Document type: Informed Consent Form

Study title: Development and Pilot Test of an mHealth Interactive Education and Social Support Intervention for Improving Postnatal Health – Phase 1

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POST-GRADUATE INSTITUTE OF MEDICAL EDUCATION AND RESEARCH & UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
STUDY TITLE: Maa Shishu Swasthya Sahayak Samooh (MeSSSSage): INTERVENTION DEVELOPMENT
Aim 2: Intervention Consent

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This is a research study to develop a mobile intervention to provide information and support for women who have recently had a baby. The study researchers, Drs. Duggal (PGIMER), Singh (IIIT-D), Diamond-Smith (UCSF), and El Ayadi (UCSF), or their representative, will explain this study to you.

DETAILED STUDY INFORMATION

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you are about to have a baby. This goal of the study is to develop a mobile intervention to provide support and information to women who just had a baby focused on maternal and child health.

Why is this study being done?

This study is being done to understand women's preferences for the format and delivery of a mobile information and support intervention to improve maternal and child health.

This study is funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (U.S.).

How many people will take part in this study?

About 48 women will take part in the main part of the study which includes participation in the intervention and an interviewer-administered questionnaire. Among these, up to 30 women will also be requested to also participate in an in-depth interview.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

First, we will wait until after you give birth to make sure that everything is fine with your health and the health of your baby. To participate in the main part of the study, you will need to be in good health (i.e., without any maternal complications). If you or your baby suffer a complication, we will contact you 3 weeks or so post-delivery to see how you are, check in on if you need any additional support, but we will not ask you to participate in the study.

If you are able to participate and choose to continue, the following will occur:

- You will be provided with a mobile phone, SIM card and airtime. You will be oriented on how to use the phone to participate in the intervention.
- You will be asked to participate in 6 weeks of group phone calls with other women who have just had a baby around the same time as you did. This will involve calling in via the phone for 1 hour each week. Information about how to connect to the group intervention and when will be shared with you.
- On the phone calls, a trained facilitator will share information about maternal and child health with you for 20 minutes, and during the next 40 minutes, participants will be encouraged to ask questions and discuss any issues that are important to them.
- You will be able to ask questions and talk to other women.
- Group conversations will be recorded.
- At the end of 6 weeks, a researcher will call you to ask your opinion about the group calls. You will be asked to respond to a series of questions about the program over the phone. You may be asked to participate in an in-depth interview.

Study location: All these procedures will over your phone.

How long will I be in the study?

Participation in the study will take a total of about 6.5 hours over a period of 6 weeks.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- You may feel inconvenienced because of the time and effort it takes to participate.
- You may find one or more topics addressed or questions asked be emotionally sensitive. Participation in the study is voluntary, and you do not have to respond to any question that makes you uncomfortable. You may end your participation at any time without penalty or loss of any benefits to which you are entitled. Moreover, if you would like to discuss your feelings with a professional, you will be referred to a trained counselor.
- Breach of confidentiality is a potential risk (i.e., something you say may be accidentally provided to others), but we will take precautions to minimize this risk. We will ask all group participants to will make sure that

information shared during the sessions are kept confidential. Anything that you say in the session will not be shared with anyone (including your husband or other family members). The survey will be done at a time that is convenient for you, and can be rescheduled for privacy if needed. All data will be stored securely in an electronic format and will be destroyed after the study is complete. Also, no reports from the study will contain any identifiers that could link the results with you or your village.

Confidentiality maybe breached by the other members of the education and discussion group. Other participants may not respect the request for complete confidentiality in the names of the other people in the group or private information that is shared. We will ask everyone to keep the discussions completely confidential and not share what is stated in the support group outside of the group – however, we cannot guarantee that everyone will keep the discussions private.

For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

If you choose to participate in the study, you will receive information to improve your own health and the health of your baby. You will be able to ask questions to a trained health care provider and you will be connected to other women like yourself whom you can talk to about shared experiences. You will also be allowed to keep the phone that you are given to participate in the study. The information that you provide will help the researchers to refine a mobile informational and support intervention to improve postnatal maternal and child health.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Despite confidentiality protections, confidentiality is not absolute. For instance, if we learn about a threat of serious harm to you or someone else, we will take steps to protect the person or persons endangered even if it required telling the authorities without your permission, but we will only disclose the information necessary to prevent harm to the person or persons believed to be endangered.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California, Indraprastha Institute of Information Technology, Post-Graduate Institute of Medical Education and Research

The researchers will ask you and the other people in the group to use only first names during the group sessions. They will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private.

Will I be paid for taking part in this study?

In return for your time and effort, you will be provided with 50 Indian Rupees per group meeting attended. You will also be allowed to keep the phone that you were given to participate in the intervention after the study has ended.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the researcher(s) Dr Mona Duggal/ Dr Rashmi Bagga at PGIMER, CHANDIGARH 9915816281/ 8968772905.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at *0172-2755266*

CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent (or thumbprint)
Date	Person Obtaining Consent

Date	Witness – Only required if the participant provides thumbprint above