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Study title: Development and Pilot Test of an mHealth Interactive Education and Social Support Intervention for Improving Postnatal Health – Phase 2

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Specific Aims: We propose developing a mobile interactive education and support group intervention, *Maa Shishu Swasthya Sahayak Samooh (MeSSSSage),* to improve the health and well-being of Indian women and infants in the postnatal period using a provider-moderated group approach. *MeSSSSage* will provide culturally tailored educational programming, increase women's health-related communication with providers, refer women in a timely and appropriate manner, and connect them with a virtual social support group of other new mothers. *MeSSSSage* aims to reduce postnatal care barriers arising from distance, economic burden, cultural practices, and fatigue, and provide social support in this time to help reduce women's postpartum isolation.

Postnatal health care includes education and clinical care necessary for ensuring maternal and infant health: neonatal care practices (breastfeeding, newborn hygiene, etc.), prevention activities (immunization, recognition of infant danger signs, etc.), assessment of maternal physical recovery from childbirth, postpartum mental health, and postnatal contraception adoption. Postnatal care improves maternal physical and mental health, and well-being.[1–3] In Haryana state, India, only 40% of women received at least one postnatal health check in the two months after delivery.[4] Extending group-based pregnancy care or women's group models that have proven successful in improving maternal and neonatal outcomes in South Asia and elsewhere to the postnatal period could show health improvements.[2] However, barriers exist to successfully implement postpartum group care, including logistical challenges of traveling to the facility or group meeting with a young baby and limited mobility in South Asia, including postnatal seclusion.[6] Applying an mHealth approach to postnatal care may help new mothers overcome such challenges, and high mobile phone penetration in Haryana state, India, supports the feasibility of testing a group mHealth intervention in this population.

Most mHealth interventions for maternal and child health (MCH) in low and middle-income countries, including India, have focused on unidirectional and non-interactive approaches, primarily text messaging.[5] However, ample evidence suggests that provider-led, interactive educational programming and social support are key for improving health behaviors and outcomes.[7,8] Thus innovative mHealth approaches that promote interactive education and facilitate social support have great potential to improve MCH outcomes. The two-phase development of *MeSSSSage* will include Phase 1: exploratory development on functions and platforms and Phase 2: a mixed-methods randomized pilot study using a factorial design of specific intervention functions and platforms confirmed in Phase 1. The specific aims of this study are:

Aim 1. To develop optimal intervention functions, processes, and mHealth platforms for education and peer support among postnatal women in rural India. In Phase 1, we will explore potential interactive education and peer support group intervention functions (education, emotional support, instrumental support, referrals, linkages, follow-up on postnatal visits), processes (group interactions; frequency, length and timing of groups; engagement opportunities, participant profiles) and mHealth delivery platforms (voice, text chat, app options, interaction features). This two-month developmental component will include four groups (n=48; 12 per group) to assess different modalities and functions. We will ascertain women's preferences for functions, processes, and platform features using survey and in-depth interviews (IDIs), and capture levels of engagement via back-end data. This process will also inform the intervention's health information content. Findings will be used to formalize the group mobile intervention details to be examined in Phase 2.

Aim 2. To assess the feasibility and acceptability of the optimized *MeSSSSage* intervention. In Phase 2 we will evaluate the feasibility and acceptability of two intervention components using a controlled 4-arm factorial design (n=160; 40 per arm): 1) real-time mobile voice information and support group alone, 2) asynchronous/ on-demand text-based group support only, and 3) real-time mobile voice information and support group plus asynchronous/on-demand text-based group support. Feasibility and acceptability will be assessed via back-end data, surveys, and IDIs with purposively selected participants (n=30) and moderators.

Aim 3. To explore the preliminary effectiveness of the optimized *MeSSSSage* intervention components on six-month maternal and neonatal health outcomes. Phase 2 data will help us develop a preliminary understanding of the impacts of the intervention components on MCH health-related knowledge, behaviors and outcomes including exclusive breastfeeding, immunization, family planning uptake, postnatal visits, mental health and empowerment; however, it is not statistically powered to formally assess effectiveness.

This study is significant and innovative in addressing key priorities of NICHD's Pregnancy and Perinatology Branch and using systematic, user-centered and experience-driven design approach. These results will inform the most acceptable, feasible, and potentially efficacious intervention design to be robustly tested through an R01 mechanism to assess effectiveness for maternal and infant health outcomes, explore other research questions relevant to intervention development and scale-up for postnatal health among South Asian women, and explore generalizability across populations.

Significance

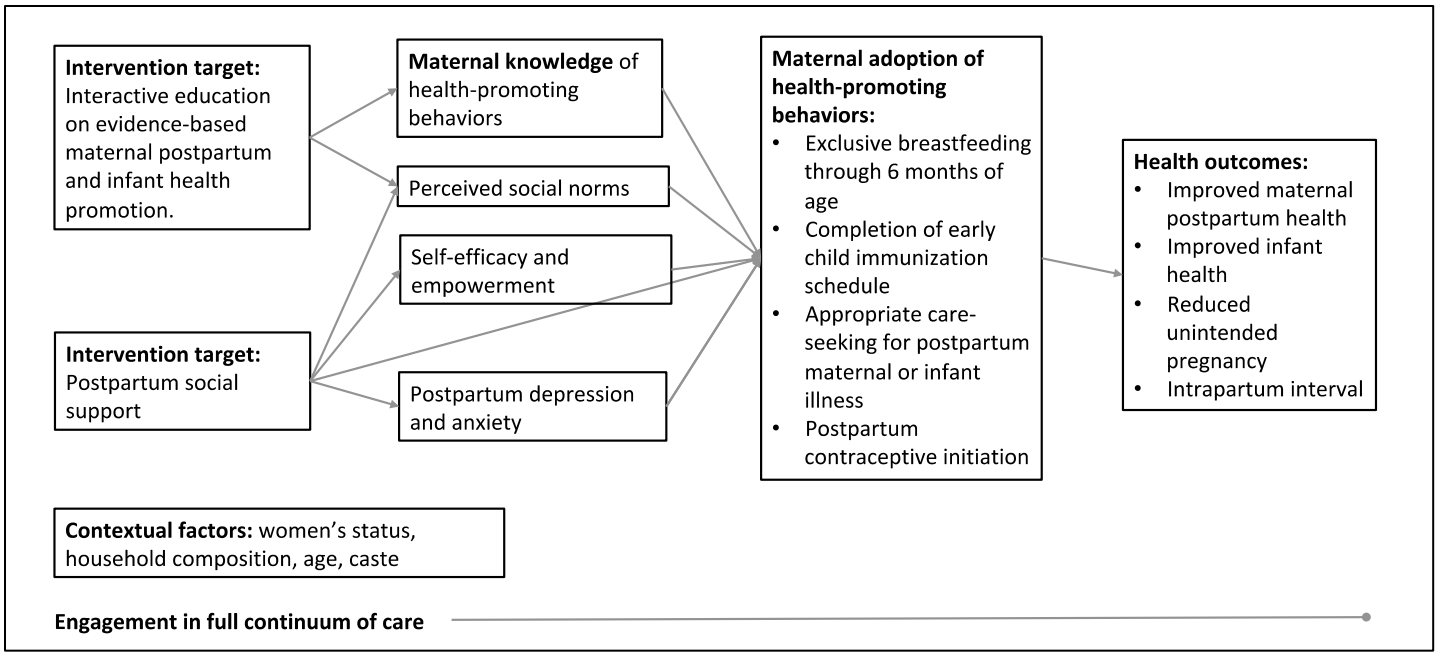
Postnatal care and support improve both infant and maternal health and save lives. However, the majority of interventions are focused on antenatal care, skilled delivery, and family planning; substantially less attention has been paid to the postnatal period. The government of India's Reproductive and Health Program recommends three postnatal visits; however, these are infrequently achieved.[4,9] Recent Indian studies found postnatal checkups to be associated with reduced neonatal mortality.[2] Furthermore, postnatal care and support can help improve practices essential for newborn health, including exclusive breastfeeding and immunization, which were at 50.3% and 62.2%, respectively, in Haryana state, the site of this study, according to the most recent Indian Demographic and Health Survey.[4] Postnatal care, in addition to antenatal care and facility delivery, is associated with women's uptake of family planning in India.[10] Haryana state is designated as a high focus state for family planning by the Indian Ministry of Health and Family Welfare,[11] and unmet need for family planning is high; one study reported that 64% of Indian women had an unmet need for family planning in the early postnatal period.[12]

Women's groups and group-based care models are promising for improving perinatal health. Group-participatory learning and action models have significantly improved a variety of maternal and neonatal health indicators[13,14] and group-based care provision models such as Centering Pregnancy,[15] group-based prenatal care, and others have found increased rates of exclusive breastfeeding, increased postnatal contraceptive uptake, reduced postnatal depression, and increased immunization.[16–19] Health improvement through women's groups and group-based care models capitalize on improved efficiency of education and information delivery associated with the group setting and through strengthening social support networks.[20] Furthermore, the group delivery model is acceptable to women. Social support is positively associated with postnatal health,[21,22] particularly for the prevention of postnatal depression and anxiety[23,24] and for breastfeeding maintenance.[25,26] Group care has been associated with women's empowerment.[27] Extending group care into the postnatal period is an innovating and promising approach for improving health outcomes for the mother and neonate.

Significant logistical barriers prevent mothers from physically attending postnatal social support groups at facilities or other locations that may be far from their homes, particularly in India.[28] mHealth approaches offer an innovative opportunity to overcome these barriers. Common logistical challenges of transportation and scheduling are exacerbated in India by rural geographic distances, cultural and linguistic barriers to care, women's practice of postnatal seclusion and generally low levels of mobility in marriage; all combine to significantly reduce care access.[29–31] Further intergenerational and gender-based hierarchical roles structure decision-making in Indian households, particularly for couples living in extended-family households, with decision-making largely outside of the hands of mothers[32], especially those who are young and newly married. Despite women's physical mobility limitations in this setting, there is broad access to cellular telephones in India with 88% of households nationally owning a mobile phone.[33] In our target region Haryana state, 51% of women own their own feature mobile phone.[34] Mobile learning platforms have been successfully used for training among other populations such as community health workers in constrained environments by members of our research team.[35] Testing the acceptability, feasibility, and effectiveness of a group care mHealth model is exciting and practical given increasing access to mobile technology globally, and such a model overcomes the physical and cultural barriers inherent to in-person group models.

Providing targeted education and support to women in the postnatal period through a mobile social network holds potential to improve postnatal recovery, neonatal care practices, nutritional status, general health, knowledge and care seeking - positively impacting maternal and child health. Mobile support and education groups are based on prominent health behavior change theories such as the capabilities and motivation constructs of the COM-B framework,[18,19] and have positively impacted a variety of other health outcomes in both developed and developing world settings.[2,10] Targeted interactive education and support to women in the postnatal period through a mobile social network is hypothesized to meet their knowledge needs, improve self-efficacy and maternal mental health, and alter perceived social norms. All of these are important for appropriately identifying infant and maternal danger signs and timely care seeking for routine and emergency visits (including referrals), and reduce infant and maternal mortality and morbidity (**Figure 1**). Furthermore, mHealth group support could help encourage and sustain exclusive breastfeeding, and improve uptake of postnatal family planning and childhood vaccination, which positively impact maternal and child health in both short and long term. The social support component will encourage free discussion, allowing women to share experiences and tips for success (advice on soothing a crying baby, balancing family obligations with caring for her own healing body, etc.), providing informational social support. Interventions targeting informational and emotional social support have previously resulted in improved maternal and neonatal health, including reduced postnatal depression[36,37].

Figure 1. Conceptual Framework of MeSSSSage Intervention Targets and Outcomes



Innovation. The approach taken in this research will add to the scientific understanding of whether mHealth interventions can successfully include group components and interaction between users. It will also expand our toolkit of approaches for intervening in the postnatal period, with applications for other times in the life course and populations. If proven successful, this study will lead to the development of a tested tool ready for next steps in the scale up process to robustly test effectiveness. It extends the current evidence in two primary ways:

1. This study seeks to develop an mHealth group care intervention, combining the potential for mHealth to reach vulnerable populations in lower resource settings with the key health benefits of multidirectional, social interactions with both social support and health care providers. Most mHealth interventions are unidirectional, do not involve social support, or are targeted towards health providers, rather than clients themselves.
2. We extend the solid evidence base for group care in pregnancy to the postnatal period, a neglected and vital period for infant heath outcomes, as well as maternal mental and physical health outcomes. Postnatal care is especially challenging in settings like rural India where women live far from facilities, have restrictions on physical mobility, and practice seclusion after childbirth.

Approach

The mobile platform we will adapt was developed by our IIIT-Delhi research collaborators, and has been tested with SWACH, our implementing partner. This innovative platform provides a single collaborative learning environment optimized for use by both basic feature phones and smartphones. This lowers cost while increasing reachability while accommodating increasing technology access. The back-end of the system is built on Interactive Voice Recognition (IVR) technology that facilitates easy data collection for analysis on user participation, storing the knowledge generated in each interactive session. Recently the system has been extended by applying state-of-the-art natural language processing techniques to extract the audio and create a knowledge base which can then be used to deliver automated answers.[38] It has previously been tested for feasibility with SWACH in the general population, and as a training for health workers and found improvements in health worker knowledge.[35,39] Members of the team have also developed a platform similar to WhatsApp that may be integrated into this design or added on to support the *MeSSSSage* design.

Study Site and Population. This study will occur in Kurukshetra district, Haryana state, India. Household mobile phone ownership is high, with 90% of households, and 50% of women, in this district owning a mobile phone.[4] The current national guidelines for postnatal care in India are for women to receive three home visits from an ASHA within the first week following childbirth.[4,9] In this setting, women are seen by an Accredited Social Health Activists (ASHA) in pregnancy and postpartum. The role of the ASHA in postnatal care is to counsel the mother on recognition of and referral for complications. The ASHA also counsels the mother on adoption of postpartum family planning. For newborns, the ASHA provides skin, eye and cord care, monitors infant weight gain, supports exclusive breastfeeding, and provides general newborn care and referral. **However, data from our study state,**

Haryana, suggest that less than half of women receive any postnatal care,[4] and ASHA visits are typically short, all of which restricts the information and support that women receive in the postnatal period.

Phase 1: Aim 1. To develop optimal intervention functions and mHealth technology delivery platforms for education and peer support among postnatal women in rural India: The prototype *MeSSSSage* will include a weekly mobile call-in group meeting, including recently delivered women and moderated by one trained health worker, an experienced ASHA facilitator. Each group will consist of 12 women whose infants were born within approximately two weeks of each other. Women will attend these group meetings by calling in on their mobile phone, and the meetings will last approximately one hour. In each group, the ASHA facilitator will provide approximately 20 minutes of health education specifically tailored to the common health needs of the mother and infant at the specific infant age, followed by 40 minutes for group discussion. Aim 1 will inform exact length of education and discussion per meeting), and if and at what frequency reminder messages are required.

Development of optimal modalities: We will pilot the prototype *MeSSSSage* platform in three groups of recently delivered women for a period of two months by testing different modalities over that time, as described in **Table 1** (N=48). The goal of this formative phase is to orient women to a variety of experiences to reflect on when seeking their feedback, so as to design the most appropriate intervention for full piloting.

Table 1: Modalities to be explored to identify optimal intervention functions, processes and platforms (Phase 1).

Modality	Description of modalities	Goal
Group structure	(1) Frequency: How often groups are held (2) Length: How long groups last (3) Timing: What time of day/day of week	To determine the best group structure
Participants	(1) Number (2) Breadth of gestational age (3) Age of respondents	To determine the best group structure
Group Interaction type	(1) Women have to "raise their hand" virtually, by typing a specified number into their phones if they have a question or comment, and then the moderator gives "permission" to women to speak one by one (2) Open line where women can speak at any point. (3) Moderator call out individual women to ask if they have questions or comments	To measure: ● Level of comfort with participation ● Amount of engagement and interactions between participants ● Conversation dominated by certain participants ● Communication patterns
Content	(1) Additional information desired (2) Level of detail of information (3) Language and approach used by moderators	To adjust and expand the content/topics covered
Text-based group addition	Offer an additional freer-form, ongoing, text-based group (e.g., WhatsApp)	To determine: ● Number of interactions ● Barriers for women with low literacy ● Group sense of support

Procedures: Primiparous women will be recruited in their last month of pregnancy by the ASHA and a research assistant during the ASHA's regular home visit. At enrollment, the study protocol and informed consent will be described to the women, written informed consent will be obtained from interested women, and phone numbers collected (and tested). Women who do not personally own a phone will be provided with one. Airtime for all participants will be covered during this 2-month preliminary phase. Consent will also be obtained from family members per local cultural practices. Consent will cover phase 1 intervention and the evaluation components.

Women age 18 or above are eligible if this is their first birth. Women with high risk pregnancies will be ineligible for participation, and enrolled women will be removed from the study if they deliver preterm, suffer severe maternal complications (c-section or hospitalization), or they or their baby are otherwise sick in the first week postnatal. When women give birth, the ASHA and facilitator will inform the research team, and women will be assigned to groups based on date of delivery to cluster delivery dates in within approximately two weeks.

Back-end data will be captured from all participants A brief phone survey with all participants and in-depth interviews with half of participants will be conducted after 2 months (~ 8 group meetings).

Surveys and backend data: All 48 respondents will be called via phone to participate in a short (10 min) survey about their experiences with *MeSSSSage* group components, including preferences regarding functions and modalities and level of satisfaction with each, using likert-type response scales (1-5). Data will be recorded on a tablet. We will calculate means and standard deviations for each preference and function variables. Each group discussion will be audio recorded, transcribed, and translated into English. We will analyze group discussion content for function, using Atlas.ti. We will review intervention engagement including text-messaging (number

and topic), number of participants per session, engagement with the health worker and each other, etc. The study team has previously analyzed prior technological study data; we will use a similar method, in STATA v15.

In-depth interviews (IDIs): We will recruit a subset of Phase 1 participants (n=30), equal numbers from each group, for IDIs. The interviews will explore women's experiences participating in *MeSSSSage*, the components they liked and disliked, and how to improve programming. Specifically, we will focus on timing and frequency of the group meetings, as well as feedback on the modalities tested in the different arms. We will explore their experience of the social support component of *MeSSSSage* and how this, or another, mobile technology might increase the support available to them. We will also explore which health topics related to postnatal maternal and infant health are most needed, and their main health-related concerns. IDIs will also be conducted with ASHA facilitators delivering the educational content of the mobile voice groups and moderating the mobile text groups to understand their preferences around the group components, their experiences conducting the sessions, and their perspectives on mobile provision of education, care, and support. IDIs will take place at the respondent's home, or another private location. IDIs will be transcribed and translated into English. IDI data will be coded by the research team using a grounded theory framework, using Atlas-ti text analysis software.

Phase 2: Pilot test of optimized intervention, assessment of feasibility and acceptability (Aim 2) and preliminary effectiveness on maternal and infant health outcomes (Aim 3). After analysis of Phase 1 data, we will adapt *MeSSSSage* based on participant feedback and expand content to cover topics relevant to the first 6 months postnatal. If Phase 1 data suggest the tested mobile group forum modalities are not appropriate for this population, we will adapt our study protocol to explore other feasible means to provide information and support (e.g., SMS or video). We anticipate developing and testing 2 modalities of postnatal education and support in a factorial design with a control arm for a total of 4 different group compositions. All women, including the control group, will receive the standard of care provided by the Government of India and described above. We will conduct a pilot test of the intervention using 3 groups per intervention modality (8 groups total) among 160 women (Table 2). Group structure and duration will be informed by Aim 1, but we anticipate the following:

Table 2: *MeSSSSage* components to be tested in feasibility and acceptability assessment (Phase 2).

	Arm 1	Arm 2	Arm 3	Control
Real-time live voice call group meeting: Interactive educational program with scripted didactic component plus discussion/question. Lead and moderated by health professional.	X		X	
Text-based, asynchronous, on-demand social support: App-based small group text-based communication. Moderated by health professional.		X	X	
Standard of care: 3 visits in the first 7 days postnatal (facility and home)	X	X	X	X

Procedures: Unless found not feasible or acceptable within Phase 1 activities, women will be recruited using the approach described above (Aim 1). At the time of enrollment, the study protocol will be described to the women per informed consent procedures. Written confirmation will be obtained from interested women and their phone numbers will be collected (and tested). Women without a phone will be provided with a phone and all participants' airtime will be covered for the length of the 6-month research project. Women who consent will be randomly enrolled into 1 of the 4 study arms using a random number generator. We will test each study condition using 2 groups of women, with intervention initiation staggered 1 month apart. Women in the control group will receive the standard of care. All women will be given 50 Indian Rupees for participation in each session (in addition to airtime and phone if needed), and ASHAs will receive 150 Indian Rupees for moderating each session. Assessment of feasibility and acceptability (Aim 2) and preliminary effectiveness (Aim 3) will be accomplished using mixed-methods including quantitative surveys, in-depth interviews, and technology assessment.

Survey data collection: Baseline and endline surveys will be administered by a research assistant in the respondent's home. Endline survey will be collected roughly 6 months postnatal, after potential participation in ~24 *MeSSSSage* sessions (details to be determined during Phase 1). We will capture women's health record cards and ASHA registers to validate self-reported health outcome data. Data will be collected on a tablet using the secure REDCap mobile research administration app, stored in a password protected database at UCSF, and no identifiable information will be included with analytic datasets (identifiable data will be stored separately).

In-depth interviews: Additionally, in-depth interviews (IDIs) will be conducted with a selection of 10 women from each intervention condition (30 IDIs), purposively sampled based on high/low participation rates determined by the end line survey. We will collect data on experiences with *MeSSSSage* and how to improve it.

Technology assessment: Finally, we will collect and analyze the quantitative backend data from the prototype to gain more insight into women's participation in the intervention, including attendance and level of participation

in group interactive educational sessions, use of mobile social support platform (number of posts, frequency, topic), etc. Text data from transcripts of the educational sessions and content of group messaging will be analyzed for content in order to understand primary educational needs and interests for postnatal women.

Group moderator survey and interview: ASHA facilitators moderating the groups will be asked to respond to a short questionnaire after each group session to understand: preparation and delivery time, content, efficiency, acceptability and satisfaction with the group model, perspectives of impact, challenges, and any follow-up/referral necessary.[40] Regarding facilitation of groups that receive the text-based messaging intervention component only, ASHA facilitators will report on experiences in the prior week. We will conduct monthly semi-structured interviews with each of the ASHA facilitators to understand their preferences for group components, experiences preparing for and conducting the sessions, and their perspectives on mobile provision of education, care, and support.

Measures: The baseline survey content will include sociodemographic characteristics and knowledge about maternal and infant health, self-efficacy, and perceived social norms regarding MCH-related health promoting behaviors. The endline survey will include acceptability questions such as women's satisfaction with and perceptions of *MeSSSSage*, maternal and infant knowledge-, behavior-, and health-related questions including about breastfeeding, complementary food introduction, immunization, family planning uptake, maternal physical and mental health, etc. which have previously been used in this setting (Table 3) [4].

Table 3: Participant survey measures (Phase 2)

Category	Measures
Sociodemographic characteristics	Age, age at marriage, educational attainment, caste, language spoken, household assets, women's status/decision-making, social support and relationship quality.
Health-related knowledge (effectiveness)	Knowledge on maternal and neonatal danger signs, best practices for infant care, family planning.
Health-related behaviors (effectiveness)	Breastfeeding and complementary food introduction practices (breastfeeding initiation, length of exclusive breastfeeding, length of breastfeeding, timing of complementary food introduction), appropriate management of early childhood illnesses.
Health outcomes (effectiveness)	Early childhood immunization, postnatal depression and anxiety, postnatal family planning adoption.
Intervention perspectives (feasibility, acceptability)	Self-reported engagement in intervention components and topics, satisfaction with intervention components, likelihood of participating again, likelihood of recommending program, value on knowledge and social support gained from participation.

Analysis. Aim 2. Feasibility and acceptability of the optimized MeSSSSage intervention components. We will use a mixed methods approach, triangulating data from quantitative baseline and endline data, qualitative IDIs, and technology assessment. Feasibility and acceptability will be measured by participation rates at each session, participation trajectories over time, and user engagement (via technology assessment backend data). Women's reports of use and satisfaction (survey and IDI will shed light on barriers and facilitators to participation. Moderator acceptability will be assessed by satisfaction, fidelity to topic/content based on protocol and perspectives on impact. We will test for differences in feasibility and acceptability between the three intervention arms to understand if both components (group meetings and text) or only one is the best approach, using ANOVA for continuous outcomes and chi-square or Fisher's exact tests, as appropriate, for categorical outcomes.

Aim 3. Preliminary effectiveness of the MeSSSSage intervention components on six-month MCH outcomes. Using the quantitative survey data, we will statistically evaluate differences by study arm in improvements in women's knowledge, behaviors, and maternal and child health outcomes, compared to the control group (including effect sizes, controlling for relevant socio-demographics as necessary). Figure 1 displays the outcomes that are theoretically related to our intervention targets. Our main *knowledge* outcome will be a composite score representing the proportion of correct answers from a knowledge scale on breastfeeding, newborn and infant care, maternal and infant danger signs, newborn care, and family planning, topics that will be covered within our interactive educational group component. Our main *behavior* outcome will be self-reported exclusive breastfeeding at 6 months. Our main *health related* outcomes will be: (1) completion of early childhood immunization schedule; and (2) postnatal family planning uptake. We will measure women's social support and related mental health status (depression and anxiety) using scales that have been previously validated in similar populations such as the Hopkins Symptom Checklist[41] and the Multidimensional Scale of Perceived Social Support[42]. Finally, women's empowerment will be measured using decision-making and mobility scales.[43,44]

Sample Size. This pilot development study is not formally powered to detect significant differences in outcomes, but will give insight into directionality of changes. The per group sample size was selected based on feasibility

of recruitment, intervention delivery, and the interpersonal interaction important for a group-focused intervention. The sample is sufficiently large to assess the feasibility and acceptability outcomes through descriptive statistics.

Timeline. Phase 1, which includes the intervention optimization and development period, and Aim 1 data collection, will occur in quarter 2 (Q2) of Year 1 (Y1), after Q1 is spent preparing for the study (IRB, instruments, training research team). In Y1Q3 we will finalize the details of the mhealth platform and prepare for Phase 2 (tool development, IRB modifications, training research team). From Y1Q4-Y2-Q2 we will recruit and collect data for Phase 2, which is a 6 month pilot intervention. Y2Q2-Q3 will be spent in in-depth data analysis for Aims 2 and 3. The final part of the grant (Y2Q3 and Q4) will be spent in dissemination (local and international) including meetings, presentations, academic manuscripts, and conferences. We will also apply for a larger grant to test this at scale. Please see our timeline table in the human subjects and clinical trials supplement.

Capacity building. IIIT Delhi has a new Social Science Department; however, most faculty and students have little training in research methods such as mixed-methods and qualitative research. Drs. Diamond-Smith and El Ayadi are experienced in leading workshops on study design and analysis, particularly for these topics. They will teach a one-week workshop to IIIT Delhi faculty and students on designing and evaluating interventions, and mixed-methods approaches for evaluation, including qualitative data analysis. Furthermore, IIIT PhD students will participate in this workshop and assist in collecting the qualitative interviews in Phases 1 and 2, as well as analyzing the qualitative data. Drs. Diamond-Smith and El Ayadi will mentor students throughout, including preparing manuscripts with them for publication in a 3-day writing workshop at the end of the project. The research team proposed herein has recently been awarded a two year capacity development award through the Government of India, Ministry of Human Resource Development, Scheme for Promotion of Academic and Research Collaboration to provide training on mHealth design and evaluation for maternal and child health.

Potential problems and alternate strategies

Recruitment and retention. The research team has successfully conducted research among women in the postpartum period living in this area, and have been successful in recruitment and retention. We do not anticipate challenges to recruitment of study participants or retention during the full study period. If women appear to be lost to participation, the local ASHA will be notified and she will follow up with the woman participant to determine the barriers to her participation in the intervention.

Gender gaps in mobile phone access. While mobile phone penetration is increasing dramatically across all of India, significant gender gaps exist in ownership and use of mobile technologies. For example, among the adult population, 84% of males are considered primary mobile phone owners compared to 65% of females.[34] Younger individuals have higher mobile phone ownership than older individuals; our target population of primiparous women is likely to fit within an age group of higher mobile ownership. We will provide participants who do not personally own their own phone with a phone to reduce barriers to participation resulting from multiple household phone users, and will provide airtime for the study to all participants.

Low literacy among target population. Recent data from Haryana state show that 75% of women of reproductive age are literate[4], and thus it is possible that women's low overall literacy, and potentially low technological literacy, will reduce their ability to engage in *MeSSSSage*. However, the research team's experience has not found this to be a problem for prior research projects among the target population. Additionally, given the young age of participants, we anticipate that they will be more literate and tech-savvy than average. Our experience of our team in the field at this specific study site has found that WhatsApp is extensively being used for communication and husbands are more actively involved in pregnancy and can support their wives. The *MeSSSSage* platform will allow illiterate women to speak to answer questions, thus making it more accessible to low literacy women. At enrollment, the research assistants will provide one-on-one training participation in the group meeting and text-based components of the intervention, including basic instructions on texting. Given the population we seek to generalize our findings to, we will not exclude illiterate women from this study.

Expected outcomes and future directions. Our pilot results will inform the design of a larger R01 trial to robustly test the effectiveness of *MeSSSSage* on postnatal maternal and infant health behaviors and outcomes. We expect to positively impact women's postnatal health knowledge and behaviors, and improve health outcomes for women and their infants in the first six months. We will also disseminate the findings to health professionals and community members, as well as appropriate Indian stakeholders (Government, NGO, etc.). Our study will help build the evidence on mHealth for maternal and perinatal health, and group care models for postnatal care, contributing to reducing disparities in women's access to care through the removal of geographic and social barriers.

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OVERALL STRUCTURE OF THE STUDY TEAM

This project will be done jointly between the Indian and US teams, who will work closely together throughout the study and co-author publications resulting from the study. The overall study PIs (UCSF) and local Indian PIs will report adverse events and information on safety indicators to Data and Safety Monitory Board (DSMB).

The roles of each teams are specified as bellow:

- **US team**: The team will be led by Dr. Nadia Diamond-Smith and Dr. Alison El Ayadi (Co-Principal Investigators) with support from Dr. Dallas Swendemen (Co-I) and Laura Weil (Co-I). The roles for the US team are:
    - **Principal Investigators**: Drs. Diamond-Smith and El Ayadi are responsible for finalizing the design of the study, acquiring UCSF IRB approvals, ensuring the fidelity and compliance of the intervention development and refinement according to study protocol, and leading qualitative and quantitative analyses on data collected through the study. They are also responsible for addressing protocol violations, adverse events, and incidents that might occur as a result of the study, and reporting them to the IRB, NIH, and DSMB within the timeframe proper for each. They will lead the primary publications resulting from this study and capacity building training activities with the Indian partners.
    - **Co- Investigators**: The Co-Is will provide support and advice to the co-PIs for all activities and responsibilities listed above, specifically related to mhealth intervention development and evaluation (Swendemen) and postpartum and group care (Weil). They will also contribute to data analysis, and the dissemination of results of the study in academic journals and conferences in collaboration with our Indian colleagues.
- **Indian team**. There are three primary groups that make up the Indian team. First, Indraprastha Institute of Information Technology, Delhi (IIIT-Delhi), which is the technology partners, lead by Dr. Pushpendra Singh (local Co-PI). Second, The Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, who serve as research and maternal/child health partners, under the leadership of Dr. Mona Duggal (local Co-PI), Dr. Rasmi Bagga and Ankita Kankaria. Third, Survival for Women and Children Foundation (SWACH), who serve as the implementing partner, under the leadership of Dr. Vijay Kumar. All members of the Indian team will participate in different aspects of data analysis and manuscript preparation, resulting in publications and dissemination.
    - **Indraprastha Institute of Information Technology, Delhi (IIIT-Delhi)** will be responsible for the development of the mobile platform that underlies the intervention, lead by Dr. Singh. Also, their students and faculty will receive training from the US team, and thus be involved in data collection, analysis, and manuscripts.
    - **The Postgraduate Institute of Medical Education and Research (PGIMER)** will be responsible overseeing study procedures conducted by SWACH, including ensuring adherence to ethical and research protocols. This team, lead by Ms. Kankari, and supervised by Dr. Duggal, will be responsible for ensuring data quality and leading training of research personnel. Dr. Bagga will be responsible for ensuring that the content of the intervention meeting Indian guidelines and providing clinical expertise.
    - **Survival for Women and Children Foundation (SWACH)** will be responsible for overseeing and leading the intervention implementation and data collection in the field, from enrolment, informed consent process, and the course of the intervention. Dr. Vijay Kumar will oversee the project, and data collection and intervention activities will be managed by one Research Associate, overseeing 6 field investigators. SWACH will also do data entry.

Study Timeline

As can be seen in the table below, Phase 1, which includes the intervention optimization and development period, and Aim 1 data collection, will occur in quarter 2 (Q2) of Year 1 (Y1), after Q1 is spent preparing for the study (IRB, instruments, training research team). In Y1Q3 we will finalize the details of the mhealth platform and prepare for Phase 2 (tool development, IRB modifications, training research team). From Y1Q4-Y2-Q2 we will recruit and collect data for Phase 2, which is a 6 month pilot intervention. Y2Q2-Q3 will be spent in in-depth data analysis for Aims 2 and 3. The final part of the grant (Y2Q3 and Q4) will be spent in dissemination (local and international) including meetings, presentations, academic manuscripts, and conferences. We will also apply for a larger grant to test this at scale.

	Year 1				**Year 2**			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Phase 1/Aim 1: Study set-up including IRB and instrument development, hiring team and training	X							
Phase 1/Aim 1: Intervention Development Phase data collection and cleaning		X						
Phase 1/Aim 1: Data analysis		X						
Phase 2: finalization of mHealth platform development, adaptation of study protocol and instruments		X	X					
Phase 2: Research and implementation team training and IRB modification			X	X				
Phase 2: Recruitment and study implementation (rolling)				X	X	X		
Phase 2: Data collection and data cleaning				X	X	X		
Phase 2/Aim 2 and 3: Data analysis						X	X	
Dissemination activities, apply for scale up funds							X	X

15. Inclusion of Women and Minorities

All research participants for the proposed research will include women over the age of 18 who have recently delivered an infant (postpartum women). Research participants are limited to women due to the postnatal health focus of this research. Women will be recruited in the end of pregnancy, but the intervention will begin postpartum.

It is possible that some ethnic or religious minority groups will be part of the study population. According to the 2011 Census of India, the vast majority of the population in Haryana state is Hindu (87.5%), followed by Muslims (7.0%), and Sikhs (4.9%) as the largest minority groups. We will not include or preclude respondents based on their ethnic or religious status. All research activities will be conducted in the Hindi language, which is the prevalent language of this region.

16. Inclusion of Children

Individuals over the age of 18 will be eligible for study participation. The study sample will include women who recently gave birth (recruited at the end of pregnancy). We will collect data on birth weight, health seeking behaviors, and infant health outcomes. No infant will be over 6 months of age by the end of the study. If infant health problems are detected, infants will be referred to the local hospital for evaluation and treatment. We are working closely with health providers, both the community health workers and higher-level providers, and there are medical professionals (an OBGYN and a nurse midwife) on our research team. When an infant is identified as having any serious illness, he/she will be referred to the appropriate health facilities.

Worldwide, an estimated 3 million newborns die within the first month of life. Over 40% of the under-5 child mortality occurs during the neonatal period. The infant mortality rate in our study population is 22/1,000 live births. This study will follow infants during the neonatal period and may identify intervention approaches that would reduce rates of neonatal morbidity and mortality among a vulnerable group of infants.

RECRUITMENT AND RETENTION PLAN

Recruitment. Study participants will be recruited by a team consisting of an Accredited Social Health Activists (ASHA) and a research assistant, overseen by the SWACH project and principal investigators. ASHAs are familiar with the women in this study population, as they already provide information and support about health to them in the community. Primiparous women will be recruited in their last month of pregnancy during the ASHA's regular home visit. At the time of enrollment, the study protocol will be described to the women following informed consent procedures and written informed consent will be obtained from interested women. Consent will also be obtained from family members given the cultural practices in the study population. Names and contact information will be collected and stored in a password protected and encrypted computer in a locked facility.

For Aims 2 and 3 (Piloting the intervention), We will recruit for the three intervention and the one control arms using a staggered approach, recruiting one group for each arm in month one of the intervention period and one group for each arm in month two of the intervention period, to result in a total of eight groups (two per condition), for a total of 160 participants. Such a staggered approach is preferred to ensure that women are enrolled into groups with other women whose infants are similarly aged, and is feasible given the population size of our study districts.

Retention plan (i.e. Attrition reduction plan). We will carefully monitor attrition in this study.
Retention is facilitated by engagement of the ASHA, who has familiarity and experience working with the community, and previous knowledge of the participants. Contact information, including names, addresses, and phone numbers, will be collected at baseline to facilitate tracking. One of the aims of this study is to measure participation and engagement in the intervention, thus, we will be measuring retention as one of our outcomes.

PROTECTION OF HUMAN SUBJECTS

Risks to Human Subjects

Human Subjects Involvement and Characteristics of Potential Subjects

The proposed two phased project will enroll a total of (160+48) women to develop the optimal design and then understand the acceptability, feasibility, and preliminary effectiveness of the *MeSSSSage* intervention on maternal and infant health outcomes in India.

Inclusion criteria are:
Phase 1: 18+ years old, primiparous (pregnant with their first birth)
Phase 2: 18+ years old, primiparous (pregnant with their first birth)

Prospective participants will be screened for eligibility by the local community health worker (ASHA) and a member of the research staff. Research assistants will read through the consent form with prospective participants and will assess that they understand what the study involves, including risks and benefits, and that the participant is sufficiently oriented to make an informed decision regarding study participation. Study participants will be asked for multiple forms of contact information.

All recruitment and consent procedures are detailed more fully below. All research procedures described in this application will be overseen by UCSF's and the Postgraduate Institute of Medical Education and Research (PGIMER) Human Subjects Protection Committees/IRB.

Potential Risks to Participants (Phase 2)

The overall risk to participate in this study is minimal.

Psychological Distress. The group will focus on issues important to maternal and child health care during the postpartum period, so it is unanticipated but possible that participants may experience psychological distress if discussing issues around maternal and infant health, postpartum mental health or social support.

Confidentiality: There is the potential for violation of participant confidentiality, but we believe the safeguards that we have integrated into the study methodology, as described below, will effectively limit this risk.

Adequacy of Protection Against Risks

Participants will be recruited by the local community health worker (ASHA) and a member of the research assistant, who will be trained and supervised by study staff. Recruitment will occur in the last month of pregnancy in the woman's home. Study staff will answer any questions potential participants may have. During the consent process for study participation, study staff members will describe the details of the nature of the participant's involvement in the study, the possible risks and benefits of participation, and the ability to withdraw from the study at any time without consequence. The participant will have the opportunity to ask questions about the study, after which written consent will be obtained.

Informed Consent. To obtain individuals' consent to participate, the study staff will provide participants with a detailed verbal description of the study. After discussion the study procedures, potential risks, and potential benefits, being informed of its voluntary nature, and having their questions answered, participants will give written informed consent. Written consent will be an obtained as well as verbal consent from necessary family members (given the nature of household dynamics in this setting). A copy of the study description will be offered to the participant. Participants will be informed that the data are used exclusively for research purposes and that identifying data will not be released by the investigators to any other individuals or organization. They will also be informed of procedures for ensuring their confidentiality, including: the use of codes/ID numbers rather than participants' names and the placement

of all data in locked files. Participants will be informed that despite confidentiality protections, confidentiality is not absolute. For instance, if researchers learn about a threat of serious harm to the participant or someone else, they would take steps to protect the person or persons endangered even if it required telling the authorities without the participant's permission, but they would only disclose the information necessary to prevent harm to the person or persons believed to be endangered.

Protections Against Risk

Psychological Distress. Participants will be referred to a mental health professional for counseling services if warranted and/or desired by the participant. Participants also have the right to refuse to answer specific questions and to stop the interview or survey at any time.

Confidentiality. To protect confidentiality, the following steps will be taken:

Participants' data will be saved according to a code and will be locked. Thus, no assessment will contain identifying information. All study staff will be thoroughly trained in confidentiality protection procedures in advance of fieldwork. Databases will not contain identifying information.

Potential Benefits to Study Participants

Women will receive a small airtime incentive for participation and those that do not have a phone will be provided a phone. Women will also receive 50 Indian Rupees per meeting, and ASHA's will receive 150 Indian Rupees for each meeting that they lead. Women will also receive information and support through the intervention in the postpartum period.

Importance of the Knowledge to be Gained

This model has the potential to improve women's knowledge, health and care seeking behavior in the postpartum period, resulting in potential improvements in breastfeeding, infant health, immunization, postpartum depression, and family planning uptake, among other outcomes. If proven successful and acceptable, *MeSSSSage* could be scaled up easily through the ASHA community health worker network, which is in every state of India, or through health care facilities or other already established mechanisms. Such a successful model could easily be adapted for other South Asian countries, leading to larger and longer-term impact on health care provision and health outcomes.

Data and Safety Monitoring Plan

We have several mechanisms in place to ensure data confidentiality and integrity. All study staff will be trained to promote standardized and objective collection of participant information. Follow-up assessments will be reviewed by the project director for consistency and completeness. All data will be stored in a password- protected database that is backed up through a secure offsite connection. All electronic files are stored in password-protected files. Files are identified only by a participant's ID number. Confidentiality policies and procedures are reviewed with all new staff and reviewed annually with current staff.

STATISTICAL DESIGN AND POWER

The proposed research includes two separate research phases to achieve our research aims: 1) To develop optimal intervention functions and mHealth technology delivery platforms for education and peer support among postnatal women in rural India; and to pilot test the optimized intervention and assess 2) feasibility and acceptability, and 3) preliminary effectiveness on maternal and infant health outcomes. Due to the exploratory nature of these aims, the sample sizes for our two study phases have been designed for feasibility, not for adequate power for statistical testing. After completing the study activities proposed herein, we plan to robustly test the effectiveness of our mobile educational and social support intervention through a larger multi-site R01 study.

Phase 1 (Aim 1). As described within our research strategy, the developmental phase 1 will employ a prototype platform will assess women's preferences for intervention functions, processes and platforms in order to design the most appropriate intervention for full piloting. Data collection during this phase includes capture of back-end data for participation and content, and survey (all participants) and in-depth interview (subset of participants) to understand preferences.

- Backend data: intervention participation, intervention engagement, content of group discussions, content of text messaging.
- Survey: Preferences regarding group components, functions and modalities.
- In-depth interview: Preferences regarding group components, functions and modalities.

Quantitative data will be analyzed for means and proportions using STATA version 15. Text data from discussion/messaging and in-depth interviews will be analyzed for content and themes using Atlas.ti software.

Phase 2 (Aims 2 & 3). Our pilot test of the optimized intervention functions, processes and platforms will use a four-arm controlled factorial between-groups design:

MeSSSSage components to be tested in Phase 2.	Arm 1	Arm 2	Arm 3	Control
Real-time live voice call group meeting: Interactive educational program with scripted didactic component plus discussion/question. Lead and moderated by health professional. **(voice)**	X		X	
Text-based, asynchronous, on-demand social support: App-based small group text-based communication. Moderated by health professional. **(text)**		X	X	
Standard of care: 3 visits in the first 7 days postnatal (facility and home)	X	X	X	X

The following intervention characteristics will be assessed:

Feasibility. To evaluate feasibility of the intervention, we will monitor enrollment rates and moderator effort required (e.g. number of staff hours). An enrollment rate of 70% or higher will be considered feasible, as the established standard in intervention literature. Through moderator report we will confirm effort required for preparation, session delivery, and follow-up. We will also capture any technological challenges. This information will inform staffing needs and retention protocols for a subsequent full trial.

Acceptability. To measure acceptability, we will use a client satisfaction questionnaire which will capture self-reported engagement in intervention components and topics, satisfaction with intervention components, likelihood of participating again, likelihood of recommending program, and value on knowledge and social support gained from participation.

Preliminary effectiveness. To measure effectiveness, we will health-related knowledge (maternal and neonatal danger signs, best practices for infant care, and family planning), health-related behaviors (breastfeeding and complementary food introduction practices (breastfeeding initiation, length of exclusive breastfeeding, length of breastfeeding, timing of complementary food introduction), appropriate management of early childhood

illnesses), and health outcomes (Early childhood immunization, postnatal depression and anxiety, postnatal contraceptive adoption.)

Quantitative analyses: With a between-groups design, each participant will participate in only one arm of the trial, thus we will assess quantitative intervention outcomes by factor (voice and text) through fitting a series of the following linear regression model:

$$y_i = \beta_0 + \beta_1 Z_{1i} + \beta_2 Z_{2i} + \beta_3 Z_{1i} Z_{2i} + \varepsilon_i$$

Where y_i is the outcome for the ith participant, β_0 is the coefficient for the intercept (standard of care), β_1 represents the mean difference in factor 1 (voice), β_2 represents the mean difference in factor 2, (text) β_3 represents the interaction between factor 1 and factor 2 (voice + text), Z_{1i} is the indicator variable for factor 1, Z_{2i} is the indicator variable for factor 2, and ε_i is the residual for the ith participant. Due to the modest sample size, significance testing will be deemphasized and we have not included power analyses for this study.

Hypotheses for preliminary/exploratory analyses on effectiveness. Exploratory hypotheses will be evaluated as part of the study feasibility assessment process. Means and proportions will be plotted by group over time to enable descriptive evaluation of overall patterns of change across time in the outcomes for the intervention and control groups. For example, we expect that following intervention exposure, relative to control group participants, intervention participants will have improved health-related knowledge, health-related behavior, and health outcomes. We also anticipate that intervention participants receiving both voice and text components will have the highest report of the prior outcomes and reported social support, and we will explore differences in these outcomes and in levels of reported social support between the groups as described above.

DATA AND SAFETY MONITORING

The proposed pilot educational and social support RCT carries a minimal level of risk as compared with clinical trials testing medications and/or procedures (see Human Subjects section). The plan described within this document will be implemented to monitor the trial and to address data safety and monitoring. All elements of the data and safety monitoring plan will be reviewed by the UCSF and in country IRBs and provided to the NIH institute overseeing this project.

Introduction. This two-year project seeks to develop and pilot test a provider-moderated mobile interactive education and social support group intervention to improve the health and well-being of Indian women and their infants in the postnatal period using a using systematic, user-centered and experience-driven design approach. The study uses a mixed methods approach for intervention component optimization and assessment of feasibility, acceptability, and preliminary effectiveness. The assessment and intervention sessions pose no more than minimal risk to participants. The Data and Safety Monitoring Plan includes identifying and convening a Data Safety and Monitoring Board (DSMB) to monitor data and safety related risks to human subjects. Serious adverse events will be reported promptly to the chair of the DSMB, the UCSF IRB, the in country IRB, and NIH project officer. Risks, monitoring procedures, reporting, and action plans are described below for data and safety-related risks.

Data and Safety Monitoring Board (DSMB). With consultation from NIH we will identify a minimum of three DSMB members. These will include individuals with expertise in behavioral RCTs, mHealth, and research with postpartum women. The DSMB will meet via teleconference. The initial DSMB meeting will occur prior to the start of the trial to discuss the protocol, the DSBM charter, quorum definitions, and study monitoring guidelines. Subsequent meetings will be held every six months to monitor study progress throughout the course of the study.

Data risks and monitoring

Data-related risks. Potential data-related risks to participants include circumstances where insufficient data was collected for answering the research questions or high/systematic attrition in the trial or intervention participation affecting receipt of adequate intervention dose.

Data monitoring procedures. Overall recruitment goals will be monitored monthly, as well as missing data and follow-up failures. Ongoing monitoring of study progress will be coordinated by Dr. Alison El Ayadi, ScD, Co-PI, with support of Dr. Nadia Diamond-Smith, PhD, Co-PI.

Data-related risk reporting and action plan. Research assistants will be responsible for compiling numbers of participants recruited, completing required assessments, maintaining databases, and identifying missing data and missing follow-up assessments. Research assistants will prepare recruitment and missing data reports for weekly review by the Co-PIs and Co-Is. All data will be de-identified and stored on a firewall-protected server. Upon recognition of unacceptable recruitment or follow-up rates, or of missing data, the Co-PIs will intervene with strategies to remedy the shortcomings. Investigators will discuss with the DSMB stopping the study due to early recognition of research questions when and if necessary, and will report such action to the IRB and the project officer. Intervention completion rates will be monitored similarly.

Safety risks and monitoring

Safety-related risks. Safety-related risks may include: 1) sensitivity related to questioning about postpartum physical and psychological health, and infant and self-care practices, 2) release of confidential information about the participant, and 3) recognition of the need for treatment for physical or psychological health concerns.

Safety monitoring procedures. All safety-related risks will be routinely monitored at assessment or intervention session. The security of confidential information will be monitored regularly. Research assistants and intervention moderators will be trained in asking questions about sensitive topics in a caring and non-threatening manner and will stop questioning at the first sign of discomfort or on request. Privacy and confidentiality will be emphasized in intervention sessions with facilitators requesting that participants agree to respect the privacy and confidentiality of other group member, and not to disclose information shared with the group in confidence to anyone outside of the group. Participants will be informed that confidentiality will be maintained for survey and in-depth interview responses. Research assistants will be trained to identify a

participant who reports any physical or psychological health concerns, and protocols will be developed to refer participants for treatment.

Safety-related risk reporting and action plan. Research assistants and intervention moderators will report any breaches of confidentiality risks to the Project Coordinator who will then inform the PIs. Any participant in need of treatment due to physical or psychological health concern will be referred for appropriate services per protocol, and the Project Coordinator and PIs will be informed. The PI will be responsible for informing the DSMB chair, IRB through IRB adverse reporting procedure, and the Project Officer through immediate email for life-threatening incidents and through annual report of other incidents per IRB policy. The PI will take appropriate action to stop the study, release a participant from the study, or modify procedures to reduce and/or eliminate the abovementioned risks if they occur at an unacceptable level.

Adverse events. Adverse events will be tracked and referral and follow-up will occur. An adverse event form will be developed to record each incident, actions taken, supervisor notes, and follow-up steps. The form, supplemented by any notes, will be sent immediately to appropriate agencies, including the DSMB chair, IRBs, and NIH, with any action recommended by DSMB or IRB conveyed to the NIH. The DSMB will be responsible for the monitoring and reporting of any adverse events.

The UCSF Committee on Human Research (CHR). All problems related to participant safety will be reported to the CHR by the PI within 10 working days. Specifically, we will report in writing: 1) all serious adverse events associated with study procedures, and 2) any incidents or problems involving the conduct of the study or patient participation, including problems with recruitment or consent processes. The PI will provide a discussion of any side effects or problems noticed in the course of the study to the CHR on an annual basis.

Training, Quality Assurance (QA) and Supervision. The investigators are experienced in staffing, training, and supervising clinical research studies, including behavioral and mHealth intervention trials. Our current QA proposal is based on this experience.

Data collector training. Research assistants will be selected based on their prior experience with data collection and familiarity with the study population. We will develop a training manual for the training and ongoing supervision of research staff. An initial training to be led by the PIs and Co-Is will cover: 1) general research interviewing skills; 2) specific training relevant to this study; 3) extensive training in research ethics and human subjects' protection certification; and 4) observed practice and certification as research assistants.

Assessment quality assurance. The PIs and PC will oversee the QA of data collection and provide feedback and supervision as appropriate.

Intervention training. A training workshop occurs for all intervention staff, and an intervention manual will guide the training and ongoing supervision. This training includes detailed overviews of the intervention approach and procedures, the content covered, and general topics related to intervention research and research ethics. Techniques for adhering to a manualized intervention while allowing for flexibility to address individual participant needs will be taught, role-played, and supplemented by instructional readings. Ongoing training will provide updates and troubleshooting on the content area and address any individual supervision or procedural issues in intervention implementation.

Quality assurance of intervention procedures. Intervention fidelity is crucial to maintaining internal validity in intervention trials. Given the nature of the intervention and the clinical issues that arise with this population, facilitators are clinically trained and have knowledge in clinical trials and behavioral science. QA procedures of intervention delivery across facilitators and over time during the course of the study include: 1) development of detailed manuals for each of the sessions; 2) intensive training; 3) incorporation of mock sessions that enable us to ensure that moderators meet performance criteria for intervention delivery, leading to certification of staff based on common performance standards; and 4) QA feedback are incorporated into routine supervision.

Supervision. Separate weekly supervision meetings will be held for data collection and intervention staff, covering progress of the study assessment and intervention protocol problems, providing a setting for staff support and development, and an atmosphere conducive to constructive discussions of dealing with problematic participants and situations. The investigators and project coordinator will schedule individual supervision meetings as appropriate.

DISSEMINATION PLAN

At the end of the study period, the findings of this pilot will be shared with the community members of the populations in which we are conducting the study, in the villages of Haryana. This will include a local village meeting where community leaders, health providers, and village members will be invited.

Findings will also be shared with the larger organizations of the investigators, including the implementing partner (SWACH), and faculty and students at PGIMER Chandigarh, IIIT-Delhi, UCSF and UCLA through seminars. We will also reach out to interested other stakeholders (NGOs, universities) to offer to share findings. Finally, findings will be shared with the international community through peer-reviewed publications and conferences.