PARTICIPANT INFORMATION SHEET FOR SCREENING FOR STUDY ELIGIBILITY

Information sheet for **Mothers** who are willing to take antenatal classes, and who we are inviting to participate in research on maternal health. The title of our research project is

"Randomised Evaluation of a Preventive Intervention for Postnatal Depression in High-risk Populations in Pakistan and Türkiye: PREVENT-PND"

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Name of Sponsor: Medical Research Council (MRC) United Kingdom

Introduction

Thank you for reading this

We are researchers (working for Marmara University School of Medicine, for Türkiye site and Health Services Academy, for Pakistan site). We are inviting you to take part in a research study about the prevention and/or treatment of depression for pregnant women. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take as much time as you wish to read this information and discuss it with others. Ask us if there is anything that is not clear or if you would like more information. You can take all the time you need to decide whether or not you wish to take part.

Some information about Perinatal stress and depression and its Interventions

Mothers who suffer from stress or depression during pregnancy can have adverse health consequences and hence cause problems for their growing baby. It can lead to impaired brain development and poor growth in the infant in the long term. Timely treatment can prevent these complications. Perinatal stress or depression can be treated effectively with talking therapies.

Who are we, and what do we do?

Thinking Healthy Program (THP) was developed as a psychosocial therapy by Prof Rahman and his team, adopted by the World Health Organization as its official first-line treatment for perinatal depression. Prof Rahman is a child psychiatrist at the University of Liverpool and an expert in developing and evaluating culturally appropriate psychosocial interventions across the life course. THP has been translated by Prof Boran and adapted into Turkish. Prof Boran is a paediatrician at Marmara University working in the field of child health since 2002 and she is leading her PhD program on social paediatrics. Prof Abid Malik is an academic psychiatric

and a global mental health expert in implementing complex interventions and he was part of Prof Rahman's team who developed THP in 2008. Since November 2018, we have been systematically adapting THP into a group version which can be integrated into antenatal pregnancy schools. In 2021, we adapted the THP into group version and delivered it online in routine antenatal pregnancy schools, which is called THP-BGV (Thinking Healthy Programme-Brief Group Version).

What is THP?

THP is an evidence-based intervention that incorporates behavioural activation, active listening, collaboration with the family, and homework. The adapted THP-BGV consists of 5 integrated sessions. Session 1 introduces the programme, focuses on engagement of participants and practicing breathing exercise and muscle relaxation. Session 2 focuses on review of the programme, mother's own personal health and well-being and problem solving. Session 3 focuses on the mother-baby relationship. Session 4 will be about strengthening social support and time management technique. Session 5 focuses on preparing for parenthood, imagery thinking and provides closure of therapy. In our previous study, we integrated the THP-BGV into routine antenatal classes, and the programme was successfully delivered online to a group of women.
We would like to recommend this intervention to pregnant women with high risk for perinatal stress attending the antenatal pregnancy classes; however, we need to know whether this intervention is effective in preventing perinatal stress. This means: is it possible to relieve perinatal stress by delivering THP-BGV in routine online antenatal classes in group sessions?

The PREVENT-PND Study

We are embarking on an exciting journey to gather this evidence by recruiting 664 pregnant women (332 at each site in Istanbul and Islamabad) at high risk for perinatal stress, attending the pregnancy classes. This recruitment is entirely voluntary; that is no one can be forced to take part. To find out if any therapy is effective one must compare two groups of women, one who have received the treatment to another who have not. With this in mind, half of these 332 women will be receiving the THP-BGV while the other half will continue on their normal program (which includes attending the pregnancy classes, access all usual care) One hundred sixty-six of these women will be identified by 'random allocation'; this means that all women have an equal chance of being in either group; and it is not dependent on any characteristic of the women. Pregnant women who are recruited into the treatment group will receive 5 sessions of THP-BGV through local pregnancy school nurses over 5 weeks. All 332 women will get a detailed assessment (described below) initially and postpartum at 6-8 weeks and 6 months.

Why are we asking you?

We know that you have volunteered to attend the pregnancy classes. For our study we are aiming to include 332 pregnant women at risk for perinatal stress between 14-34 weeks' gestation who are living in the study area, are over 18 years old and intend to attend all 5 sessions of the antenatal classes. We are hoping that after you read this information leaflet, you will think about volunteering for this study. If you consider taking part in the study, we need to evaluate if you are eligible to take part in the study, since the study is designed to involve high risk women for perinatal stress. This means that you will be screened for eligibility by asking

questions related to your mental health. The process related to the evaluation of your eligibility for the study will be described below.

Do I have to take part?

Taking part in screening for edibility is entirely voluntary. You are free to choose whether or not to take part. If you do decide to take part you can keep this information sheet for reference and you will be asked to sign a form giving your consent to taking part in screening for eligibility.

What will happen if I volunteer?

For the study, all potential pregnant women like you, will be identified from the daily registers of the antenatal nurses. These antenatal nurses are responsible for enrolling all pregnant women like you into the routine antenatal health educational classes.

We will first assess your eligibility for the study as mentioned above. To assess this, we first have to determine your level of stress. The antenatal nurses as part of the process will take your contact information. This information will be shared with the study research team. The research team will approach all potential women, like you and will inform you of the study, if you will be interested, your eligibility to participate in the study will be assessed by the research team member at that point. Your eligibility will be assessed by two questionnaires called PHQ-9 (patient health questionnaire-9) and GAD-7 (Generalised anxiety disorder-7). Once you have consented, the trained research team member will ask you these questions (on the phone in Türkiye and face to face at Federal Government Hospital in Pakistan).

Depending upon the total score, your eligibility will be determined. If you are not eligible for the study but still wish to participate in antenatal pregnancy education, you will be directed to the relevant group education program. If you are eligible for the study, the research team member will provide you with further information about the study and will continue the assessment depending upon your consent.

Any participants found to be extremely stressed or depressed at either of the interviews (i.e., at enrollment into the study or after the antenatal sessions have completed) will be informed about their mental health status and connected to a psychiatrist over the phone for further assessment and case management at the hospital in your area.

Please note in this study we will not be doing any physical examinations or investigations on you, such as blood or urine tests or X-rays.

What is the THP-BGV intervention?

THP is an evidence-based intervention tailored to the perinatal period that has been shown to be effective for depressed or stressed mothers. Mothers' physical and mental health will determine how the baby will progress. The program helps women to overcome the problems she encounters in carrying out her daily activities, pay attention to her personal health, practice helpful behaviours, and reactivate social networks. The program enables mothers to provide best quality of care to her baby.

The routine on-line antenatal classes consist of 5 weekly group sessions that incorporate education about pregnancy and new-born care. The groups usually consist of 8-10 mothers. In 2021, our adapted 'group' version of the Thinking Healthy Programme (THP-BGV) was incorporated into these antenatal pregnancy classes and was found by the attending women and the delivering nurses as a useful programme. The adapted THP-BGV consists of 5 integrated sessions that will last for 45 to 60 minutes except for the introduction session which will last for 90 minutes. Session 1 introduces the programme, focuses on engagement of participants and practicing breathing exercise and muscle relaxation. Session 2 focuses on review of the programme, mother's own personal health and well-being and problem solving. Session 3 focuses on the mother-baby relationship. Session 4 will be about strengthening social support and time management technique. Session 5 focuses on preparing for parenthood, imagery thinking and provides closure of therapy.

The five weekly sessions will be delivered to the women in the second or third trimesters. In between these sessions, you will be asked to spend half an hour every day at home practicing the techniques discussed in the sessions. A small number of sessions may be audio recorded as an additional assessment of intervention fidelity. The recordings that your facilitator takes will be discussed with the PREVENT-PND team to improve adherence to the intervention protocols. The data will be stored in a secure way and will be kept confidential.

How will be the information I provided managed?

To ensure your confidentiality, privacy, and security of your data, our research team will adhere to strict guidelines and protocols for the management and storage of information collected during the course of this study. Your personal identifiers will be stored separately from the research data, and access to this data will be restricted to password-protected electronic devices. The data you provided for the research will be separately managed by assigning a unique identifier to anonymize your data. Only authorized members of the research team will have access to participant data. All personal data will be destroyed once the dataset is locked.

Data will not be shared with external parties and individual participant data will not be disclosed in publications.

Are there any side effects?

In our previous pilot study, we did not observe any unwanted effects related to intervention or assessments, but there is a potential risk of feeling upset or distressed as a result of responding to the questionnaires over the phone. Clearly it takes additional time of yours in relation to the sessions, the home practice we expect from mothers and assessments. Previous studies conducted globally found the intervention very acceptable and no adverse consequences were encountered.

What are the possible disadvantages and risks of taking part?

We do not anticipate that this study will result in any disadvantages or risks to families. Again, questionnaires that you will be answering may results feelings of distress.

What are the current possible benefits of taking part?

All women in this study (i.e. those in both the treatment and non-treatment groups), will have detailed assessments from skilled professionals at the beginning and at the end of the study. The facilitator will be in touch with all of you regularly through the study to find out how you are progressing and to hear your experiences and reactions. You will have an opportunity to attend antenatal pregnancy classes where women attend weekly group sessions that incorporate education about pregnancy and new-born care. Most women find this useful. The educations that you will receive during the study including the THP-BGV programme may be helpful to you, your baby and your family. Most excitingly the results of this study will help in the development and integration of group format of the THP-BGV programme to the routine antenatal pregnancy classes and help other families.

Reimbursements

You will not be given any other money or gifts to take part in this research. You will not be charged for joining the PREVENT-PND, if you are selected in the PREVENT-PND group. However, in exchange for your valuable time, you will be given online web packages as incentive for facilitating your participation to online session in Türkiye. Transportation costs will be reimbursed for attending the face to face sessions in Pakistan. For providing time for the assessments, you will be given a package of baby diapers for each assessment.

What happens when the research stops?

After the research period you will continue with your regular treatment.

What if something goes wrong or if I have a question or complaint?

You will have independent routes of complaint to senior university officials.

Will the information obtained be kept confidential?

All the information that we obtain during the course of the study and assessments will be kept strictly confidential and will be stored in anonymized form. You may tell us things during our assessments that would be useful to pass on to the other professionals; for instance, matters that might help in their treatment of you. In this case we will discuss this with you and get your consent before any information is passed on in this way. As mentioned earlier all your information will be kept secure.

What will happen to the results of this study?
We will be keeping you updated as to the progress of our research during the study by a newsletter to all families. The results of the study will begin to emerge in the 6 to 12 months after the study finishes. We will publish the main results in scientific publications. None of this reporting will include any information that could identify you as an individual or family.

Who is organizing and funding the research?
This research is being funded by the Medical Research Council (MRC) United Kingdom. An international organization dedicated to funding research to improve human health. The lead management of the study is being undertaken from the University of Liverpool but the local PREVENT-PND Teams in Istanbul, Türkiye and Islamabad, Pakistan and will be responsible for their own part of the research work and as a contact for you.

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.

Alternatives to Participating
If you do not wish to take part in the research, you will be provided with the established standard treatment available at the antenatal classes.

For Türkiye:

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Who has reviewed the study?
This study has been reviewed and approved by scientific referees from the MRC, UK and by the Research Ethics Committee of the University of Liverpool and Marmara, Türkiye. These are committees whose task is to ensure the protection of human rights and the well-being of research participants.

Contact information of the Research Ethics Committee of the Marmara University, School of Medicine:

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You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

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This study has been reviewed and approved by scientific referees from the MRC, UK and by the Research Ethics Committee of the University of Liverpool and Health Services Academy,

Pakistan as well as National Bioethics Committee, Pakistan. These are committees whose task is to ensure the protection of human rights and the well-being of research participants.

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