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Evaluation of a preventive intervention for postnatal depression in high-risk populations in Pakistan and Türkiye

Submission date
12/08/2024

Recruitment status
Recruiting

Registration date
29/08/2024

Overall study status
Ongoing

Last Edited
19/09/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Building on a successful feasibility study in Istanbul, Turkey, the study is aimed to address the significant public health issue of postnatal depression in high-risk communities by evaluating the effectiveness of a universal and brief group antenatal intervention delivered by non-specialists. By conducting a definitive study in two diverse settings, this study aims to provide insights into preventing postnatal depression and its associated consequences on maternal and infant well-being. The primary objective of the trial is to evaluate the effect of an evidence-informed, universal, brief group antenatal intervention based on Thinking Healthy Programme (THP) principles, using cognitive behaviour therapy strategies, plus enhanced usual care in pregnant women, compared with enhanced usual care alone, on perinatal depression at six to eight weeks postpartum. Secondary objectives include evaluating the impact of the intervention plus enhanced usual care on the prevalence of anxiety, maternal functioning, quality of life maternal attachment, childcare abilities, and infant-related outcomes as well as the cost-effectiveness of the intervention. The study will examine and explore possible mechanisms of intervention effects.

Who can participate?
Women aged 18 years old and above who are between 14-34 weeks gestation, in low-income rural areas and underprivileged areas in Islamabad, Pakistan, and socioeconomically deprived urban populations in the catchment area of Marmara University, Turkey

What does the study involve?
The intervention is based on the THP and aims to modify maladaptive thinking and behaviour, promote behavioural activation, and enhance problem-solving skills. The control group will receive enhanced usual care, which includes educational sessions about pregnancy, birth, newborn care, and well-being, in addition to brief psychoeducation and information about mental health care referrals. The primary outcome of interest is the presence of postnatal depression, evaluated using a questionnaire after 6-8 weeks postpartum. Secondary outcomes include anxiety symptoms, functioning, quality of life, maternal attachment, childcare abilities, and infant-related outcomes. The study will also investigate cost-effectiveness and potential

mediational mechanisms behind the intervention's effects. The primary analysis will follow the intention-to-treat principle, and a range of statistical models will be employed to analyse primary and secondary outcomes, accounting for potential covariates and subgroup analyses. The research adheres to CONSORT guidelines for reporting randomized trials.

What are the possible benefits and risks of participating?
All women participating in this study, whether in the treatment or non-treatment groups, will undergo detailed assessments by skilled professionals at both the beginning and the end of the study. Throughout the study, a facilitator will regularly check in with all participants to monitor their progress and listen to their experiences and feedback. Participants will also have the opportunity to attend antenatal pregnancy classes, which include weekly group sessions focused on education about pregnancy and new-born care. Many women find these classes beneficial. The educational content provided during the study, including the intervention program, could be valuable for mothers, their babies, and their families. The potential benefits of participating include gaining access to expert assessments, ongoing support, and educational resources that may help improve maternal and infant health. However, there may also be some risks, such as the time commitment required to participate in assessments and classes, or any discomfort that may arise from sharing personal experiences or undergoing evaluations.

Where is the study run from?
The data will be collected at public tertiary care facilities from two sites, namely, Federal Government Hospital, Islamabad, Pakistan and the Department of Social Pediatrics, Marmara University, Istanbul, Türkiye.

When is the study starting and how long is it expected to run for?
November 2023 to October 2026

Who is funding the study?
Medical Research Council, UK

Who is the main contact?
Prof Atif Rahman (Principal Investigator), atifr@liverpool.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Randomised evaluation of a preventive intervention for postnatal depression in high-risk populations in Pakistan and Türkiye: PREVENT-PND

Acronym
PREVENT-PND

Study objectives
The goal of our project is to prevent postnatal depression (PND), a disorder of public health significance, by targeting an antenatal group intervention for women who live in socioeconomically deprived communities and are at high risk for the condition. In a previous MRC-funded seed grant, we established the feasibility and acceptability of this group intervention in Istanbul, Türkiye. In the current project, we aim to conduct a definitive Randomized Controlled Trial (RCT) in two countries to answer the following questions:
a) What is the effectiveness, and cost-effectiveness, of the group intervention vs routine antenatal care in preventing postnatal depression in high-risk women in two diverse settings?
b) Does the intervention improve functioning, maternal attachment, and childcare abilities?
c) What are the mechanisms and processes through which the intervention achieves its effects?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/05/2024, Central University Research Ethics Committees, University of Liverpool (Foundation Building, Brownlow Hill, Liverpool, L69 7ZX, United Kingdom; +44 (0)151 794 2000; ethics@liverpool.ac.uk), ref: UoL001844

Study design
Individual randomized controlled trial

Primary study design
Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied
Perinatal depression

Interventions
The intervention is based on the Thinking Healthy Programme (THP), an evidence-based intervention that employs cognitive behavior therapy strategies to achieve three main goals: a) To identify and modify maladaptive styles of thinking and behaving – in particular those leading to poor self-esteem, inability to care for their infants, and disengagement from social networks; b) behavioral activation – adopting behaviors, such as self-care, attention to diet, and positive interactions with the infant, and practising these between sessions; c) problem-solving to overcome barriers to practising such strategies. The adapted THP brief group version (THP-BGV) employs similar strategies adapted for prevention rather than treatment of perinatal depression. An additional element is support from the facilitator and other group members. The intervention consists of five group sessions: 1) Engagement and introduction to the programme; 2) psychoeducation and problem-management skills; 3) focusing on one's personal health and well-being; 4) establishing the mother-infant bond, and 5) reactivating relationships with others and closing the therapy. The study aims to schedule the five intervention group sessions weekly; however, it is understood that unforeseen circumstances may arise. Therefore, a flexibility window of up to two weeks will be provided after the target date for scheduling a group session. If a group session is not scheduled within this extended timeframe, it will be considered a missed visit.
The programme is fully manualized and includes instructions for the delivery of each session with culturally appropriate pictorial illustrations aimed at reinforcing key messages and encouraging family involvement. The groups will be integrated into routine antenatal care groups and delivered online in Türkiye and face-to-face in Pakistan by antenatal group facilitators.

Intervention Type
Behavioural

Primary outcome(s)
Presence of postnatal depressive symptoms measured using the 9-item Personal Health Questionnaire (PHQ-9) after 6-8 weeks of giving birth

Key secondary outcome(s))
Maternal Secondary Outcomes:
1. Perinatal anxiety remission rates and symptom severity: Measured using the Generalized Anxiety Disorder 7-item (GAD-7) scale at baseline, 6-8 weeks postnatal, and 6 months postnatal.
2. Maternal disability: Measured using the World Health Organization Disability Assessment Schedule (WHO-DAS), with disability defined by the total mean scores of this measure at baseline and 6 months postnatal.
3. Maternal quality of life: Measured using the EuroQol 5-Dimension (EQ-5D) questionnaire, with quality of life defined by the total mean scores of the EQ-5D at baseline, 6-8 weeks, and 6 months postnatal.

Infant-related Secondary Outcomes:
1. Exclusive breastfeeding: Measured using a 24-hour maternal recall and defined by the World Health Organization's (WHO) definition of exclusive breastfeeding at 6-8 weeks and 6 months postnatal.

2. Immunization: Measured using data collected from the vaccination cards provided to all parents up to the age of 12 weeks postnatal.
3. Parental time spent playing with the infant: Measured using the Client Services Receipt Inventory (CSRI) at 6-8 weeks and 6 months postnatal.

Mediational Analyses (Exploring Mechanisms):
1. Behavioural activation levels: Measured using the PREMIUM Abbreviated Activation Scale (PAAS) at baseline, 6-8 weeks, and 6 months postnatal.
2. Perceived social support: Measured using the Multidimensional Scale of Perceived Social Support (MSPSS) at baseline, 6-8 weeks, and 6 months postnatal.
3. Problem-solving skills: Measured using the Problem-Solving Confidence subscale of the Problem-Solving Inventory at baseline, 6-8 weeks, and 6 months postnatal.
4. Cognitive restructuring skills: Measured using the Cognitive Restructuring subscale of the Frequency of Actions and Thoughts (FATS) scale at baseline, 6-8 weeks, and 6 months postnatal.
5. Maternal attachment: Measured using the Maternal Postnatal Attachment Scale (M-PAS) at 6-8 weeks postnatal.
6. Maternal self-efficacy: Measured using the Maternal Self-Efficacy Scale (M-SES) at 6-8 weeks postnatal.
7. Sleep quality: Measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline, 6-8 weeks, and 6 months postnatal.
8. Infant sleep patterns and behaviours: Measured using the Brief Infant Sleep Questionnaire (BISQ) at 6-8 weeks and 6 months postnatal.

Completion date
31/10/2026

Eligibility

Key inclusion criteria
1. Pregnant women aged 18 years and over
2. Within the 2nd to early 3rd trimester of pregnancy (13 to 34 weeks pregnancy)
3. Having current mild depressive symptoms with a score between 5 to 9 on PHQ-9 and/or having significant symptoms of anxiety with a score of or above scores on GAD-7
4. Intending to reside in the study area for the entire duration of the follow-up (approx. one year)
5. In Türkiye, ownership, and ability to use a smartphone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Women requiring immediate inpatient care for any reason (medical or psychiatric)
2. Women who are currently receiving any form of counselling or mental health care or report suicidal ideation
3. Women who do not speak and/or comprehend local, Urdu languages (Urdu, Potohari or Punjabi in Pakistan and Turkish language for Türkiye)

Date of first enrolment
30/05/2024

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
Pakistan

Türkiye

Study participating centre
Federal Government Hospital
NIH Road
Islamabad, Islamabad Capital Territory
Pakistan
44000

Study participating centre
Department of Social Pediatrics, Marmara University
Eğitim, Fahrettin Kerim Gökay Cd
Istanbul
Türkiye
34722

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/047d2d387

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The anonymised data will be deposited with the Institute of Population Health (University of Liverpool) data repository and made available to interested parties after the formal permission of the investigators, Prof Atif Rahman (Principal Investigator), atifr@liverpool.ac.uk.

Data Quality and Security of Data
The data managers (based at sites, in Pakistan and Türkiye) will ensure the confidentiality and anonymity of personal data principally through procedures to separate study data and participant's personally identifiable data e.g., names. All personal information/data of study participants will be gathered at the eligibility stage of the study by the assessment team. This personal information will not be made part of the study data, which will be gathered during the entire study and at the time of analysis. However, this personal information will be stored separately in an Excel document (i.e., encrypted/password protected). This process of anonymization will be irreversible, and the personal data will be destroyed once the dataset is locked. This information will only be accessible to the trial data manager.
For the quantitative data, the data gathered in the tablets for each participant at baseline will not contain any personal identification items and will be linked through a unique trial/study ID to the personal identifier information needed to follow up with participants. These identifier data will be stored electronically in a password-protected folder and hard copies of the consent form will be stored in a locked cupboard with access restricted to the data manager and the site PIs. All subsequent data will be collected and collated using only the trial/study ID numbers.

Data Monitoring
Data stored at the server will be checked for missing or out-of-range values (via range checks) and checked for consistency within participants over time. Any suspect data will be returned to

the site team in the form of data queries. Data query forms will be produced at the server from the trial database and sent electronically. Sites will respond to the queries explaining/resolving the discrepancies and return the data query forms to the server. The forms will then be filed along with the appropriate audit logs and the appropriate corrections will be made on the database.

IPD sharing plan summary

Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	16/04/2024	23/08/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes