

Attached to protocol: SHARE-THPP-P, Rawalpindi

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: 5 minutes

Anticipated number of subjects: 560

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

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.

Research has shown that mothers who experience stress and emotional distress may need extra support for themselves and their infants. We are carrying out a research project in Kallar Syedan to study the benefits of such a support system called the “Thinking Healthy Program – Peer-delivered (THPP)”. In order to do so, we first need to identify women who have recently experienced stress.

What do I need to do?

After leaving this information sheet with you for at least one day, we will come back to you to ask you whether you would be interested in responding to our questions on stress-related illness. Once you decide to participate, a research team member of us will approach you and ask you some questions on your feelings and emotions in order to find out if you meet the criteria for stress-related illness. This will take approximately 5 minutes of your time. If your responses indicate that you might be stressed, we will provide you with more information about our study and invite you to take part in it.

Do I have to take part?

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

What happens next?

If your responses indicate that you might be stressed, we will provide you with more information about our study and THPP and invite you to take part in it.

Confidentiality

All information collected about you 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 yourself. In case you need additional support which we may not be able to provide (e.g. medical help, help from other services in the community, or additional help from your family) we may inform your LHW, physician, or family so that you can receive the best treatment and care which is appropriate for your situation.

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 institutions with appropriate protections for human subjects in place.

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@hdrfoundation.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 maternal health needs of 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 would be required to do as participant, 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):
