M-SAKHI—Mobile health solutions to help community providers promote maternal and infant nutrition and health using a community-based cluster randomized controlled trial in rural India: A study protocol

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Abstract

Reduction of childhood stunting is difficult to achieve by interventions that focus only on improving nutrition during infancy. Comprehensive interventions that extend through the continuum of care from pregnancy to infancy are needed. Mobile phones are now successfully being used for behaviour change communication to improve health. We present the methodology of an mHealth intervention “Mobile Solutions Aiding Knowledge for Health Improvement” (M-SAKHI) to be delivered by rural community health workers or Accredited Social Health Activists (ASHAs) for rural women, below or up to 20 weeks of pregnancy through delivery until their infant is 12 months of age. This protocol paper describes the cluster randomized controlled trial to evaluate the effectiveness of M-SAKHI. The primary objective of the trial is to reduce the prevalence of stunting (height-for-age < -2 z-score) in children at 18 months of age by 8% in the intervention as compared with control. The secondary objectives include evaluating the impact on maternal dietary diversity, birth weight, infant and young child feeding practices, infant development, and child morbidity, along with a range of intermediate outcomes for maternal, neonatal, and infant health. A total of 297 ASHAs, five trained counsellors, and 2,501 participants from 244 villages are participating in this study. The outcome data are being collected by 51 field research officers. This study will provide evidence regarding the efficacy of M-SAKHI to reduce stunting in young children in rural India, and if effective, the cost-effectiveness of M-SAKHI.

KEYWORDS

behaviour change communications, infant and young child feeding, infant growth and development, mHealth, mobile phone communications, stunting

1 | INTRODUCTION

Globally, the prevalence of stunting and underweight in children under five has decreased by more than 25% between 1990 and 2016; however, experts predict that this progress will not be sufficient to meet the Sustainable Development Goals target two of having less than 100 million stunted under five children by 2025 (UNICEF WHO & World Bank., 2015). Two of five stunted children live in South Asia (World Health Organization., 2017), and a third of the world's stunted population (46.6 million) is attributed to India (Fanzo et al., 2018). Childhood undernutrition was the fifth contributor to the burden of disease amounting to 113.3 million disability-adjusted life years (GBD, 2015). Food security, ending of hunger, and improving nutrition are the second topmost target of the Sustainable Development Goals (Christian et al., 2013), because undernutrition is responsible for almost half the under five child deaths in low and middle-income countries (Fanzo et al., 2018). Improving nutrition is also an important strategy to end preventable deaths in children under five, which is the third topmost target of the sustainable development goals (Friedman & Gostin, 2016). In a study to assess performance in reaching sustainable development goal targets of 188 countries, India ranked 143rd and had only met 46% of its stunting and 51% of its wasting reduction targets (Global Burden of Disease Study). Improving birthweight and infant and young child feeding (IYCF) practices are critical in reducing child undernutrition, morbidity, and mortality in India, which has a third of the world's undernourished children (Fanzo et al., 2018).

Behaviour change communications (BCCs) have been used to improve maternal and child health practices including nutrition in multiple settings (Bhandari et al., 2005; Menon et al., 2015; Zaman, Ashraf, & Martines, 2008). However, results are variable as interventions differ in their characteristics, implementation methods, frequency, fidelity, and utilization (Pelto et al., 2004; Santos et al., 2001). Lack of standardization in how interventions are deployed may also result in varied effectiveness. The use of mobile phones may help to address some of these standardization, implementation, and utilization challenges of BCC interventions (Robert et al., 2006).

There has been an exponential rise in the use of mobile phones in India with an estimated subscriber base of 478 million by June 2018 affecting the way community health is being managed (Delhi, 2018). Mobile phones enable health care providers to monitor patient's health parameters real time, deliver certain clinical services, and provide a unique opportunity for BCC to improve health and nutrition behaviours (Arie, 2015).

A recently conducted systematic review reported nearly 8,500 health interventions being implemented using mobile phones (mHealth interventions) for maternal and child health in low- and middle-income countries (Lee et al., 2016). There are nearly 70 mHealth applications (apps) and interventions being implemented in India that enable training of community health workers, timely immunizations of mothers and infants, counselling for reproductive health, hygiene, sanitation, and guidance on optimal health practices during pregnancy and post delivery (Ministry of Health & Family Welfare, 2018).

Key messages

- The study will demonstrate whether a mobile phone-based behaviour change communication intervention is cost-effective when deployed in rural India by community health workers and public health systems to strengthen the pathways that improve maternal nutrition, infant development, and infant nutrition to ultimately reduce rates of child stunting. The findings from the proposed trial will have international significance and have the potential to provide new evidence about the impact, cost-effectiveness of a mobile phone intervention to improve the health and nutrition of infants and young children and thereby their growth and development.

Evidence suggests that mHealth platforms have the potential to improve the quality of pre pregnancy and post pregnancy care and are increasingly being utilized to collect pregnancy-related outcome data. Studies have reported that mHealth interventions, particularly those delivered through short message service, were associated with improved utilization of preventive maternal health care services, including uptake of recommended antenatal and post-natal care services (Feroz, Rizvi, Sayani, & Saleem, 2017). Short message service reminders have been predominantly utilized for client education and BCC (Datta & Mullainathan, 2014; Entsieh, Emmelin, & Pettersson, 2015).

A study evaluating the effect of mothers directly communicating with health care providers revealed enhanced access to emergency obstetric care (Lund et al., 2012). Other potential uses of mHealth platforms include data collection to ensure data timeliness and completeness (Meankaew et al., 2010), enable provider to provider communication, augment provider care support for clients (Ladak et al., 2013), and as an electronic health record system to ensure availability of health information (Haskew et al., 2015).

Another recently published pilot trial reported significant improvement in breastfeeding practices and pregnancy outcomes in those pregnant women who received text messages and cell phone counselling (Patel et al., 2018). This pilot trial informed the methods of the current study. There were three key limitations to the results of this pilot trial. First, the intervention tested in the pilot was mainly directed at breastfeeding and did not attempt to increase the diversity or frequency of complementary feeds, which are associated with child undernutrition. Second, the study was conducted in a disadvantaged urban population. Thus, the intervention needed to be examined in rural populations, which also have high mobile phone coverage. These populations are more susceptible to unsupervised home deliveries, and access to health care providers is limited. Third, it used only two functions of the mobile platform, namely, text messages and mobile phone to mobile phone counselling by the health care provider to the participant. Thus, a large-scale trial was needed to confirm the

findings of this pilot, to test effectiveness in a rural population and to establish the impact of a more comprehensive mobile phone intervention on stunting. It has been observed that most mHealth interventions for maternal and child health tend to use one or two functions of a mobile platform, such as the use of apps for data collection or use of text or voice messages or direct phone communication. However, there are few mobile phone interventions that integrate all elements of mobile phone communication in a single bundle of service that provides a comprehensive BCC package.

This protocol describes a BCC intervention package “Mobile Solutions Aiding Knowledge for Health Improvement” (M-SAKHI) that includes trained community health workers (Accredited Social Health Activist or ASHAs) collecting real-time client data in part to trigger client-specific messages. It describes how the intervention encourages behaviour change in participants regarding reproductive maternal health, maternal nutrition, child health, and appropriate IYCF using text and voice-based pushed messages, and direct phone to phone counselling.

1.1 | Study aims and hypotheses

This study aims to assess the effectiveness of a mobile phone intervention package, compared with the standard of care with rural women during prenatal, natal, and post-natal periods to reduce the prevalence of stunting and improve infant development in children at 18 months. Educational elements of this package describe how the intervention helps in creating awareness and encourages desirable behaviour change in participants regarding adequate nutrition in pregnancy, appropriate IYCF, early identification of maternal and child illness, and appropriate hygiene and sanitation practices.

1.1.1 | Primary hypothesis

In a community-based, cluster randomized controlled trial of women from a rural community in Maharashtra, India, a mobile phone intervention package that supports improved maternal dietary intake and iron-folic acid consumption in pregnancy, exclusive breastfeeding, appropriate timing and diversity of complementary feeding, improved hygiene and sanitation, prompt identification of illness and access to care, will reduce the prevalence of stunting (height-for-age < -2 z-score) in the children at 18 months of age by 8% (35% in control to 27% in intervention group) compared with villages with no mobile phone intervention package.

1.1.2 | Secondary hypotheses

The M-SAKHI intervention will improve maternal dietary diversity, the mean birth weight and reduce low birth weight, median duration of exclusive breastfeeding, the percentage of infants exclusively breastfed up to 5 to 6 months, the percentage of children consuming greater than four food groups at 9, 12, 15, and 18 months, infant development at 12 and 18 months of age and decrease the number of days children are ill with diarrhoea, acute respiratory illness, or

fever, in addition being cost-effective in reducing stunting at 18 months.

2 | METHODS

2.1 | Study design

We will evaluate the effectiveness of the intervention using a community-based cluster randomized controlled trial with two-arm parallel groups, superiority design, and 1:1 allocation ratio. This design will ensure that both the intervention and control villages use the existing standard of maternal and infant care services. The 20 intervention clusters will additionally be receiving the M-SAKHI package (Figure 1).

2.2 | Study setting

We will conduct the M-SAKHI trial in Bhandara and Nagpur districts in Maharashtra, India (Figure 2). Maharashtra state has the second highest population in India and is ranked at 12th for its levels of stunting (Indian Institute for Population Sciences, 2018b). Nagpur has a population of 4.6 million, 1,903 villages, and 49 primary health centres (PHC), whereas Bhandara has a population of 1.2 million, 881 villages, and 33 PHCs (Maharashtra Government Public Health Department. Primary health care and facilities in Maharashtra). Both districts are predominantly semirural populations with 33.9% and 40.5%, respectively, of their under five children stunted (z-score below -2 z-score of height-for-age) (Indian Institute for Population Sciences, 2018a; Indian Institute for Population Sciences, 2018).

2.3 | Ethical consideration

The trial was approved by three Institutional Review Boards (local IRB: Lata Medical Research Foundation and Sir Gangadharrao Chitnavis Trust and by the Indian National IRB: Indian Council of Medical Research, and University of Sydney Human Research Ethics Committee (Ref: 2015/990). A written signed informed consent will be obtained from each woman in the presence of a witness. A copy of the consent will also be handed over to the participating woman for her reference.

Trial Registration Number: CTRI/2018/02/011915.

2.4 | Clusters and eligibility criteria

Maharashtra state has many districts, which are territorial and administrative divisions, containing one large city, many smaller towns, and villages. The districts have many primary health care centres that provide public health services to approximately 30 villages in the vicinity. Each primary health care centre covers an average population of 26,000 with approximately 30 villages. We will define clusters of villages (range three to eight) that provide a population of approximately 8,000 persons per cluster, from rural areas of two districts. Each

FIGURE 1 M-SAKHI study design

cluster will only have villages that are covered by one PHC to avoid contamination that might occur by knowledge sharing among ASHAs, who meet monthly at their PHCs during their scheduled meetings. We will define clusters as consisting of three to eight selected villages (about 8,000 persons per cluster) from rural areas in Nagpur and Bhandara districts. Clusters will be eligible if they have greater than 70% of their land area with mobile network coverage, no other

ongoing child nutrition interventions, are at least >4 km apart, and are in the coverage area of separate primary health centres. Using these criteria, there are 165 eligible villages in Nagpur and 79 in Bhandara for grouping into clusters.

2.5 | Formative research and pilot studies

A pilot trial was conducted in four urban maternity hospitals in Nagpur to understand the effectiveness of using mobile phones for personalized lactation counselling and health messaging to promote appropriate IYCF practices. The results demonstrated a positive impact of this intervention on breastfeeding practices and high rates of satisfaction of the women receiving the intervention (Patel et al., 2018). Subsequently, a formative study was conducted in rural areas similar to the M-SAKHI trial settings, to understand the use of mobile phones by ASHA workers, ownership and use of mobile phones by pregnant women and their families, the perceptions of pregnant, lactating, and postlactating women about acceptance and utility of text messages regarding health, current dietary, and hygiene practices, and its impact on their health-seeking behaviour. This study was a part of a larger South Asian Infant Feeding Research Network study in Sri Lanka, India, Bangladesh, and Pakistan (Weerasinghe et al., 2016). Another pilot study was conducted in collaboration with Dimagi (developer of CommCare software for mobile apps), to assess the feasibility of using an ASHA and field supervisor applications to collect and monitor data and improve health awareness of ASHA clients during antenatal, natal, and post-natal care in rural Maharashtra. This pilot helped the research team understand the level of health awareness of ASHA workers, refined the CommCare ASHA and field supervisor applications as tools to collect data to trigger specific messages for the clients in this study and to understand the training needs of the ASHA workers (Dimagi). Finally, we conducted in-depth interviews and focus group discussions of pregnant and lactating women living in the M-SAKHI study areas to assess the clarity of the text messages and videos to be used in M-SAKHI. We have also pilot-tested the ASHA app.

2.6 | Description of study arms

The existing standard of care and the routine Maharashtra state health services will be left undisturbed for the participants in both control and intervention clusters. The pregnant women enrolled in the M-SAKHI trial intervention clusters will additionally receive the services described below. The intervention will begin when a mother is enrolled in the trial and it will continue through delivery until her child is 12 months old. In most cases, we will use mobile phones that are already owned by a family member or the participating woman. However, we will supply a mobile phone with a subsidized calling plan and training in its use for the women, enrolled in the intervention clusters, that do not own a handset (expected to be about 30%).

FIGURE 2 Map of Nagpur and Bhandara districts

2.7 | Usual care—Standard maternal and child health care practice

The usual maternal and child health care services are the standard health care services provided by government health care centres. Women are registered at the government primary health centres when they report their pregnancy. Each village has an ASHA worker who has a list of all pregnant women. The Janani Suraksha Yojana from the National Rural Health Mission is a safe motherhood intervention to promote institutional delivery among the poor pregnant women. In this programme, the ASHA worker is the link between the community and the health system and facilitates the utilization of outpatient services, diagnostic facilities, and institutional deliveries and inpatient care in her village (Ministry of Health & Family Welfare—Government of India, 2013.)

2.8 | M-SAKHI—The intervention components

The word “SAKHI” in Hindi and Marathi languages means a female friend. The M-SAKHI intervention has been designed to enable ASHA workers to reduce child undernutrition by improving IYCF practices in a rural community. The BCC intervention is based on the “Transtheoretical model,” which proposes a change in behaviour as a process of six stages (Prochaska & Velicer, 1997). The intervention provides information at the precontemplation and contemplation stages where the risks of current behaviour and benefits of changing behaviour are informed to the participant. At the preparation and

action phases, the intervention will focus more on opportunities for changing health behaviours, their implementation, and sustenance. The components of the intervention are listed in Table 1, but more details are provided below:

1. “ASHA” app for real-time data collection and face to face counselling with clients: We will develop an android system CommCare app for use by ASHA workers to standardize the collection of routine health care data, to use the participants responses to trigger tailored text messages and counselling support, and to enhance the ASHA's communications about appropriate health and nutrition care in pregnancy and early childhood (Figure 3).

The ASHAs will interview the mothers once every month at a prearranged time with the aid of an audio file in the app that presents the question in the local language. This will ensure the questions are asked in the same standard way by all ASHAs, who will then enter the responses to the question options in the app. Each question in the app will be also denoted with a regionally appropriate picture (for example, a question that inquires about the age of the participant will have a picture of a young Asian woman in a sari). The app will be programmed to autocalculate numeric fields to avoid manual entry errors, for example: calculating participant's age from her birth date, the expected date of delivery, gestational age, and the next visit date from the previous visit date. To minimize errors, logical skip patterns and range checks will also be embedded. With the app, the ASHA workers will be able to collect data offline and synchronize it with the CommCare server when the mobile network is available.

TABLE 1 M-SAKHI Intervention components

Component	Provider	Recipient	Medium of the intervention provision	Schedule and frequency
Data collection in real-time and face-to-face counselling	ASHA	Participant	Using CommCare ASHA app with embedded counselling messages and health videos	Monthly home visits starting from enrolment until 12 months of infant age
Delivery of pushed text messages	Server delivered and programmed	Participant	Automated and programmed through data entered in ASHA app	Thrice a week, starting from enrolment until 12 months of infant age
Delivery of pushed voice messages	Server delivered and programmed	Participant	Automated and programmed through data entered in ASHA app	Once a week, starting from enrolment until 12 months of infant age
Delivery of alert (text) messages	Server delivered and programmed	Participant, ASHA, and study ANM counsellor	Automated and programmed through ASHA app	Conditional, based on any danger signs recorded in ASHA app, starting from enrolment until 12 months of infant age
Mobile phone to mobile phone counselling	Study ANM counsellor	Participant and her family	Using CommCare ANM app with autogenerated dates for scheduled calls and recording call details	Every fortnightly, starting from enrolment until 12 months of infant age
Field supervisory app	Field supervisor	ASHAs	Using CommCare field supervisor app for real-time monitoring of ASHAs	During monthly meeting of project managers, starting from enrolment of participant until 12 months of implementation

Abbreviations: ANM, auxiliary nurse midwife; ASHAs, accredited social health activists.

In addition, the app will be embedded with health-promoting audio and video counselling messages (developed using recommendations from WHO, UNICEF, and the Indian government) for maternal and infant nutrition, appropriate health and hygiene practices. These messages will be tailored to the participants' responses to routine health care questions. If a response suggests that the participant is not performing an expected health practice (e.g., not attending antenatal care or introducing bottle feeds), the app will trigger alert text messages to both the client and her designated study Auxiliary Nurse Midwife (ANM) who has been trained as a phone counsellor. The project staff will monitor in real time, the data collected by the ASHAs on the CommCare server.

2. Delivery of pushed text and voice messages to participants: We will develop one-way, pushed text, and voice messages in the regional language, Marathi, for each trimester of pregnancy, the delivery and post-natal periods till 12 months of infant age. The messages will contain information on preventive health services available to the participant during and after pregnancy including for her child, what complications to expect during pregnancy and delivery and what appropriate action could be taken; tips on diet for a healthy pregnancy, personal hygiene, appropriate IYCF, and how to identify and prevent childhood illness. The messages will be short enough to

ensure continued engagement of the women receiving them. The content will be developed by maternal and infant health specialists and public health experts after assessing similar materials from other programmes and the government. The acceptability and understanding by participants of the draft message will be assessed before implementing them in the mobile communication system. The text messages will be sent thrice a week at a preferred time chosen by the participant. Similarly, a voice message will be sent once a week summarizing the three previous text messages received by the participant that week.

3. Delivery of alert text messages: Alert text messages will be triggered when the participant deviates from recommended health practices during and after pregnancy as recorded on the CommCare ASHA app. Reported maternal or infant health complication will also trigger a notification to the ASHA via her app who will guide the participant to seek care at the nearest health centre. The trigger from the CommCare ASHA app will also generate alert messages to study ANM designated for phone counselling of this participant.
4. Mobile phone to mobile phone direct counselling of the participants: The study ANM counsellors will use a separate CommCare ANM app to manage and schedule fortnightly counselling calls to participants. The study ANMs fortnightly counselling call will include a structured life cycle specific health review, provide nutrition

FIGURE 3 Snapshot of the CommCare ASHA app

counselling, responses to alert notifications (including review of the participant's wellness and provision of clinical support), and responses to the participant's questions. The participants will be encouraged to contact the study ANM counsellors (by calling them and then hanging up) in case they need any additional assistance.

5. Field supervision app: We will develop a separate CommCare app that will help the field supervisors monitor and grade the field performance of the ASHAs. The assessment will include metrics from the ASHA's app (such as the number of participants visited by the ASHA and the number of completed visit forms). This app will also allow field supervisors to record direct observations of the ASHAs, evaluate her interaction with the participants, reports of client-related technical issues, and her utilization of and experience in

delivering the application content. This app will enable targeted monitoring and identification of ASHAs, those in need of retraining.

2.9 | Definition of trial outcomes

The *primary outcome* of the trial is to assess change in the percentage of stunted infants (length-for-age < -2 z-score) at 6, 12, and 18 months as measured in follow up assessments starting from birth.

The *secondary outcomes* include higher maternal dietary diversity and dietary intakes during pregnancy, reduced rate of low birth weight, a higher percentage of children with timely initiation of breastfeeding, exclusive breastfeeding at 5–6 months, and higher

TABLE 2 M-SAKHI Schedule of enrolments, interventions, and assessments

Timepoint	Data collector	Participants receiving interventions or being measured/ interviewed	Interventions/tools for data collection	Schedule and frequency																			
				Allocation	Enrolment	Pregnant woman	Postallocation												Closeout				
							Child (0–18 months)																
Component				T2	T3	0	1	2	3	4	5	6	7	8	9	10	11	12	15	18	18–20		
ALLOCATION																							
Allocation ^a				X																			
ENROLMENT																							
Consent and enrolment	ASHAs/FROs	All mothers	ASHA CommCare app and paper forms	X																			
INTERVENTION																							
M-SAKHI interventions ^b	ASHA/ANM	Mother + infant ^c	1. ASHA CommCare app for data collection by ASHAs 2. Delivery of text/voice message to participants 3. Delivery of alert messages to participants, the ASHA, and the study ANM counsellor 4. Mobile phone to phone counselling of the participant by study ANM counsellor 5. Field supervisory app to monitor ASHAs field performance	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
ASSESSMENTS																							
Anthropometry	AFRO	All infants	Using AFRO CommCare app to collect child anthropometry measurements. Instruments used: Tanita® digital infant weighing scale, Omron® adult weighing scale, ShorrBoard® length measuring board, Seca® head circumference measuring tape			X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Maternal dietary diversity and intake	FRO	All mothers		X	X																		
(Continues)																							

(Continues)

TABLE 2 (Continued)

Timepoint	Participants receiving interventions or being measured/ interviewed	Data collector	Interventions/tools for data collection	Schedule and frequency																			
				Allocation	Enrolment	Postallocation																	Closeout
				Pregnant woman			Child (0–18 months)																
Component				T2	T3	0	1	2	3	4	5	6	7	8	9	10	11	12	15	18	18–20		
Birthweight	All infants ^c	FRO	Data from health facility records (paper form)																				
				X																			
IYCF practices	All infants ^c	FRO	Using FRO mobile app to obtain data on feeding practices			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Infant dietary intake	Infants ^{c,d}	AFRO	Using AFRO CommCare app to collect 24-hr dietary recalls													X		X	X	X			
Child morbidity	All infants ^c	FRO	Using FRO mobile app to recall child morbidity 2 weeks prior to interview				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Child development	All infants	AFRO	Assessed using ages and stages questionnaire third edition—ASQ 3® (paper form)														X			X			
Cost-effectiveness	Mother + infant ^d	FRO	Using structured forms for cost data collection	X													X			X			

Abbreviations: AFRO—field research officers specially trained to collect anthropometry, child development, and dietary data; ANMs—auxiliary nurse midwife; ASHAs—accredited social health activists; FRO—field research officers; T2—trimester 2; T3—trimester 3.

^aCluster randomized controlled trial in which clusters were allocated to treatment groups before subjects were enrolled.

^bMore details in Table 1.

^cFor these components, the intervention will be administered to mother/primary carer for the infant's care OR data will be recorded for infant as reported by the mother/primary carer.

^dMeasurements denoted by number will be conducted on a subsample of the study participants.

child dietary diversity and dietary intake. We will assess the differences in mean birth weight and the median duration of exclusive breastfeeding between treatment groups. Other outcomes that will be assessed in the infants are, episodes of diarrhoea, acute respiratory illness or fever, and infant development at 12 and 18 months. Cost-effectiveness of the intervention will also be estimated. Other outcomes include ASHA knowledge and performance assessment.

2.10 | Measurements

Information about the measurements is summarized in Table 2, and a description of each measurement component is provided below.

2.10.1 | Anthropometry

Trained anthropometry field research officers (AFROs) will collect weight and height measurements using established methods (Lohman, Roche, & Martorell, 1988), and which will be standardized before and during data collection. We will collect anthropometry soon after birth and second monthly until 12 months and then at 15 and 18 months. The 2006 WHO growth standard (De Onis, 2009) will be used to construct anthropometric indices and standard indicators including stunting (length-for-age < -2 z-score), wasting (weight-for-length < -2 z-score), and underweight (weight-for-age < -2 z-score). Growth velocity will also be assessed. Birthweight will be captured from health facility records as we expect nearly all births to occur in a health facility which will not allow our field staff to interview our study participants while in the facility.

2.10.2 | Maternal dietary diversity

We will use the FAO/FANTA III recommendations (FAO and FHI 360, 2016) for measuring minimum dietary diversity in women in each treatment group in the trial. The questionnaire asks about the women's consumption of 10 defined food groups the previous day or night. We will create a dichotomous indicator which considers if the women have consumed at least five out of 10 defined food groups over the previous day, which we will use as a proxy indicator for higher diet quality and micronutrient intake.

2.10.3 | Maternal dietary intake

The dietary intake of all women recruited into the study will be measured during the third trimester of pregnancy using a 136 item semi-quantitative food frequency questionnaire (FFQ). The FFQ will be developed specifically for pregnant women, and we will assess its reliability and relative validity in ranking nutrient intakes in pregnant women. Briefly, food lists required to develop the FFQ will be generated using dietary recalls collected from pregnant women in the villages where M-SAKHI will be carried out. Nutritionists familiar with local food habits will check the food list for face validity and include any common foods missed. Trained field research officers (FROs) will administer the FFQ to the trial participants using a separate

CommCare mobile phone data collection tool (app). For the foods listed, they will record the usual frequency of consumption (per "day," "week," "month," or "year") over the previous three months and estimate portion sizes using common utensils.

2.10.4 | IYCF practices

FROs will capture infant feeding practices with a questionnaire administered monthly until 12 months, and then at 15 and 18 months. We will ask if the child is breastfed and if other liquids or solid/semi-solid foods were given in the 24 hr prior to the interview, and over the preceding month since the last contact, and if it was the first time any of these foods were introduced to the infant. We will capture this information with the FRO app, which will logical checks to trap errors including checking earlier responses about liquids and foods given to the infant.

2.10.5 | Infant and young child dietary intake

Dietary intakes of a subsample of infants participating in the study will be assessed using a multipass, 24-hr recall method (Gibson, 2005). Trained AFROs will use a mobile phone-based 24-hr recall tool to interview the mothers at their home to record food consumed by their infants during the previous 24 hr. The guided recall of consumption will include timing of meals (e.g., breakfast, lunch, dinner, or snack), food and drink (food/dish name), and the amount consumed. At the end of the recall, the interviewers will prompt the mothers for any food or drink that may have missed. The tool will be built with features to calculate the total reported energy intake in real time to help identify extreme under-reporting or over-reporting of intakes. For both the maternal FFQ and the infant 24-hr recalls, we will calculate nutrient and food intakes using the Indian Food Composition Tables (Longvah, Anantan, Bhaskarachary, & Venkaiah, 2017). The study nutritionists will monitor the dietary data collection and entry and will carry out checks to minimize reporting errors.

2.10.6 | Infant and young child morbidity

FROs will elicit a 2-week recall of common symptoms of childhood illness including diarrhoea, fever, cough, and respiratory symptoms using standard questions from the National Family Health Survey of India. The responses will be recorded in the FRO app. FROs will also record any hospital admissions and immunizations of the infant participants.

2.10.7 | Infant and young child development

Trained AFROs will assess child development using the Ages and Stages Questionnaire third edition (ASQ 3; Squires, Twombly, Bricker, & Potter, 2009). They will collect the ASQ scores in participants from both arms to assess the motor (fine and gross), language (receptive and expressive), and cognitive development of infants at 12 and 18 months of age using ASQ scoring paper forms.

2.11 | Health economic measurements

The standardized ingredient approach will be used to determine the costs in the intervention and control groups. This involves gathering information about the quantities and unit costs of physical inputs needed to develop and deliver the intervention and the quantities and unit costs of the health care resources utilized by the intervention and control groups over the study period. Trained FROs will collect these data in both arms from participants on standardized cost paper forms, during monthly home visits, starting from enrolment until the child is 18 months of age. Intervention costs will be abstracted from project records using standardized forms.

2.12 | Sample size and power

We calculated the sample size for the primary outcome using the following assumptions and calculations. Each cluster will consist of three to eight villages with an average population of 8,000 per cluster. We expect ~130 births over a 12 month period per cluster for the current expected annual crude birth rate of 16.4/1,000 total population. If we enrol 130 pregnant women, prior experience indicates that 10% of pregnancies will be lost prior to birth, also approximately 25% of pregnant women will deliver outside their village and about 5% of women will be unwilling to participate. Approximately 84 mother–infant dyads are expected to be available per cluster over 12 months which exceeds the required 62 per cluster (see sample size calculation below). Assuming 90% power and a 5% two-sided significance level, an intraclass correlation coefficient of 0.01 (based on analyses of child anthropometry from the National Family Health Survey of India 2005–2006 survey data for rural child populations (Indian Institute for Population Sciences, 2007)), an expected difference in stunting prevalence between treatment groups of 8% (35% in control to 27% in intervention group or 28.5% relative reduction), we estimate the required sample size using standard formulae (Cook & Wheeler, 2005) is 2,480 mother–infant pairs (1,240 each in intervention and control group). To achieve this sample size on 2,480 participants in 1 year, 40 clusters of ~5–8,000 persons each (three to eight villages each) will be selected from the two districts.

2.13 | Recruitment and consent of participants

We will seek “gatekeeper” consent for the trial from the village authorities and ASHA supervisors. In each cluster, ASHAs will enrol women by taking written informed consent from pregnant women who are below or up to 20 weeks of gestation, agree to be followed up until their child is 18 months of age. ASHA workers will detect pregnancy at monthly visits from the women's report of a delay in the last menstrual period beyond 5 weeks. In order to enrol women as early as possible, eligible couples will be provided home pregnancy test kits, so that the woman can report to the ASHA as soon as she misses her periods.

2.14 | Randomization and assignment of treatments

Before we start recruitment, we will assign the treatments to eligible clusters using a fixed randomization scheme with a uniform allocation ratio of treatments. We will select clusters with similar baseline characteristics which we will assess using a propensity score index. Randomization will be stratified by district, and then, we will randomly allocate treatments using block randomization (size = 2, 4, 6) to ensure balance between treatment groups (intervention and control) within each district. The random allocation sequence will be generated using Stata® software. The nature of the intervention precludes the masking of the treatments. This design will control for potential confounding factors (observed and unobserved) as an adequate number of clusters (40) will be randomly allocated to the intervention and control groups. Contamination of intervention will be constrained by the administrative and geographic separation of the clusters and by the nature of the intervention that involves use of special purpose mobile phone apps, which are not available to the public nor can be shared by participants from different clusters.

2.15 | Data collection

Information on all explanatory and outcome variables (Tables 2 and 3) will be recorded by separate interviewers or FROs in both control and intervention clusters using an android tablet app (FRO app) with structured and pretested questionnaires. Similarly, anthropometry and dietary intake measurements will be taken by AFROs and recorded in a separate CommCare app. The digitally collected data will be transmitted directly to a server for cleaning and analysis.

The data collection time points for FROs will be at enrolment, once at each trimester during the antenatal period, at delivery, every month after delivery until the child is 12 months of age and then at 15 and 18 months. At enrolment, we will obtain basic sociodemographic information about the participants' family and maternal characteristics. During the antenatal period, we will collect information on maternal dietary intake and morbidity. Delivery and newborn data will be recorded about a week after delivery.

The data collection time points for AFROs will be every 2 months starting at birth until the child is 12 months, later at 15 and 18 months. Infant dietary intake will be taken at 10, 12, 15, and 18 months. Infant development will also be assessed at 12 and 18 months.

2.16 | Process evaluation

We developed a program impact pathway for the M-SAKHI trial. We will conduct the process evaluation to examine the fidelity, dose, reach, and intensity of the intervention and explore the response of the participants to the interventions. The process evaluation will include the following elements: mobile phone owned and possessed by participants to receive the text messages, the frequency of mobile phone counselling, participants' acceptability and satisfaction with the counselling, their acceptability and satisfaction with the text messages,

TABLE 3 M-SAKHI outcome indicators

Outcome	Description of indicators	Data collection methods and sources
A. Improvement in maternal health outcomes		
Antenatal and post-natal visits	Number of antenatal and post-natal visits at health facility	Separate FROs will collect data from participants on android tablets, using standardized questionnaires, starting at enrolment, once at second and third trimester, at delivery, monthly until post-natal 12 months and then at 15 and 18 months of child's age.
Iron and folic acid (IFA) consumption	Total number of IFA tablets consumed during pregnancy	
Place of delivery	Number of facility and home deliveries	
Mode of delivery	Number of vaginal/c-section deliveries	
Maternal immunizations	Number of tetanus immunization completed during pregnancy	
Maternal hospitalisations	Number of times mother hospitalized during antenatal and post-natal period	
Maternal mortality rate (MMR)	Number of maternal deaths	
Maternal nutrient intakes	Ranking of women's intake of macronutrient and selected micronutrients assessed by food frequency questionnaire	Trained FROs will collect data from participants on android tablets, using standard methods of food frequency (FFQ) and dietary habits questionnaire (DHQ) during second or third trimester in pregnancy.
Maternal dietary diversity	Consumption of greater than or equal to four food groups as assessed by 24 hr recall	
Hygiene and sanitation practices	Number of times open defecation Number of times hand washing before meals and after defecation Number of times disposal of stools of infants appropriately	Trained FROs will collect data from participants on android tablets, starting at enrolment, once at second and third trimester, at delivery, monthly until post-natal 12 months and then at 15 and 18 months of child's age.
B. Improvement in Foetal/neonatal/infant outcomes		
Foetal loss	Number of miscarriages and abortion Number of stillbirths	Trained FROs will collect data from participants on android tablets, starting from enrolment, once at second and third trimester and at delivery.
Preterm deliveries	Number of preterm (based on LMP and EDD < 37 weeks)	
Low birth weight (LBW)	Number of low birth weight (<2.5 kg) infants	Trained FROs will collect data from participants on android tablets, starting from delivery, monthly until 12 months and then at 15 and 18 months of child's age.
Neonatal complications	Episodes of birth asphyxia, sepsis, jaundice, pneumonia, diarrhoea, and other conditions requiring hospitalizations	
Infant immunizations	Number of immunizations completed, as per the immunisation schedule till 12 months of age	
Infant morbidity	Number of days ill with diarrhoea, fever, or cough	
Infant hospitalizations	Number of times neonate/infant hospitalized for any complications	
Rates of neonatal/infant mortality (NMR/IMR)	Number of neonatal and infant deaths	
Exclusive breastfeeding	Proportion of infants 0–5 months of age who are fed exclusively with breast milk	Trained FROs will collect data on android tablets, starting from delivery, monthly until 12 months and then at 15 and 18 months of child's age based on WHO 24 hr recall method.
Early initiation of breastfeeding	Proportion of children born in the last 24 months who were put to the breast within 1 hr of birth	
Timely introduction of solid, semi-solid, or soft foods	Proportion of infants 6–8 months receiving solid, semi-solid, or soft foods	
Minimum dietary diversity	Proportion of children 6–23 months who receive foods from four or more food groups	
Minimum meal frequency	Proportion of breastfed and nonbreastfed children 6–23 months, who receive solid, semi-solid, or soft foods (but also milk feeds for nonbreastfed children) the minimum number of times or more	

(Continues)

TABLE 3 (Continued)

Outcome	Description of indicators	Data collection methods and sources
Stunting or low length-for-age and wasting or low weight for length	The proportion of children at 2.4, 6, 8, 10, 12, 15, and 18 months with low length-for-age or weight-for-height z-score (<-2 z-score calculated from the 2006 WHO growth standard)	Trained AFROs will collect data on android tablets using CommCare app. For anthropometry every second month from birth until 12 months and then at 15 and 18 months. For infant diet at 10, 12, 15, and 18 months.
Nutrient adequacy of infant diet	Quantified macronutrient and micronutrient intakes from dietary recalls and comparisons to national/WHO recommended nutrient intakes	
Infant development assessed by Ages and Stages Questionnaire third edition (ASQ 3)	ASQ scores to assess the motor (fine and gross), language (receptive and expressive), and cognitive development of infant	Trained AFROs will collect data using ASQ-3, scoring paper forms, once at 12 and 18 months.
C. Other outcomes		
Knowledge and performance assessment of ASHA	Number of ASHAs with adequate grades in pretraining and posttraining knowledge tests Proportion of ASHAs receiving with good participant visit targets (those receiving green icons in FS app)	These scores will be obtained by ASHAs in pre- test and post- test and their performance as assessed by project managers. ^a
Cost-effectiveness	Cost of developing and implementing M-SAKHI intervention Incremental cost-effectiveness ratio of the M-SAKHI intervention compared with usual care Cost per child of underweight saved by the intervention	Trained FROs will collect data in both arms from participants on standardized cost paper forms, during monthly home visits, starting from enrolment until child is 18 months of age.

Abbreviations: AFRO, AFRO-field research officers specially trained to collect anthropometry, child development, and dietary data; ASHAs, accredited social health activists; FRO, field research officers; FS, field supervisor.

^aAll data collection will be collected for both intervention and control arms, except the knowledge and performance of ASHAs, which will be conducted only in the intervention arms.

their acceptability and satisfaction of the counselling provided by ASHA at home, barriers and facilitators to adherence to the messages, and contextual factors that influence women's adherence to the messages. We will also assess the challenges of implementing the programme by interviewing project managers, counsellors, ASHAs, and field supervisors. Process evaluation data will be collected through in-depth interviews and focus groups of women, family members and project staff, and observation of ASHAs' home visits. A separate manuscript detailing the process evaluation theory and methods is under preparation.

2.17 | Data analysis

Data analysis will be by intention to treat. Analyses will be conducted at the mother–infant dyad level and adjusted for the cluster randomization (Murray, 1998). Primary analyses will compare the prevalence of stunting (height-for-age < -2 z-score) in children at 18 months using Pearson's chi-square tests and 95% confidence intervals for the group difference, adjusted for clustering. Secondary analyses will examine each outcome variable (birth weight, height-for-age, feeding patterns, and mean nutrient intakes) considering the repeated measurements within children by using separate mixed models. We will use linear mixed models for continuous outcomes (e.g., height-for-age z-score) and generalized linear mixed models for noncontinuous outcomes, logistic mixed models for binary outcomes (e.g., percentage exclusively breastfed). Models will include treatment group as a fixed effect, infants as a random effect to account for repeated measurements, and community-cluster as a random effect to account for cluster effects. STATA® will be used for all analyses.

2.17.1 | Cost-effectiveness

Data on the cost-effectiveness of the mobile phone communications compared with usual care will be collected on structured and validated paper data forms. The economic evaluation will be conducted in two phases: (a) Trial-based economic evaluation that assesses the cost-effectiveness of the intervention within the time frame and context of the trial. (b) Modelled economic evaluation that assesses the long term cost-effectiveness of the intervention by projecting the lifetime costs and disability-adjusted life years averted for participants in the evaluation (Briggs, Sculpher, & Claxton, 2006).

3 | DISCUSSION

This study has been designed to generate evidence on how mobile phones can be used as a behavioural change communication intervention to improve the communication skills of rural community health providers, nutrition, and health-seeking behaviour of rural women during pregnancy through their delivery until their infants are 18 months of age.

The purpose of this cluster randomized controlled trial is to reduce the prevalence of stunting at 18 months of age in the intervention

clusters by 8% as compared with the control clusters. The secondary outcomes will assess maternal dietary diversity, birth weight, and infant feeding indicators, namely, early initiation of breastfeeding, exclusive breastfeeding, timely introduction and nutrient adequacy of complementary foods, and dietary diversity and child development. It specifically aims to serve the enrolled rural pregnant women (less than and up to 20 weeks of gestational age) from their pregnancy to 12 months of their infant's age.

Mobile phones can potentially enable improved coverage of maternal and child health services in otherwise hard to reach rural areas, enable improvement in staff efficiency, and aid in better engagement of participants who have become accustomed to the use of mobile phones. Therefore, we expect that this comprehensive intervention will ultimately improve the growth and development of infants of women who participate in this trial. It intends to achieve this outcome by improving nutrition practices, facilitating early recognition of illness, improve health care seeking behaviour at the facilities for timely management of illnesses and improve personal hygiene and sanitation practices. It leverages the increased penetration of mobile phone network services in rural areas of India, their affordability to rural Indians, the existing network of ASHAs who are trained to use mobile phones and the rural public health infrastructure that enables the delivery of this intervention. To the best of our knowledge, this is the first of its kind comprehensive mobile phone intervention that enables data collection, counselling both face to face and through standard cell phone counselling messages and videos, and, provides automated delivery of tailored and timely text, voice and alert messages. This trial will comprehensively assess all the elements of the programme through the continuum of care from pregnancy until the child is 18 months old. This study is a demonstration project that will help explore the solutions needed in the ecosystem to enable and sustain the desired health and nutrition behaviour change and how much it will cost the public health systems to achieve improved infant growth and development as enabled by a mobile phone-based BCC intervention.

3.1 | Current status of the trial

At present, 2,501 participants from 244 villages have been enrolled of which 1,250 are receiving the intervention and 1,251 are from control clusters. Currently, the data on the listed outcomes are being collected at the prespecified data collection visits (Tables 2 and 3). The outcome data from control and intervention clusters are being collected by 51 FROs of whom 20 are AFROs, who collect data exclusively on anthropometry, infant dietary practices, and infant development.

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CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

CONTRIBUTIONS

ABP, PK, MJD, AA, and SM conceptualized and designed the intervention. ABP, MJD, AA, PK, SM, TL, PNK, YP, AP, and SK developed the study protocol. They collaborated together to refine and pilot test the instruments to measure outcomes and intervention process indicators and developed the systems for data collection, monitoring data quality, and the data management. MJD, SM, and MA designed the nutrition evaluation component. NF was involved initially in inter site coordination and protocol amendments. ABP drafted and revised the manuscript, which has been reviewed and edited by the team. All authors have read and approved the final manuscript.

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