Technology-assisted Cognitive-behaviour Therapy Delivered by Peers Versus Standard Cognitive-behaviour Therapy Delivered by Community Health Workers for Perinatal Depression: A Cluster Randomised Controlled Non-inferiority Trial

Informed Consent Form

16-11-2021

Thinking Healthy Programme-ENHANCE Information Sheet for Eligibility

Invitation Paragraph:
Greetings! My name is [XXXX], I am a research team member at The Department of Health. We have been working on maternal and child health for the last 15 years in partnership with the Rawalpindi Medical University, Rawalpindi. You are being invited to participate in our research study. Before you decide whether to participate, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully and feel free to ask us if you would like more information or if there is anything that you do not understand. We would like to stress that you should only agree to take part in it if you want to so otherwise feel free to decline to participate.

Thank you for reading this.

Purpose of the Thinking Healthy Programme
Research has shown that along with the physical health of mothers, their emotional well-being is also an important component for optimal infant development. Mothers who experience stress and emotional distress may need extra support for themselves and their infants. For this purpose we are carrying out the research project, this program, there is a talking therapy for such women who experience stress and emotional distress during their pregnancy and after the birth of baby, it is called the Thinking Healthy Programme (THP) we also want to test the effectiveness of the program. This program has already been completed with the collaboration of the world health organization in various areas of Pakistan, which has helped many families.

Why have I been approached to take part in this study?
We have approached you to take part in this study since you reside in the sub-district of Kallar Syeddan, Gujar Khan and Rawalpindi, are eighteen years or elder and happen to be within your 2nd to early 3rd trimester of pregnancy (4 to 8 months pregnancy).

What happens next?
Our female team members will assess, by asking you questions in relation to your mood and associated symptoms such as sleep, appetite and current functioning, whether you currently are experiencing any stress and/or emotional distress or feeling low/sad. It will only take 5 to 10 min. If you are found to have stress, then this will make you eligible to participate in the program. Furthermore, we will provide you with more information about our study and invite you to take part in it. If you agree to take part in the study, all the information and data collected on you will be anonymized, and only used to publish findings/results of this study. Your name and identity will be kept confidential and will never be revealed at any time point to anyone.

Do I have to take part?
No. Participation is completely voluntary. Saying ‘no’ will have no negative effect on the health care you receive from the lady health workers (LHWs) or health care provided at the Basic Health Unit (BHUs).

Confidentiality

All information obtained from you during the eligibility will be kept confidential and will be used for research purposes only. All information obtained from you will be stored in a password-protected computer at our research institute. We will only use your information and opinions for research purposes. However, the confidentiality will be breached if we find out the suicidal ideation, which could be harmful to yourself or your baby. In such situation, we may inform your LHW or primary care physician, without your permission so that you may receive the best treatment and care which is appropriate for your situation.

Whom should I contact for further information?

If you would like to receive more information regarding our study, or if you would like to discuss your rights regarding participation in this study please contact

Liaquat Ali

Phone#: 0346-8544460; Email address: liaquat.ali@hdrfoundation.org

Consent Level 1

Participant consent form

Please initial all boxes

1.	I confirm that I have understood the information in the attached document. I have had the chance to carefully consider it and ask questions. I was provided with satisfactory replies for my questions.	
2.	I agree to take part in the study.	

Name of participant	Date	Signature or Thumb Impression
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Name of person taking consent	Date	Signature
.....	.....	.....

Thinking Healthy Programme- Baseline Information Sheet

Introduction of the team

Greetings! My name is [XXXX], I am a research team member at The Department of Health. We have been working on maternal and child health for the last 15 years in partnership with the Rawalpindi Medical University, Rawalpindi. You are being invited to participate in our research study. Before you decide whether to participate, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully and feel free to ask us if you would like more information or if there is anything that you do not understand. We would like to stress that you should only agree to take part in it if you want to so otherwise feel free to decline to participate.

Thank you for reading this.

Purpose of the Thinking Healthy Programme

Research has shown that along with the physical health of mothers, their emotional well-being is also a very important component for optimal infant development. Mothers who experience stress and emotional distress may need extra support for themselves and their infants. For this purpose we are carrying out this research project, in this program, there is a talking therapy for such women who experience stress and emotional distress during and after their pregnancy, it is called the Thinking Healthy Programme (THP).

This program will deliver through community workers (CW) and Lady Health Workers (LHW) belonging to your local area. These community workers trained and can help you with specific problems you might have, discuss issues with you regarding your well-being as well as the health of your baby CWs/LHWs will listen to you, provide advice on specific problems you might have, and discuss issues with you regarding your health as well as the health of your baby. CWs/LHWs might have faced similar issues as you in the past, and possess specific knowledge about motherhood and family life which they will share with you.

How will I be chosen?

The research team member asked you questions about your feelings and emotions to find out if you meet the eligibility criteria for being included in the study. Your answers to these questions have indicated that you can be a potential participant in our study.

Do I have to take part in this study?

No. Participation is completely voluntary. It is your choice to participate in this study or not. If you choose to participate, you retain the right to refuse answers to any questions that you do not feel comfortable with. Also, you retain the right to withdraw from this study at any point in time without giving any reason, prior to having your information/data anonymized. Refusal to participate will have no detrimental effect on the health care services you or your family members are receiving from your Basic Health Unit (BHU) or your LHW.

What will happen to me if I take part?

If you agree to participate from now onwards, our research team member will ask further questions which include your basic information (Age, Marital Status, Education, and Employment Status) as well as information regarding your well-being, social support, quality of life and health services related questions. It will take approximately 20 to 30 minutes of your time.

Women who will be the potential participants in the study, will be divided into two groups:

- Standard Thinking Healthy Programme:
    - One group of women will receive the thinking healthy programme through a book/manual, which will be delivered by trained Lady Health Workers - LHWs
- Technology-assisted Thinking Healthy Programme: We have developed the electronic or digital mobile application of the Thinking Health Programme which is called the Thinking Healthy Programme-Application (THP-App).
    - This will be another group of women who will receive thinking healthy programme through tablets or mobile devices, will be delivered by trained Community Workers - CWs (lay women from the same locality)

These LHWs and CWs are trained so that they can help you with specific problems you might have, to discuss issues with you regarding your well-being as well as the health of your baby. You will be asked to sit and talk with your delivery agent for around 45 to 60 minutes in individual sessions.

We will also collect some information at two other time points which once when your baby is 3 months old and then once your baby is 6-months old. One of our female research team members will visit and ask you some questions about your health, emotional wellbeing, stress and, anxiety, whether you feel anxious or down, the support you receive, the nature of your relationships, daily functioning, adverse events you may have experienced, variety of infant related questions such as breastfeeding, and use of health care services during your pregnancy and after child birth. The interview will take approximately 25 to 30 minutes of your time

If you agree to take part in the study, it is to inform you that all your information and data collected will be anonymized, and used to publish findings from this study. Your individual name and identity will be kept confidential and will never be revealed at any time point.

Can I choose in which group I want to be in?
No. Unfortunately, you cannot choose which group you would like to be in. This selection is based on an equal chance of you being in either of the two groups and this selection is done by a computer program (this process is similar to tossing a coin and then deciding in which group you will get to be in).

What are the possible benefits of taking part?
By participating in this program, the participant mothers may be able to lower their level of stressors. The program will also help mothers notice feeling nervous and deal with it so that it is less likely to harm her or her infant. The information you will provide taking part in the study will help us to improve maternal and child health services.

During the time-period of our study, if women suffer from severe issues will be referred for specialist care. In case of any deterioration in symptoms of distress or worsening of severity, these women will be referred to either medical doctors at the primary care facility or to a specialist at the Institute of Psychiatry, Benazir Bhutto Hospital's for further care. However, in case of any reported pregnancy related complications, the team will provide referral slips to the women for Holy family hospital Rawalpindi so that timely medical assistance can be sought.

What are the possible disadvantages?
Talking about your feelings or sensitive topics may be difficult for some people, and cause emotional distress. You may choose not to answer any of the questions which make you feel

uncomfortable or even stop the interview altogether. If you become upset, you will be able to speak with an appropriate member of the research team. Our research team is trained in dealing with these situations and emotional disturbances and will help you to cope with such feelings.

Ensuring safety from COVID
All our staff members and the Lady Health Workers are trained to follow the Government of Pakistan advised steps that help reduce the risk of coronavirus. During all our interactions, masks will be worn by all research members and a distance of two meters will also be maintained between you and us at all times. Furthermore, you will also be provided with a mask to wear during the sessions. We will also ensure that the room in which the sessions take place are well ventilated. Hand sanitizers will be used and the tablet will also be wiped with sanitizer before it's used delivering the sessions. In case anyone of your family members or you seem to have any symptoms we will reschedule our visit through the Lady Health Worker of your village. This will also be the case for our team members that is both the Community Worker and the research team member.

Confidentiality
All information collected from you and about your baby will be kept strictly confidential. At baseline and follow-up assessments, your information (data) will be captured electronically on smart phones/Tablets. All your information will be saved and stored in a secure online depot (which we refer to as database). This online depot will be managed by Amazon Web Service. Amazon Web Service is a USA based company that provides services across the world, to support and manage such online depots. This online depot storing your information will be based in USA but all rights of accessing and/or using the information will reside only and only with our organization in Pakistan and study lead in University of Liverpool, UK. Please note, that we and any researchers who are working on this study will ensure privacy and confidentiality for all study-related data, documents, and findings. The results of all assessments will never be linked to you. The information gathered from you will only be identifiable by a specifically assigned study ID (i.e. a number) and not by using your or your baby's name or using any other personal identifiers. Data will be stored in a password-protected computer at HDRF, and the study results will be reported in a way that ensures complete confidentiality**.**

However, this confidentiality will be breached if there is concern about you or your child's health and wellbeing such as; suicidal ideas, or domestic violence. In such a scenario we may inform the primary care physician and your LHW so that appropriate and timely support can be provided to you.

To maximize the scientific knowledge to be gained from your participation in the project, at the completion of the study your de-identified data (data identified by a code or number) will be made available to qualified researchers external to this project for additional analysis. The data made available will include the de-identified data of you and your baby which was collected in the study. Data access will be limited to qualified researchers at domestic and international institutions with appropriate protections for human subjects in place.

Will I receive a compensation for this study?
No compensation will be offered for participating in this study. However, in lieu of your time, a token of appreciation will be given to you at the end of the interviews consisting of a few household items.

What if I am unhappy or if there is a problem?
If you are unsatisfied or unhappy with any of the study procedures described above, you can call the given numbers on this information leaflet. Our team will inquire and respond accordingly to help address any concerns you may have.

Whom should I contact for further information?
If you would like to receive more information regarding our study, or if you would like to discuss your rights regarding participation in this study please contact.

Name: Liaquat Ali
Contact number: 0346-8544460
Email address: liaquat.ali@hdrfoundation.org

We believe that this is a very important research project as it will provide vital information to improve maternal health care in Pakistan. We hope that you will participate in this important study and help us in researching the health needs of pregnant women and mothers in your community, and in designing appropriate programs, by signing this form below.

Thank you for your cooperation.

Consent Level 2

Participant consent form

Please initial all boxes

1.	I confirm that I have understood the information in the attached document. I have had the chance to carefully consider it and ask questions. I was provided with satisfactory replies for my questions.	
2.	I understand that my participation is entirely voluntary. I am free to withdraw at any time without giving any reason, prior to having my information/data anonymized. In addition, I understand that I am free to decline to answer any particular question or questions	
3.	I understand that my responses will be kept strictly confidential. I give permission for members of the research team to have access to my fully anonymized responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research.	
4.	I understand that the information I provide will be held securely and in line with data protection requirements at the research office. Only anonymized data will be used for reporting in journals and conferences to help support future research.	
6.	I agree to take part in the study.	
7.	I was given 24 hours to confirm my participation in this program.	

Name of participant	Date	Signature or Thumb Impression
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Name of person taking consent	Date	Signature
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