

Research Article

Effects of a smartphone application on maternal health knowledge and dietary diversity among pregnant women in India: a randomized single center pilot study

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Background

India contributes to one-fifth of infant and maternal deaths globally. Healthy lifestyles during pregnancy combined with good quality health care can help to avoid many maternal and neonatal deaths. Access to appropriate information is important for developing or maintaining a healthy lifestyle. The increased coverage of smartphones across low- and middle-income countries (LMICs) has given rise to smartphone apps supporting healthy pregnancies. The objective of this study is to evaluate the effects of the smartphone application *Together For Her* on maternal health knowledge and dietary diversity among pregnant Indian women.

Methods

We ran a randomised single-centre pilot study in a private hospital in Maharashtra, India. We randomly selected pregnant women at ≤ 20 weeks of gestation who were invited to download the application, in addition to regular antenatal care. The control group only received regular antenatal care. Knowledge about a healthy lifestyle during pregnancy, self-reported dietary diversity and individual characteristics were collected via telephone interviews at baseline (T0), midline (T0 + 4 weeks) and endline (T0 + 12 weeks).

Results

Complete data were collected for 179 respondents (intervention:94; control:85). Respondents in the intervention group showed larger increases in their knowledge over the 12-week study period, with an overall knowledge increase of 13.4 percentage points (P<0.001). The largest effects were found in the modules anaemia, breastfeeding and skin-to-skin contact. Self-reported diversity in nutritional intake also improved significantly more in the intervention group than in the control group.

Conclusions

Smartphone applications can effectively supplement antenatal care by increasing women's knowledge about a healthy lifestyle during pregnancy, which is likely to reduce the risk of adverse maternal health outcomes. Future research includes the roll-out of a larger multi-centre RCT to assess the effect of the smartphone application on health outcomes.

India contributes to one-fifth of infant and maternal deaths globally and has the highest number of newborn deaths.¹ Nonetheless, India made remarkable progress: maternal mortality reduced from 481 per 100,000 live births in 1990 to 99 in 2020.^{2,3} This improvement has been attributed to a substantial increase in institutional deliveries, efforts to improve educational attainment and reductions in household poverty.^{4,5}

About half of pregnant women in India are anaemic.⁶ This high prevalence of anaemia may be attributed to in-

adequate dietary intake during pregnancy and the lactation period.⁷ Pregnant women are more prone to anaemia due to their increased need for iron because of fetal growth, alterations in maternal tissues and metabolism.^{8,9} Indian diets often comprise plant-based diets with low iron bioavailability and few anima-associated products.^{10,11} This can lead to dangerous levels of anaemia (low red cell blood count) in pregnant women, of which they are often unaware.⁹ Furthermore, maternal illiteracy and low socioeconomic status

have been reported as risk factors for anaemia during pregnancy.¹²

Appropriate information about iron supplements and available and affordable vegetarian iron-rich foods such as leafy greens, sprouts and nuts can help pregnant women to prevent anaemia.¹³ This reduces the chances of premature birth, low birth weight, postspartum depression and even infant and maternal deaths.¹⁴ While mild anaemia does not directly threaten the expecting mother's or baby's health, severe anaemia increases the risk of maternal and perinatal mortality and low birth weight.^{15,16} Adherence to healthy lifestyles after pregnancy and quality health care are considered major safeguards against maternal and neonatal mortality. An important condition for developing or maintaining a healthy lifestyle is access to appropriate information. Pregnant women in high-income countries have access to many sources to support a healthy lifestyle. The increased coverage of smartphones across LMICs has given rise to the introduction of mobile health (mHealth) interventions in these settings. Mobile phone technology to improve health has proven to be an effective tool to encourage and reinforce healthy behaviours.¹⁷ In high-income settings, mHealth interventions during pregnancy show promising results.¹⁸ However, little is known about the potential of mHealth solutions to improve mother- and childcare in LMICs. A review by Feroz et al.19 on maternal mHealth interventions in LMICs included fourteen studies. of which only four reliably estimated the intervention's effects. This signals a need for robust impact evaluations of such interventions to strengthen the evidence base and effectively inform policymakers in LMICs.

mHealth interventions implemented in the field of maternal and neonatal care provide various functionalities, including educational information, support, reminders, emergency response and monitoring.²⁰ A systematic review by Sondaal et al.²⁰ suggests that mHealth interventions in LMICs can increase antenatal and postnatal care attendance, facility-based deliveries, skilled attendance at birth, and vaccination rates. A study conducted in Mumbai in the Indian state of Maharashtra found that exposure to mHealth in the form of a voice message service was associated with significant improvements in knowledge and health-related behaviours, particularly for birth preparedness and antenatal care visits.²¹

So far, most mHealth interventions in LMICs targeting pregnant women involve simple text messages or a form of two-way text messaging.^{20,22,23} Most studies into mHealth interventions in LMICs are characterised by a non-randomised or pre-post measurement design which does not allow for estimating causal effects.^{24–28} Interactive components in mHealth interventions are expected to have a larger effect on the intended behaviour change because of the stimulating learning effect.¹⁸ Impact studies applying a rigorous design to estimate the effectiveness of mHealth interventions are recommended in the review by Mildon and Sellen because critical gaps in the mHealth evidence base remain.²⁹

This study aims to fill part of that gap by rigorously evaluating a single-centre pilot of the *Together for Her* (TFH) smartphone application among randomly selected pregnant women in Pune, India. This impact evaluation estimates effects on maternal health knowledge and self-reported dietary diversity, which we hypothesise will increase due to the app. This TFH smartphone application is a digital pregnancy care program for expectant mothers developed and implemented by Avegen Ltd in India. The application is designed to improve maternal health outcomes by increasing access to reliable information about a healthy lifestyle and recommended health care utilisation. The TFH application builds on evidence-based information and personalised health education targeting different stages of pregnancy. The intervention empowers women with knowledge and aims to activate healthy behaviours. The results of this pilot study will be used to further develop the smartphone application and serve as input for assessing a future updated version of the app through a larger multi-centre randomised controlled trial.

METHODS

From June 2021 to December 2021, a randomised singlecentre study was conducted to estimate the impact of the TFH pilot intervention on maternal health knowledge and diversity in dietary intake among Indian pregnant women. The TFH application was launched in July 2020 and to date, the application has had over 600.000 downloads across India. Randomly selected pregnant women at ≤20 weeks of gestation were invited to download the application, in addition to regular antenatal care. The control group only received regular antenatal care. Knowledge about a healthy lifestyle during pregnancy, self-reported dietary diversity and individual characteristics were collected via telephone interviews at baseline, midline and endline.

STUDY SETTING

The healthcare system in India is decentralised and primarily administered at the state level. Health insurance is available but not mandatory; hence most Indians lack health insurance and out-of-pocket costs make up more than three-quarters of spending on medical treatment.³⁰ Consequently, catastrophic healthcare expenditures frequently cause impoverishment.³⁰ There are both public and private healthcare providers, with care at public facilities being provided at relatively low costs or for free. The public sector service is perceived as unreliable and of indifferent quality. Public care is, therefore, often not the first choice for those who can afford private care.^{31,32} As the maternal mortality ratio (MMR) was very high earlier, the government of India launched the National Rural Health Mission (NRHM) in 2005 to improve the health system by providing universal access to equitable, affordable, and quality health care.³³ Later, in 2013, this program was extended and renamed National Health Mission (NHM) with a specific component to incentivise pregnant women to deliver at accredited health centres.³⁴ Large socioeconomic inequalities persist throughout India, with the northern states having the highest MMR, while rates in the southern states are comparable to other middle-income countries.

Government-driven anaemia control programs have so far not achieved the desired reductions in anaemia, partly due to a lack of focus on knowledge and behavioural barriers.³⁵ By addressing these underlying causes of maternal anaemia it is likely that significant improvements in maternal health can be made. Access to maternal health care services is higher among those with a higher educational and economic status.³⁶ Nonetheless, over 60% of illiterate women do have an antenatal care visit within the first trimester. Public and private healthcare facilities are utilised at comparable levels.³⁶

This study took place in Maharashtra, the second-most populous state in India. The state is located in the westcentral part of the country. Respondents were recruited from a private hospital located in Pune, which is the seventh most populous city in India. According to Telecom Statistics India – 2020, the penetration of smartphones among the Indian population in Maharashtra is 61%, compared to 54% countrywide in 2020.

STUDY DESIGN AND DATA COLLECTION

The study site was a purposely selected private hospital in Pune. Pregnant women at ≤20 weeks of gestation visiting the hospital for their first prenatal care visit were invited to participate in the study. When a woman agreed to participate, she was asked to sign the informed consent form. A fieldworker, who was blinded to the allocation of the respondents across intervention and control groups, made a phone call to the respondents to further explain the process of the study. Allocation to the control and intervention group was based on the randomly assigned number of each respondent, with the odd-numbered respondents selected into the intervention arm and the even-numbered respondents into the control arm. While this is not exactly the same as full randomisation, there is no reason to assume that in practice, this does not result in random assignment to intervention and control group. Subsequently, the respondents in the intervention group were assisted by phone in downloading the TFH application. The control group was not directed toward the TFH application, nor did they receive any information regarding the TFH application but they were called for the same telephone interviews as those in the intervention group.

The intervention group was exposed to the TFH application and regular antenatal care, while the control group received only regular antenatal care. While the respondents in the control group were aware that they were part of a study, they did not receive any information about the mHealth intervention.

The telephone interviews at baseline (T0), midline (T0 + 4 weeks) and endline (T0 + 12 weeks) were conducted identically to allow for the identification of changes in responses. When respondents did not answer the phone, the fieldworkers continued trying for seven days. Fieldworkers collected individual characteristics, and health characteristics were available via the healthcare professionals for which the participant had provided consent. A compensa-

tion of Rs. 1000/- (\pm 10,- GBP) was offered to all study participants upon completion of the study to cover the cost of their time investment for the telephone interviews.

During the telephone interviews, data were collected on maternal health knowledge and dietary diversity using the questionnaire provided in Supplementary file S1. All collected data were entered into a standardised digital backend collecting system.

STUDY POPULATION

Pregnant women entering the health care facility for their current pregnancy's first antenatal care visit were invited to join the study. The inclusion criteria were: 1) aged between 18-35 years, 2) access to a smartphone, 3) literate in one of the app languages: English and Hindi, and 4) less than or equal to 20 weeks of gestation. The gestational week was derived from the last menstrual period unless it differed from the sonographic estimate, in which case the latter estimate was used. The following exclusion criteria were applied: 1) pregnant women who were carrying twins or more, 2) had high-risk pregnancies (as defined by the consulting gynaecologist), and 3) had any severe psychiatric comorbidities that result in cognitive impairment and prevent effective use of smartphone applications. The sample size was restricted due to this pilot's logistic and financial constraints. The intention is to build on this pilot by rolling out a larger multi-centre randomised controlled trial later. A total of 288 pregnant women were recruited, of which 243 provided informed consent. The allocation of respondents to the intervention group was, on purpose, slightly higher to account for the expected dropout. In total, 64 women were dropped from the study because they did not respond or provide data during the telephone calls at baseline, midline and endline. Respondents were included in the analyses when they responded to the baseline and endline measurements.

INTERVENTION

The TFH application guides and supports pregnant women toward healthy behaviours during pregnancy and after delivery. The content of the app is delivered to women in the form of videos, tips, and quizzes to improve their knowledge on A) anaemia, B) nutrition, C) physical activity, D) birth preparedness, E) respectful delivery care, F) skin-toskin contact and G) breastfeeding. The app also provides the location of the nearest private antenatal care provider available to the user. The gestational week of the mother is linked to the delivered content and segmented so that there is a finite amount of information to consume per week. The content was developed in collaboration with nutritionists, obstetrician-gynaecologists and other experts and is localised to urban lower-middle to the middle class in terms of dietary recommendations. The content of the application is both available in English and Hindi. Supplementary file S1 provides snap-shots of the week-based content, the video related to the gestational age, and other "did you know" short messages customised to the gestational age of the pregnant women.

MEASURES

INDIVIDUAL CHARACTERISTICS

Individual characteristics included age, highest educational attainment, socio-economic status (SES) and employment status. The response categories related to an educational level were: 1) graduate/post-graduate with a general or professional degree, 2) some college, including a diploma but not a graduate, 3) secondary school certificate / higher secondary certificate, 4) literate but no formal schooling and 5) illiterate. We combined these into the categories of high (1 & 2), medium (3) and low (4 & 5) education levels. SES was assessed using a standardised questionnaire, which derives a composite score based on occupation and education of the head of the household, type of housing and family ownership of land and material possessions.³⁷ Based on this information, the socioeconomic status was scored according to the newest SES-classification system of India.³⁷ Basic health characteristics were also collected and involved details related to self-reported anaemia status, previous pregnancies, and self-reported exercise. Finally, smartphone ownership and daily access to a smartphone were collected

OUTCOME MEASURE: KNOWLEDGE

The knowledge assessment consisted of 79 questions which correspond with the provided content in the app: (A) anaemia, B) nutrition, C) physical activity, D) birth preparedness, E) respectful delivery care, F) skin-to-skin contact, and G) breastfeeding). The number of questions per module ranged from four to nineteen questions. Local healthcare professionals developed the questions. The full questionnaire can be found in Supplementary file S2. Responses to the questions were binary coded i.e. 0 if the answer was incorrect and 1 if the answer was correct. In case of multiple choices of the available answer categories are correct, respondents needed to have provided more than half of the correct answers. The scores per module were generated by adding up the number of correctly answered questions per respondent. In order to standardise the outcomes for the modules, we estimated the percentage of correct answers per module for each respondent. The overall score of the knowledge assessment was based on all 79 questions.

OUTCOME MEASURE: NUTRITIONAL INTAKE

Nutritional intake was assessed using a 24-hour recall of dietary intake, using the Minimum Dietary Diversity for Women (MDD-W).³⁸ This validated food group diversity indicator reflects the micronutrient adequacy summarised across ten micronutrients. We also generate a dichotomous indicator from the MDD-W that identifies whether women consumed at least five of ten defined food groups. The ten food groups are presented in Supplementary file S3. For the 24-hour dietary recall assessment, respondents were asked to remember all the foods and drinks consumed during the past 24 hours. Respondents were prompted to remember

eating and drinking episodes by periods or by linking to daytime activities. The fieldworkers grouped the food into the ten defined food groups. The proportion of women that consumed at least five different food groups can be considered sufficient micronutrient adequacy, reflecting the MDD-W.

STATISTICAL ANALYSIS

Data were imported and cleaned in STATA MP version 17.0. Individual characteristics of the intervention and control group were compared to confirm that the randomisation across the two groups was successful. The statistical significance of differences across both groups was examined using a two-sample t-test for continuous data and a chi² test for categorical data.

KNOWLEDGE MODULE

For each knowledge module, we estimated the average percentage of correct answers for the control and intervention groups at baseline, midline and endline. Changes between baseline and endline were presented as changes in percentage points. The effect estimates were then determined based on the difference in change between the control and intervention groups. The non-normal distribution of the outcome variables required the non-parametric Kruskal Wallis test to assess for significant difference between the measured difference in the intervention and control group.

NUTRITIONAL INTAKE MODULE

While the MDD-W is designed as a dichotomous indicator, we also assessed the MDD-W as a continuous variable to gain insights in the diversity of food groups consumed by the respondents. We assessed the average number of food groups and the change in a number of food groups. Subsequently, the change from baseline to endline was estimated for both the control and intervention group. The change in a number of food groups was assessed on statistical significance. In addition, we also assessed the MDD-W as a dummy variable, where 0 indicated the consumption of less than five food groups in the last 24 hours, and 1 indicated the consumption of at least five food groups.

REGRESSION MODELS

We estimate two ordinary least squares (OLS) regressions to assess differences in the overall baseline scores and in the change (between baseline and endline) in overall scores while accounting for a set of explanatory variables. The OLS regression approach was chosen because the dependent variables are measured on a continuous scale. Equation 1 contains the estimated regression equation.

 $Y_i = \beta_0 + \Sigma_{j=1..4}\beta_j X_j + \varepsilon_i \quad (\text{Equation 1})$ where Y_i is the dependent variable -i.e. either the overall baseline scores or the change in overall scores. β_0 is the intercept of the model, X_j corresponds to the j^{th} explanatory variable of the model, β_j is the coefficient and ε denotes the error term. The explanatory variables are the individual characteristics (age, SES, earlier pregnancies) and the intervention variable to estimate whether both groups differed significantly in the overall knowledge score at baseline and in the change in the overall score.

PATIENT AND PUBLIC INVOLVEMENT

The intervention was designed with input and consultation with local healthcare providers. Patients and the public were not involved in the design, implementation or dissemination of the study. However, feedback from the community members (pregnant women) was used to adapt and refine the TFH application's components prior to this study's initiation. Once the results have been published, the hospital will be informed of the study findings. The finding will also be disseminated to participants and the public through the TFH app as well as social media platforms.

ETHICS APPROVAL

Ethical approval for analysis of the data provided by Together For Her (Avegen Ltd.) was obtained from the Erasmus School of Health Policy & Management Research Ethics Review Committee at Erasmus University Rotterdam under application number ETH2122-0393. Informed consent was obtained from all participants at the start of the study. The study is registered in the open science framework (OSF) registry (registration DOI: <u>10.17605/OSF.IO/</u> <u>2K7AP</u>).

RESULTS

STUDY SAMPLE CHARACTERISTICS

Recruitment of participants started in June 2021 and endline measurements were completed in December 2021. In total, 243 participants were randomly allocated to either the intervention or control group. After completion of the baseline questionnaire, 22 participants were excluded from the intervention arm and 11 participants from the control arm due to incomplete data. Figure 1 shows the flow diagram of the study and the reasons for exclusion. In the intervention and control group, there were respectively 94 and 85 participants with full item responses on baseline and endline. This resulted in a total analysis sample of 179.

Table 1 shows an overview of individual characteristics at baseline. These characteristics were highly comparable between the intervention and control groups at baseline. The only significant difference was found for exercise, with a smaller share of the intervention group reporting doing any kind of exercise. The other characteristics show that the majority of the study sample was highly educated and that half of the respondents were classified in the middle SES group. Approximately 97% of both groups had a smartphone. Those who reported not possessing a smartphone had daily access to a smartphone.

KNOWLEDGE ASSESSMENT

Average scores for all separate questions are provided in Supplementary file S4. Figure 2 provides an overview of the

change over time in knowledge for each module across intervention and control. The vertical axis reflects the average percentage of correct answers. The numbers underlying this figure can be found in Supplementary file S5. The baseline values across all modules are highly similar across intervention and control groups. The overall score (Figure 2, panel H), combining correct responses on all the knowledge modules, jointly confirms that the knowledge level at baseline for the intervention and control group is comparable, scoring respectively on average 36% and 37% of the 79 questions correct (i.e. respondents had on average 28 and 29 questions correct). At baseline, both groups scored highest on the nutrition module (Figure 2, panel C) and lowest on knowledge about skin-to-skin contact (Figure 2, Panel D). At the endline, both groups found the highest knowledge level for the physical activity module (Figure 2, Panel E). The knowledge levels regarding anaemia and breastfeeding had more than doubled over the 12-week study period in the intervention group (respectively Figure 2, Panels A & F). The figures also suggest that it takes some time for respondents to meaningfully increase their knowledge through the app, as most knowledge improvements were observed after midline data collection.

Table 2 provides effect estimates for the different maternal health knowledge modules. As Figure 2 already indicated, the knowledge levels for all modules improved in both groups over the study period. Table 2 shows that these improvements were larger in the intervention group for all modules: e.g. in the anaemia module, the intervention group increased by 37 percentage points while the control group increased with 24 percentage points. The final column of table 2 provides the differences of the change scores between the intervention and control groups. The intervention group had almost 13 percentage points (37 - 24) more improvement in the anaemia module compared to the control group. The differences in the knowledge improvements were in all modules statistically significant (p-value < 0.05), except for the nutrition module (p-value ≥ 0.05). The highest effect estimate was found for the breastfeeding module with a difference of 23 percentage points between the intervention and control group, followed by the skin-to-skin contact module with a difference of 17 percentage points.

NUTRITIONAL INTAKE

Supplementary file S6 shows the results of the dietary diversity score both as a continuous (MDD-W) and a dichotomous (MDD-W) variable throughout the study. At baseline, the control and intervention groups both consumed on average, four different food groups over the previous 24 hours. The application of the threshold of the consumption of at least five food groups in the previous 24 hours showed that one-third (33%) of the intervention group adhered to this recommendation and 41% of the control group at baseline. Supplementary file S6 also shows histograms for the intervention and control groups reflecting the baseline and endline values of the MDD-W. The histogram for the intervention groups shows that the distribution has changed over time to skewed towards the left, while the histogram of the control group shows a similar distribution over time.

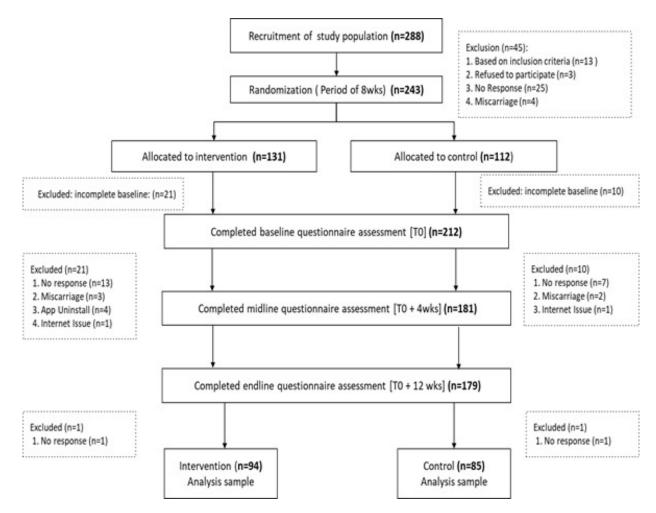


Figure 1. Trial flow diagram stratified by randomised arm.

The effect estimates, presented in the bottom part of <u>Table 2</u>, show that in the study period, the intervention group increased the number of food groups by two, while the control group, on average, increased the number of food groups by less than one food group. This difference of 1.2 is statistically significant. At the endline, 9 out of 10 respondents in the intervention group consumed at least five food groups, an increase of 57 percentage points. The increase in the control group was smaller at 24 percentage points, a statistically significant difference between the intervention and control groups.

REGRESSION RESULTS

Table 3 shows the results of both our OLS regression models. The first model shows that pregnant women aged 26 years or older were more likely to have a higher overall score at baseline than those aged below 26. The other covariate did not show a statistically significant association with the overall score at baseline. Hence, the coefficient of the intervention variable confirms that the randomisation of participants is likely to have been successful since the overall score at baseline is not statistically different between the control and intervention groups. The second model shows that pregnant women aged 31 years and older were significantly less likely to show improvement in the overall score compared to younger pregnant women. In addition, it appeared that women who were pregnant for the first time were significantly more likely to have a larger improvement in the overall score than women who had been pregnant before. Pregnant women with a high SES were also more likely to have a significantly larger improvement in their overall score than pregnant women with a low or medium SES. Finally, the largest significant positive coefficient was reported for women in the intervention group, indicating that these women had a larger positive change in overall score compared to women in the control group.

DISCUSSION

In this single-center pilot study, we examined the effects of the Together for Her smartphone application on improvements in maternal knowledge about a healthy pregnancy and the self-reported nutritional intake of Indian pregnant women in Maharashtra. Pregnant women randomly selected to the intervention group attained a greater improvement in maternal health knowledge than those in the control group. The diversity in their self-reported dietary intake in the intervention group also showed a larger improvement.

While mHealth interventions to support pregnant women have been implemented widely in high-income

	Intervention group (N=94)	Control group (N=85)	P-value
	Individual characteristics		
Age	% (n)	% (n)	0.475
18 – 25 years	44.7 (42)	37.0 (30)	
26 - 30 years	37.2 (35)	38.3 (31)	
31 - 35 years	17.0 (16)	19.8 (16)	
> 35 years	1.1 (1)	4.9 (4)	
Level of education			0.231
Low	0.0 (0)	4.8 (4)	
Middle	21.5 (20)	19.9 (16)	
High	78.5 (73)	75.9 (63)	
Socioeconomic status			0.080
Low	7.5 (7)	4.9 (4)	
Middle	52.7 (49)	51.9 (43)	
High	39.8 (37)	43.2 (36)	
Employment status			0.201
Never worked	80.7 (75)	77.1 (64)	
Stopped working	14.0 (13)	8.4 (7)	
Part-time	1.1 (1)	6.1 (5)	
Full time	4.3 (4)	8.4 (7)	
	Health status		
Self-reported anaemia			0.497
No	7.5 (7)	6.2 (5)	
Yes	3.2 (3)	1.2 (1)	
Not sure	89.4 (84)	92.6 (79)	
Earlier pregnancies			0.291
None	57.5 (54)	57.5 (49)	
One	36.2 (34)	30.0 (26)	
Тwo	6.4 (6)	10.0 (8)	
More than two	0.0 (0)	2.5 (2)	
If earlier pregnant, what type of delivery?			0.333
No complications	58.5 (23)	62.2 (22)	
Abortion	31.7 (13)	32.4 (12)	
The baby was born dead	2.4 (1)	2.7 (1)	
The baby died within the first month	4.9 (2)	2.7 (1)	
Preterm delivery	2.4 (1)	0.0 (0)	
Do you do any kind of exercise? *			0.033
No	77.7 (73)	63.5 (54)	
Yes	22.3 (21)	36.5 (31)	
	Access to a smartphone	· ·	
Do you own a smartphone?	-		0.740
No	3.2 (3)	2.5 (2)	
Yes	96.8 (91)	97.5 (83)	
Do you have access to a smartphone?			n/a
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about the effectiveness of such interventions in low- and

countries (HICs), with promising results,¹⁸ less is known middle-income countries (LMICs).¹⁹ mHealth interventions for pregnant women ultimately aim to improve maternal,

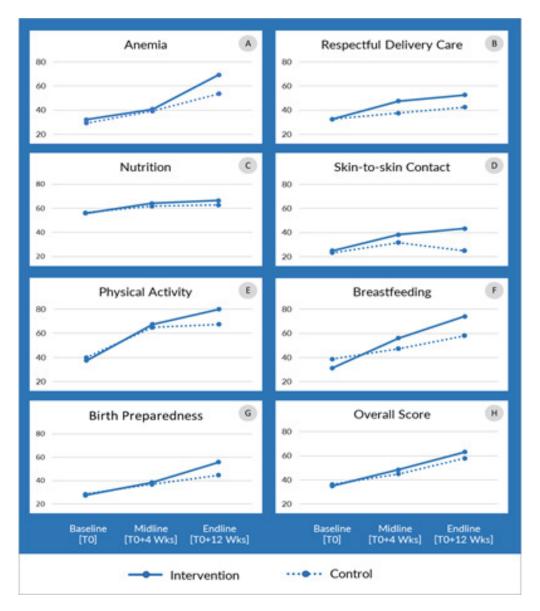


Figure 2. Percentage of correct answers across knowledge modules over time in intervention and control group.

newborn and child health. The most widely studied outcomes of mHealth interventions effectiveness studies relate to prenatal and postnatal care attendance, facility-based delivery, and vaccination uptake.^{29,39} mHealth intervention concerned with health information delivery, in the form of nutritional advice, also showed promising results, with pregnant women exposed to the mHealth intervention providing significantly longer exclusive breastfeeding.⁴⁰ In addition, another RCT revealed that mHealth interventions is also an efficient way to improve compliance of pregnant women with iron supplementation, however, this did not result in improved anaemia figures.⁴¹ Few studies assess the effectiveness of mHealth interventions on the knowledge related to a healthy pregnancy,^{26,42} although the inclusion of knowledge is essential when considering a behavioral change theory.

A large share of the available studies about LMICs, often applies a before-after comparison,⁴³ which does not allow for the causal inference about the effects of the intervention. Contrary to most of those earlier studies, this study builds on data from a randomly selected group of women who received access to the pilot intervention and randomly selected women in a control group where the intervention was not offered.

While earlier evidence from LMICs, and India specifically, on the effectiveness of mHealth interventions for pregnant women is scarce, other studies are available about the effects of increasing maternal knowledge among pregnant women and recent mothers in India. These studies relate mostly to participatory women's groups that exchange information, often supported by Accredited Social Health Activists. Tripathy et al.⁴⁴ found that these participatory women's groups led to more skin-to-skin care and resulted in a 31 % reduction in neonatal mortality rates over two years, with especially strong reductions among the most marginalised mothers.⁴⁵ Our study does not allow for estimation of the effects of the intervention on maternal and newborn health outcomes but the improvements in overall knowledge about maternal health, especially anaemia, breastfeeding and skin-to-skin contact, are promising. The

Table 2. Effect estimates of the knowledge modules and nutrition intake

	Change [Endline – Baseline]		Difference [Intervention – Control]	
	Intervention	Control		
Knowledge modules	рр	рр	pp (p-value)	
Anaemia	+37.1	+24.2	+12.9 (<0.001)	
Nutrition	+10.6	+6.4	+4.2 (0.352)	
Physical activity	+41.0	+29.2	+11.8 (0.044)	
Birth preparedness	+28.6	+16.3	+12.3 (<0.001)	
Respectful delivery care	+21.0	+9.3	+11.7 (0.015)	
Skin-to-skin contact	+18.2	+0.8	+17.4 (0.002)	
Breastfeeding	+42.7	+19.3	+23.4 (<0.001)	
Overall score ¹	+28.3	+14.9	+13.4 (<0.001)	
	Change [Endline – Baseline]		Difference [Intervention – Control]	
	Intervention	Control		
Nutrition intake	Mean	Mean	(p-value)	
Recall 24-hour (MDD-W)	+2.0	+0.8	+1.2 (<0.001)	
	рр	рр	pp (p-value)	
At least five food groups (MDD-W)	+56.9	+23.5	+33.4 (<0.001)	

¹= Knowledge modules together, pp= percentage point

Table 3. OLS regression results for the overall score at baseline and the change in overall score

	Baseline overall score	Change in overall score	
	Coeff. (S.E.)	Coeff. (S.E.)	
Age: ≤ 25 years	Ref	Ref	
26 - 30 years	4.63 (1.94) **	-2.07 (1.72)	
>30 years	7.32 (2.43) ***	-4.58 (2.16) **	
Pregnant before: No	Ref	Ref	
Yes	1.66 (1.83)	-2.83 (1.62) *	
Socio-economic status: Low/medium	Ref	Ref	
High	-1.62 (1.74)	3.10 (1.54) **	
Intervention: No	Ref	Ref	
Yes	-0.06 (1.68)	11.35 (1.48) ***	
Constant	24.96 (1.78) ***	13.02 (1.57) ***	
Observations	167	164	
R-squared	0.090	0.330	

Standard errors in parentheses, *** p<0.01, ** p<0.05, * p<0.1

earlier evidence from information shared through participatory women's groups, makes us cautiously optimistic about the potential effect of the TFH app on maternal and neonatal mortality. Furthermore, the self-reported improvement in dietary diversity over the study's twelve-week horizon suggests that mothers increased their knowledge about healthy behavior during pregnancy and made actual changes to at least their dietary behaviours. This might suggest that the app can more broadly support behavioural changes.

Within the study period of 12 weeks, improvements across all knowledge modules were reported for both the

control and intervention groups. This finding emphasises the importance of including a control group, as it is plausible to assume that pregnant women would improve their maternal health knowledge anyway when they only use antenatal care visits and/or simply because they talk about their pregnancy with their social contacts. While the improvement in knowledge was for all modules larger in the intervention group, this difference was only found to be insignificant for the nutrition module. To a certain extent, this is surprising since the findings regarding the dietary diversity score showed a significant difference between the control and intervention groups indicating that the intervention group had a larger improvement in their dietary diversity score than the control group. In general, behavioural change theory suggests that an individual first should possess the relevant knowledge related to the behaviour, which could subsequently lead to behaviour change.⁴⁶

LIMITATIONS

This study provides an early-stage evaluation of a pilot project, which is expected to inform the implementation of the intervention at a large scale and to study its effects in a large multi-centre randomised controlled trial. Limitations that come with this current pilot study relate to limited sample size and outcomes related only to knowledge and behaviour improvements, not to actual health outcomes. Furthermore, the study period of twelve weeks is relatively limited, and the main tool used to assess knowledge was made available in two different languages. While careful forward and backward translation was applied, no further validation of this tool occurred. We do, however, observe that after the first four weeks, no clear increase in outcomes was observed, effects were observed in the intervention group after this time, during the remaining eight weeks. Also, we do not yet know whether these results are generalisable to pregnant women using health care in public facilities, who make up about half of the total pregnant population. Future research, including the roll-out of a multi-centre study to assess the effect of the smartphone application on health outcomes in a considerably larger sample, is required to draw further conclusions about the long-term effects of the intervention.

CONCLUSIONS

Impact evaluations to determine the potential benefit of mHealth interventions on maternal and newborn health in LMICS are important to support policymakers with credible evidence about the potential effects of such interventions. This study provides evidence that smartphone applications can effectively supplement antenatal care by increasing women's knowledge about a healthy lifestyle during pregnancy, which is likely to reduce the risk of adverse maternal health outcomes.

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AUTHORSHIP CONTRIBUTIONS

All authors contributed to the study and manuscript.

COMPETING INTERESTS

Subhanwita Sarkar and Sumiti Saharan are employed by Avegen Pvt Ltd the party that developed and implemented the Together For Her program. Charlotte Dieteren and Igna Bonfrer report no conflicts of interest.

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