Attached to protocol: SHARE-THPP-I, Goa
Principal Investigator: Vikram Patel
IRB Protocol title: South Asian Hub for Advocacy, Research and Education on mental health (SHARE). Thinking Healthy Program – Peer-delivered (THPP): SHARE-THPP-I
Participation duration: 6 - 12 months
Anticipated number of subjects: 280

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

We are a group of researchers connected with Sangath, a non-governmental organization located in Goa, and the London School of Hygiene and Tropical Medicine, UK, who are interested in studying the well-being of mothers and the health of their babies. Research has shown that along with the physical health of mothers, their emotional well-being is also a very important component for ideal 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 Goa to study the benefits of such a support system called the "Thinking Healthy Program – Peer-delivered (THPP)". The program consists of 6 -14 individual sessions of around 45 minutes in which a woman having children herself 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. The women delivering THPP 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. THPP will be delivered to you at home or at a location of convenience to you.

How will I be chosen?

Our research assistant has just asked you some questions on your feelings and emotions. We would now like to invite you to participate in our study. If you agree to participate and sign the consent form, you will be further interviewed by the same research assistant. In this interview, the research assistant will ask a few questions regarding your age, education and family life. The interview will be administered now and will require approximately 20 minutes of your time. You will not be the only mother who will be asked to participate in our study. In addition to you, 280 other mothers like you from the Asilo hospital and the Goa Medical College hospital will be invited to consider participation 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. Refusal to participate will have no negative effect on the health care you receive at the Asilo hospital or the Goa Medical College hospital, and will not limit any other rights for you or your baby. However, information collected will still be used in the study even if you decide to leave the study.

What will happen to me if I take part?

Mothers who agree to take part will be divided into two different groups so that we can assess whether THPP is beneficial to the health of mothers and their babies.

Mothers in the THPP group will receive advice on their emotional health and motherhood from a woman having children herself. We call these women "*Sakhis*". We selected and trained these Sakhis so that they are able to help you with specific problems you might have,

and discuss issues with you regarding your well-being as well as the health of your baby. You would be asked to sit and talk with your Sakhi for around 45 minutes in 6-14 individual sessions until your baby is 6 months old. We believe that your Sakhi might be able to help you; they might have faced similar issues as you in the past and possess specific knowledge about motherhood and family life which they would be willing to share with you. It is your choice whether the Sakhi sees you at your home, or if you would like to come and meet the Sakhi at the hospital or at any other place. We will make sure that THPP is delivered at a location of convenience to you. In addition, mothers in this group will receive care from their gynecologists at the Asilo hospital or at the Goa Medical College hospital as usual.

Mothers in the other group will receive usual care by their gynecologist at the Asilo hospital and at the Goa Medical College hospital only. We will also inform your gynecologist about your emotional well-being, and provide him/her with information regarding treatment of stress-related problems. You will be also given an information leaflet which includes specific information on caring for your mental health needs during pregnancy and beyond. The information leaflet also contains information about support systems and services you can see and explains how these services might be able to help you.

Can I choose in which group I want to be in?
No. Unfortunately, you cannot choose in which group you would like to participate. You may be assigned to any of these two groups. We will also not be able to assign you; the assignment will be determined by chance (as if you would toss a coin), so that each participant has an equal chance of selection into either group.

How often will I be interviewed?
Following the start of the study, mothers in the two groups will be re-interviewed twice by our research assistants; this will happen at 3 and 6 months after your baby is born. The research assistant can conduct the interview at your home, at the hospital or at any other location which is of convenience to you. The research assistant will ask similar questions as before: you will be asked questions about your emotions, well-being, and difficulties you are experiencing concerning your health. In addition, we would like to take the weight of your baby and ask you some questions about your breastfeeding practices. These assessments will help us to determine the benefits of THPP in comparison with women who received treatment and advice on their mental health needs by their gynecologists. It is important that you do not tell the research assistant who is interviewing you in which study group you are in. This will enable the research assistant to make an objective assessment.

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 your health and your baby's health. If beneficial effects can be proven at the end of the study, additional Sakhis in your area will be trained to deliver THPP so that a greater number of mothers who suffer from emotional distress can receive help. If you are interested, we are happy to share our final results with you once we complete our study.

What are the possible disadvantages?
Talking about your feelings or sensitive topics may be difficult, and cause emotional upset in some. You may always skip any questions which make you feel uncomfortable. If you

become upset, you will be able to speak with an appropriate member of the mental health service clinical staff. Our researchers and THPP staff are trained in dealing with these situations and emotional disturbances, and will help you to cope with such feelings.

Confidentiality
All information collected about you and 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. Incidences of violence required by law to be reported to authorities may be reported to the authorities without your consent. Clinical worsening (e.g. lowering of mood or suicidal feelings) may result in referral for treatment, and the team could potentially disclose this information to individuals outside of the study or to family members. If the team believes that you are at risk of harm to yourself or to someone else, the team will report this to the physician without your consent. Furthermore, any significant new findings impacting your willingness to participate in the study will be conveyed to you.

The results of all assessments and tests will never be linked to yourself. The information gathered from you will be identified only by an assigned study ID (a number) and not by using your or your baby's name, or by using any other personal identifiers of yours. Data will be stored in a password-protected computer at Sangath, and the study results will be reported in a way that ensures complete confidentiality to the fullest extent possible.

The following individuals and/or agencies will be able to look at and copy your research records (without your name attached):
The investigator, study team members, and other health research professionals who may be evaluating the study;
Authorities from Institutional Review Boards ('IRBs');
The United States Office of Human Research Protections ('OHRP');
The sponsor of this study, the National Institute of Mental Health, including persons or organizations working with or owned by the sponsor.

To make the most of what we learn through 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 who are not part of 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. Only qualified researchers at institutions which have appropriate protections for participants will be allowed to access the data.

Will I receive a compensation for this study?
No compensation will be offered for participating in this study. However, any costs you incur due to the study (for example, if you need to travel to the hospital for an interview) will be paid by us.

What should I do in case of emergency?
If you or your baby gets sick during the course of the study, you should seek help from the Asilo Hospital, the Goa Medical College hospital or another suitable health centre where you usually get treatment. In case of emergency related to our study you may contact Mrs Kishori Mandrekar (Address: Sangath, H No 451 (168), Survey No 50/31, Succour, Porvorim, Bardez, Goa 403501; Tel: 0838 008 6296).

Who has approved the study?
This study has been reviewed and approved by a scientific committee at Sangath and the Indian Council for Medical Research, the London School of Hygiene & Tropical Medicine and the US National Institute of Mental Health.

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 Mrs Kishori Mandrekar (Address: Sangath, H No 451 (168), Survey No 50/31, Succour, Porvorim, Bardez, Goa 403501; Tel: 0838 008 6296).

We believe that this is a very important research project as it will provide vital information to improve maternal health care in India. 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 the consent form.

Thank you for your cooperation.