly, these hospitals service low-income populations experiencing financial constraints, which is one of the known barriers to engagement in mental health services.[42] Given that our target population was from lower socioeconomic status, their travel costs were reimbursed, which reduced the burden of transportation expenses and improved their engagement. A longitudinal study conducted in the USA also found that facilitating transportation helped increase the representation of underprivileged South Asians in health research studies.[43] In our study, the participants' check-ups were expedited, which helped reduce their waiting times and was reported as an important motivating factor for attending appointments along with the supportive attitude of the research staff. Prior research with this population of anxious pregnant women in Pakistan has emphasised the desire for respectful care,[41] while another review of pregnant women in the prospective birth cohort has highlighted the role of developing trusting relationships for recruitment and retention.[44] In our study, the research staff were trained in rapport-building skills and perceived by participants as empathetic and respectful, which played a significant role in building the trusting relationship and facilitated intervention delivery and research process.

The study applied the Framework Analysis approach, which allowed transparent and systematic analysis of the data. Data were collected from four different groups—trial participants, assessors, coordinators and NSPs—and findings were shared with the NSPs and the assessors for member checking. This allowed triangulation of the information and helped increase the credibility of the data. One limitation was that some interviews were conducted over the phone, which may have limited rapport building and information sharing between the interviewer and interviewees. Another limitation is that we may have not adequately sampled opinions of women who discontinued the intervention since we interviewed only a small number of dropouts. Furthermore, the study was conducted in a tertiary hospital located in a semiurban area targeting mainly the lower socioeconomic population, and therefore the findings may not be transferable to other segments of the population. Future research could explore the implementation of this programme in other LMIC settings and with more socioeconomically diverse populations.

## CONCLUSION

We conclude that non-specialists can feasibly deliver an evidence-based intervention to women with perinatal anxiety. Such management of anxiety can be integrated into routine antenatal care. NSPs are likely to be more cost effective and less stigmatising. However, further research into the scale-up of such interventions and their costs would need to be conducted.

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