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 Thinking Healthy Program – Peer-delivered study (THPP): Final outcome assessment

We hope you find our study beneficial. We thank you very much for taking part in it.

With this form we would like to ask you whether you agree to continue participation in our study. You agree to further participate in our study by signing this form below. If you agree to participate, you will immediately be interviewed by our research assistant. 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. We would also measure your baby's length and weight. The interview will require approximately 20 minutes of your time. We need to collect this information to be able to see whether the support you receive by your peer volunteer or gynecologist has a beneficial effect on your feelings, emotions and health.

It is important that you do not tell the research assistant who is interviewing you in which study group you are in. This is enabling the research assistant to make an objective assessment.

We wish to restate that participation is completely voluntary, and that you retain the right to refuse answers to any questions that you do not feel comfortable with. Also, you will always retain the right to withdraw from our 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.

We reassure you that all information which we collect about you and your baby will be kept strictly confidential. In case you need additional support during the course of the study which we may not be able to provide (e.g. medical help, violence against you or your child, needing help from other services in the community, or additional help from your family), we may either inform your physician, family, other community agencies, and/or our ethical review board of Sangath 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.

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 and tests will never be linked to yourself. Participant-related data will continue to be labeled by a code and not by using your or your baby's name. The study results will be reported in a way that ensures complete confidentiality to the fullest extent possible. Data will be stored in a password-protected computer at Sangath.

Who should I contact for additional information or if there is an emergency?

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 or in case of emergency please contact

Mrs Kishori Mandrekar (Address: Sangath, 841/1, Alto Porvorim, Bardez, Goa – 403521; Tel: 0838 008 6296).

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I have read the request for participation in ***THPP***. I have been explained the nature of the first outcome assessment 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 further participate in this study.

☐ I agree to further participate in the study.

☐ I do not wish to participate in the study any further.

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 and the first outcome assessment. 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):

_____ _____