

Attached to protocol: SHARE-THPP-P, Rawlapindi

Principal Investigator: Atif Rahman

IRB Protocol title: South Asian Hub for Advocacy, Research and Education on mental health (SHARE).
Thinking Healthy Program – Peer-delivered (THPP): SHARE-THPP-P

Participation duration: 10 months

Anticipated number of subjects: 560

Introduction of the team

We are affiliated with the Human Development Research Foundation (HDRF), which is a research-based organization located in Mandra and Islamabad. During the last ten years we have been working in different parts of Pakistan to improve mother and child health. In light of our research we advise health departments and policy makers to improve their health related services.

We work in close collaboration with the Lady Health Worker (LHW) Program of Pakistan and other public health institutions like the Health Services Academy in Islamabad, Rawlapindi, Medical College in Rawalpindi, and international institutions/organizations. We carry out rural community-based research programs, related to mother and child health.

The purpose of the Thinking Healthy Program – Peer-delivered study (THPP)

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. We are carrying out a research project in Rawalpindi to study the benefits of such a support system called the “Thinking Healthy Program – Peer-delivered (THPP)”. This program consists of 10 home based individual sessions of around 45 minutes and 4 group based sessions of equal duration; these sessions will start from your pregnancy until 5 months after the birth of your child.

For the duration of this project the THPP sessions will be conducted by a Peer Volunteer (PV) belonging to your local area. PVs 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. PVs 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.

Home based THPP sessions will be given only by the PV, while group based sessions will be given jointly by the PV and your local LHW at the LHW’s house. All PVs will be trained by HDRF.

How will I be chosen?

You have already been seen by one of our research team members. Our research team member asked you questions about your feelings and emotions to find out if you meet the criteria for stress-related illness. Your answers to these questions indicate that you might be stressed. If you agree to participate, our research team member will ask some further questions about you and your husband’s age, education, and current household environment. Responding to these questions will take approximately 20 minutes of your time.

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 mentioning any reason. 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 from your LHW.

What will happen to me if I take part?

Women who meet the criteria for stress-related illness will be divided into two groups. One group of women will receive routine/usual care by their existing LHWs in addition to services from the BHU. The other group of women will receive visits from the PV who is trained in THPP, in addition, these group of women will also receive routine/usual care from their LHWs and services from the BHU.

Women in the THPP group will receive advice from the PVs on their emotional health and motherhood. These PVs will be selected and trained so that they are able to help you with specific problems you might have, 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 PV for around 45 minutes in 10 individual sessions and 4 group based sessions, starting from third trimester of pregnancy until 5 months after child birth. We believe that your PV might be able to help you; your PV comes from a similar background as you and might have faced similar issues as you in the past. It is your choice whether the PV sees you at your own home, the PV's home or at any other place of convenience to you.

Mothers who are not in the THPP group will receive usual routine care by their LHWs as well as routine care from their respective BHUs. We will also inform your LHW about your emotional well-being and levels of stress, so that she may help you to seek care from your BHU.

Can I choose in which group I want to be in?

No. Unfortunately, you cannot choose in which group you would like to be in. This selection is based on 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).

How often will I be interviewed?

In addition to the questions about feelings and emotions as well as your family life, you will be interviewed twice by our research team during the duration of the study. This will happen at 3 and 6 months after the birth of your baby. The research team can conduct the interview at your home, or at any other location which is of convenience to you. The research team consists of female researchers only who will ask similar questions as before, i.e. you will be asked questions about your emotions, well-being and difficulties you are experiencing concerning your health. In addition, we would also weigh your baby and ask you questions about your breastfeeding practices. These interviews will help us to determine if the THPP benefits you

and your baby's health, and we will be able to compare the results with the other group of women who did not receive THPP.

If you are found to be very stressed or sad and are in need of medical attention at 3 and 6 months after the birth of your child, you will be provided with a referral letter to the IoP and provided assistance in transportation to these health services.

The study will end 6 months after your baby is born.

What are the possible benefits of taking part?

We believe that the program might have a beneficial effect on you and your baby's health. If beneficial effects can be proven at the end of the study, additional PVs in your area will be trained to deliver THPP so that a greater number of mothers who suffer from emotional stress can receive help. If you are interested, we are happy to share our overall findings with you once we completed our study.

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.

Confidentiality

All information collected from you and about your baby will be kept strictly confidential. Please note, that we and any researchers working on this study 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. In case you need additional support during the course of the study which we may not be able to provide (e.g. medical help, incidence of violence, needing help from other services in the community, or additional help from your family), we may either inform your LHW, physician, family and/or our ethical review board of HDRF so that appropriate and timely support can be provided to you. Furthermore, any significant new findings impacting your willingness to participate in the study will be conveyed to you

The following individuals and/or agencies will be able to view the information you provide but without disclosure of your name and/or identity:

- The investigator, research team members and other health professionals involved in the study;
- Authorities from the Institutional Review Board ('IRB');
- Members of the Data and Safety Monitoring Board (DSMB) who are monitoring the intervention study of safety.

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 should I do in case of emergency?

In case of emergency, please contact Mr Ikhtlaq Ahmad (Ph#+92512656172, email:Ikhtlaq.malik@hdrfoundation.org) or Dr Omer Bangash (Ph##+92512656172, omer.bangash@hrdfoundation.org) based at HDRF (Address: H#6, St# 55, F-7/4, Islamabad).

Who has approved the study?

This study has been reviewed and approved by a scientific committee at HDRF.

Who 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 Mr Ikhtlaq Ahmad (Ph# +92512656172, email:Ikhtlaq.malik@hdrfoundation.org) or Dr Omer Bangash (Ph # +92512656172, omer.bangash@hrdfoundation.org) based at HDRF (Address: H#6, St# 55, F-7/4, Islamabad).

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 and your baby 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.

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I have read the request for participation in the **Thinking Healthy Program - Peer delivered (THPP)**. I have been explained the nature of the research and what I or my baby would be required to do as participants, and I have been given my own copy of the information sheet and consent form, which I have read (or has been read out loud to me). I have had the opportunity to ask questions about the study and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for me and my baby to participate in this study.

- I agree to participate in the study.
- I do not agree to participate in the study.

Signature of Mother:

Signature of impartial witness
(if mother illiterate):

Name of mother (please print name):

Date (Day/month/year)

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Statement by the researcher/person taking consent

I have accurately read out the information to the potential participant, and to the best of my ability have made sure that the participant understands the purpose and process of the study. I confirm that the mother was given the opportunity to ask questions, and that all of the questions asked by the mother have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and that the consent has been given freely and voluntarily.

IC has been audio-recorded since mother is illiterate and impartial witness is unavailable

A copy of this ICF has been provided to the participant.

Print name of researcher/person taking the consent: _____

Print position of researcher/person taking the consent: _____

Signature of researcher/person taking the consent:

Date (Day/month/year):
