Efficacy of a Personalized Mobile Health Application in Improving Micronutrient Supplement Use among Pregnant Women in Karachi, Pakistan: A Parallel Group Randomized Controlled Trial

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Abstract

Background: Micronutrient deficiencies in folate, ferritin, calcium, and vitamin D are common during pregnancy in developing countries, often due to insufficient dietary intake. Micronutrient supplementation could address this unmet need. Incorporation of novel awareness strategies in antenatal practices could potentially enhance compliance with supplement usage.

Objective: We evaluated the efficacy of personalized mobile health (mHealth) intervention, hypothesizing a 30% improvement in supplement use in the intervention group compared to the conventional face-to-face counseling group.

Methods: In an unblinded randomized controlled trial, we enrolled 306 first-trimester pregnant women from Aga Khan University Hospital between January 2020 and September 2021 who owned smartphones with internet connection and consented to participate. Women on regular medications, dietary restrictions, or suffering from critical illnesses were excluded. Intervention group received personalized coaching about micronutrient supplement use through an mHealth application named "PurUmeed Aaghaz" (Hopeful Beginning), as thrice-a-week push messages and tailored recommendations over a 24 weeks period. Comparison group received standard face-to-face counseling at 6, 12, 18, and 24 weeks post-enrollment. Baseline sociodemographic, obstetrics, anthropometric, and lifestyle data were collected through face-to-face interviews. At each follow-up, the weekly use of folic acid, iron, calcium, and vitamin D supplements was recorded and scored as 0 (daily), 1.5 (4-6 times weekly), and 3 (?3 times weekly). These scores were summed to calculate the cumulative supplement use score (CSUS), ranging from 0-12, with higher scores indicating greater inadequacy. Further, every fourth woman was invited for biochemical assessment of micronutrient serum levels. Data were analyzed using STATA 14, with random effects linear and binary logistic panel regression to compare CSUS and each supplement usage between the two groups from baseline to end line.

Results: Of 153 participants in each group, 107 (70%) in intervention and 125 (81.7%) in non-intervention group completed the study. After 24 weeks, intervention group showed a significantly greater reduction in mean CSUS compared to non-intervention group (?:-0.40, 95% CI:-0.79, -0.01). Daily supplement use improved by 20% vs. 22.4% for folic acid, 11.2 times vs. 2.1 times for iron, 1.2 times vs. 14.2 times for calcium, and 3 times vs. 1.3 times for vitamin D in intervention vs. non-intervention group, respectively. Multivariable analysis indicated higher odds of sufficient use of folic acid (aOR:1.14, 95% CI:0.63, 2.07), iron (aOR:1.41, 95% CI:1.06, 1.89), and vitamin D (aOR:1.97, 95% CI:1.51, 2.57) in intervention group, while calcium intake improved in non-intervention group (aOR:0.62, 95% CI:0.47, 0.81). At the end line, anemia decreased in intervention group, whereas deficiencies in ferritin, calcium, and vitamin D persisted or worsened, particularly in non-intervention group.

Conclusions: mHealth intervention, if adopted appropriately, can improve antenatal supplementation of iron and vitamin D. Affordable, accessible, and personalized counseling through mHealth can potentially ameliorate the micronutrient status during pregnancy. Clinical Trial: ClinicalTrials.gov NCT04216446

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(aOR:1.97, 95% CI:1.51, 2.57) in intervention group, while calcium intake improved in non-intervention group (aOR:0.62, 95% CI:0.47, 0.81). At the end line, anemia decreased in intervention group, whereas deficiencies in ferritin, calcium, and vitamin D persisted or worsened, particularly in non-intervention group.

Conclusions: mHealth intervention, if adopted appropriately, can improve antenatal supplementation of iron and vitamin D. Affordable, accessible, and personalized counseling through mHealth can potentially ameliorate the micronutrient status during pregnancy.

Key words: calcium; folic acid; iron; mHealth intervention; micronutrient deficiencies; Pakistan; pregnancy; supplement use; vitamin D

Trial Registration: ClinicalTrials.gov NCT04216446

Introduction

Pregnancy involves profound physiological transformations, requiring optimal nutrition for fetal growth and maternal well-being [1]. Poor maternal nutrition can adversely affect the development, functioning, and programming of major fetal organs, leading to lifelong health consequences [2]. Micronutrients, including essential vitamins and minerals, are crucial for embryogenesis and placental and organ development, particularly during the early stage of pregnancy [2]. Hence, even subtle imbalances in micronutrient intake during this stage can be harmful to fetal well-being and development [3, 4].

During pregnancy, the demand for micronutrients, particularly folate, iron, calcium, and vitamin D, significantly increases compared to the pre-pregnancy state [1, 5]. The antenatal period is, hence, an opportune time for adopting healthy dietary and lifestyle behaviors for optimal outcomes [6]. Although a balanced diet is recommended, prevalent micronutrient deficiencies and inadequate dietary practices necessitate supplementation during pregnancy [7, 8].

Folate and iron are critical during pregnancy for uterine and placental development, blood volume expansion, and fetal growth, and their deficiencies are associated with anemia and adverse outcomes, including preterm birth (PTB) and stillbirth [1, 9]. Folate supplementation during preconception and early pregnancy prevents neural tube defects [10]. Daily consumption of 400 mcg of folic acid, ideally preconception, and 30-60 mg of elemental iron prevent anemia, puerperal sepsis, low birth weight (LBW), and PTB [11, 12].

Calcium, the body's most abundant mineral, is vital for enzymatic and hormonal functions [13, 14]. During pregnancy, its demand increases to support fetal growth, relying on maternal intake and

reserves. Adding 1.5 to 2.0g of elemental calcium daily from 20 weeks until the end of pregnancy has been associated with a reduced risk of hypertensive disorders and PTB [15, 16] [17]. Similarly, vitamin D is essential for maternal and fetal bone health and immune system functions by influencing calcium and phosphorus homeostasis [11]. Its deficiency increases the risk of LBW, small for gestational age (SGA) births, and PTB [10, 16, 18, 19]. Daily oral supplementation with 200 IU (5 µg) of vitamin D can prevent its deficiency [20].

Among women of reproductive age (WRA), micronutrient insufficiencies remain a significant challenge, particularly in low- and middle-income countries (LMICs). Due to inadequate dietary practices, WRA often experiences multiple concurrent deficiencies, usually referred to as hidden hunger [21]. In Pakistan, only 27.6% of WRA meet the minimum dietary diversity requirements, which is reflected in the high prevalence of anemia (43%), and low levels of ferritin (33.6%), calcium (16.2%), and vitamin D (79.6%). These insufficiencies persist during pregnancy, with around one-third of pregnant women being anemic (35.2%), with deficiencies of ferritin (46.6%), calcium (32.7%), and vitamin D (81.2%) being further aggravated [22].

Despite these deficiencies, micronutrient use remains inadequate [23]. Demographic and Health Surveys from 22 LMICs showed that 83% of pregnant women had at least one antenatal care visit, and 81% received iron-folic acid (IFA) supplements; however, only 8% adhered to the recommendations [24]. A systematic review by Torheim et al. found that over 50% of the studies reported micronutrient intakes below estimated requirements in low-resource settings [25]. In Pakistan, only 33.4% of women received IFA during pregnancy, and only 22.2% took it for at least 90 days. Additionally, only 6.2% reported multivitamin use during pregnancy [22], highlighting the need for appropriate antenatal counseling.

Due to the high inflow of pregnant women at the antenatal clinics, the interaction between the care provider and women is often brief and lacks adequate emphasis on the consumption of micronutrient supplements [26]. Hence, exploring innovative means of antenatal counseling, such as utilizing digital health technologies to enable personalized care and regular monitoring of micronutrient supplementation, is crucial.

Given the rapid proliferation of mobile phone usage, particularly smartphones, innovative digital health technologies are well-positioned to play a transformative role in antenatal care [27, 28]. Pakistan mirrors the trend of widespread adoption of mobile devices, with over 79.5% of the population being mobile subscribers and 55.1% being broadband users [29]. This offers a unique opportunity to reach expectant mothers with personalized counseling and regular monitoring. The growing penetration of smartphones and doubling of ownership rates between 2016 (17%) and 2019 (32.5%), combined with the surge in mobile app downloads, indicates a readiness among the population to embrace digital solutions [30-32]. Notably, a 29% higher likelihood of urban women owning mobile phones than their rural counterparts underscores the potential impact of targeted digital health interventions on improving maternal health outcomes across diverse demographic groups in Pakistan [33].

A wide range of services, including text messaging (SMS), voice and video calls, multimedia messaging, and specialized apps, delivered via mobile devices (phones or tablets) have been proven effective in supporting pregnant women [34]. A positive change in behaviors such as reducing alcohol consumption [35], increased skilled delivery attendance [36], enhanced access to essential obstetric care [37, 38], and improved dietary and physical activity habits [39, 40] has been reported with the use of mobile health technology. One such mHealth intervention, Smarter Pregnancy, tested among Dutch women, showed improvement in folic acid intake by 56.3% [41].

In Pakistan, mHealth interventions improved childhood immunization rates [42, 43], diagnosis of pre-eclampsia by lady health workers [44], and promotion of infant and young child feeding practices [45]. These interventions also proved effective for managing chronic illnesses such as diabetes and hypertension [46, 47], ensuring medication adherence [48], and improving providers' knowledge and practice of diabetic guidelines [49]. A few local initiatives using mHealth during pregnancy have been in the form of the Baby+ App (providing general pregnancy information) [50], the MotherCare App [51], and MARHAM, offering online appointment services [52].

Given the significant burden of micronutrient deficiencies, it is worth examining innovative approaches for nutritional counseling. mHealth offers an accessible and convenient tool compared to conventional face-to-face communication strategies. To the best of our knowledge, personalized mHealth interventions have not been evaluated to examine improvement in supplement use among pregnant women in Pakistan.

This study aimed to assess the efficacy of an mHealth coaching program (named PurUmeed Aaghaz, meaning a hopeful beginning) in improving micronutrient supplement consumption of folic acid, iron, calcium, and vitamin D during pregnancy. We hypothesized a 30% improvement in daily supplement use in the intervention group compared to the non-intervention group.

Methods

Study design and setting

We conducted a parallel group randomized controlled trial (RCT) with an allocation ratio of 1:1. The RCT was registered at ClinicalTrials.gov (NCT04216446) before participant enrollment. The trial

was conducted at the antenatal clinics of Aga Khan University Hospital (AKUH) from January 2020 to March 2022. A detailed study protocol is published elsewhere [53].

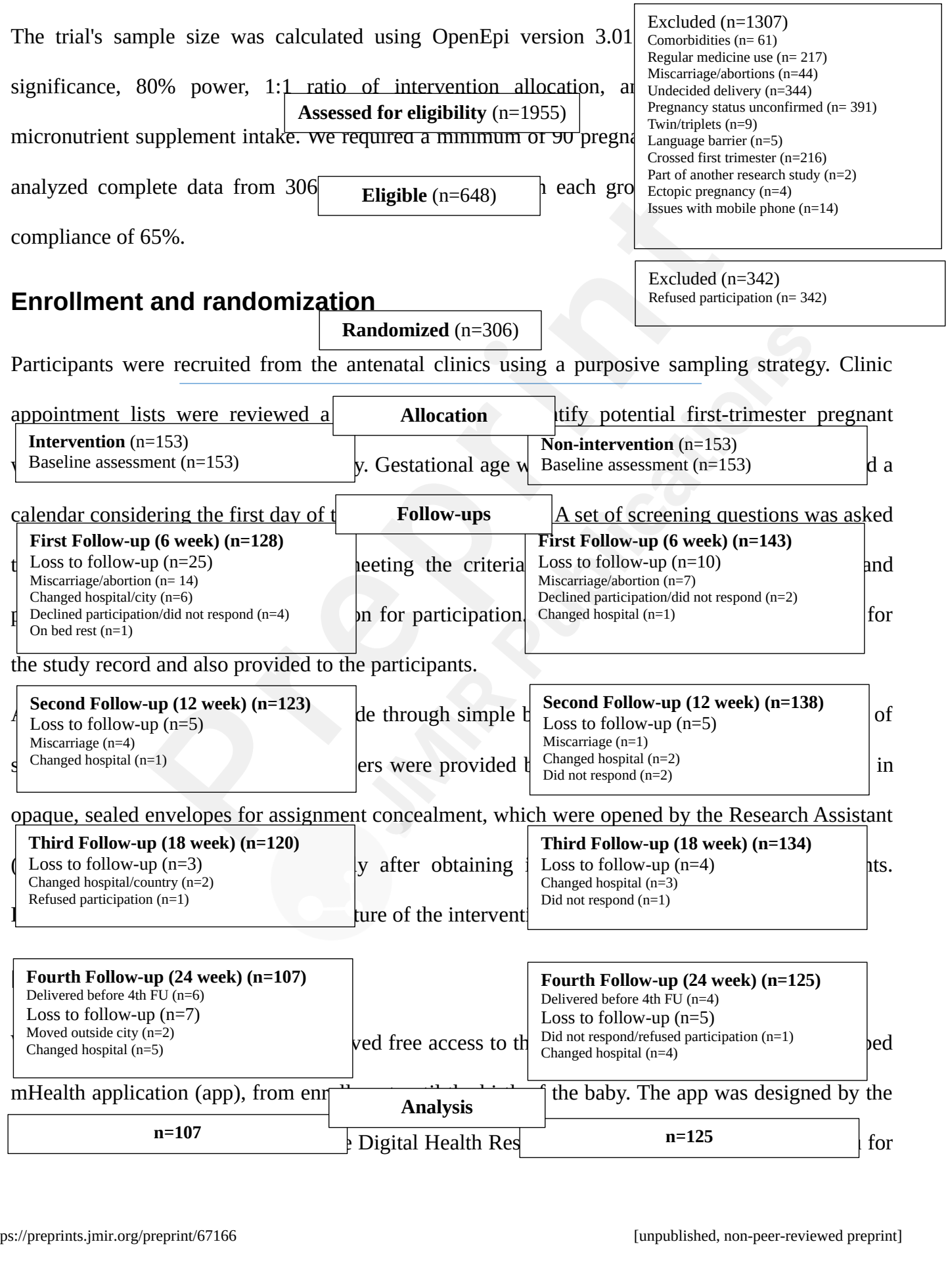
Study population

We enrolled pregnant women during their first trimester if they possessed a personal smartphone with an active internet connection, were registered for delivery at AKUH, and could read and write in Urdu and English. Women with significant comorbidities, including cardiovascular, endocrine, or autoimmune disorders, on dietary restrictions, regular medications including antihypertensive, antiplatelet aggregates, and hypoglycemic, or with a language barrier were not considered for inclusion (figure 1). The participant recruitment was carried out from January 2020 to September 2021.

Figure 1: Consort diagram

Sample size

The trial's sample size was calculated using OpenEpi version 3.01 [redacted] significance, 80% power, 1:1 ratio of intervention allocation, a[redacted] micronutrient supplement intake. We required a minimum of 90 pregna[redacted] analyzed complete data from 306 [redacted] each gro[redacted] compliance of 65%.



Enrollment and randomization

Participants were recruited from the antenatal clinics using a purposive sampling strategy. Clinic appointment lists were reviewed a[redacted] tify potential first-trimester pregnant [redacted] y. Gestational age w[redacted] d a calendar considering the first day of t[redacted] A set of screening questions was asked t[redacted] heeting the criteria [redacted] and p[redacted] n for participation. [redacted] for the study record and also provided to the participants.

A[redacted] de through simple b[redacted] of s[redacted] ers were provided b[redacted] in opaque, sealed envelopes for assignment concealment, which were opened by the Research Assistant ([redacted] y after obtaining i[redacted] nts. I[redacted] ture of the intervent[redacted]

[redacted] ved free access to th[redacted] ped mHealth application (app), from enr[redacted] the baby. The app was designed by the [redacted] e Digital Health Res[redacted] for

Android and iPhone users. DHRC established in 2011, provides strategic digital health support to the Aga Khan Development Network health agencies and their partner health institutions. Its efforts are focused on managing digital health operations and leveraging mobile technology to address health issues in LMICs [54]. Based on behavior change theories and the Trans-Theoretical Model, the app underwent a rigorous development and testing process [55] [56, 57] [58, 59]. Alpha testing addressed technical glitches, followed by beta testing, where the research team evaluated performance and integration, communicating concerns to DHRC for resolution. In the gamma-testing phase, 10% of pregnant women used the app, replicating study procedures and providing feedback for final adjustments. After comprehensive testing, the app was registered on the Google Play Store and Apple Store.

The app incorporated data collection questionnaires to complete at enrollment and subsequent follow-ups (6, 12, 18, and 24 weeks). After completing the questionnaire, women received personalized recommendations tailored to their supplement use history, using an algorithm based on the micronutrient guidelines for pregnancy (figure 2) [53]. Additionally, participants received up to three short and easily understandable push messages per week via mobile app sent through the web portal. These messages advised supplement use and the importance of key micronutrients during pregnancy (figure 3). When sent, these push messages appeared as notifications on women's mobile phones and were saved in the advice section of the app for later access.

Figure 2: Examples of recommendations in English and Roman Urdu

Supplement history	English	Roman Urdu
If women consumed folic acid daily	Well done! Continue taking folic acid daily, as advised by your doctor.	Bohot ache. Shabash! Aap rozana folic acid khana jaari rakhein, jese aap ke doctor ne tajweez kia hai.
If women did not consume folic acid daily	Folic acid is recommended to be taken daily, as it prevents neural tube defects in the first 12 weeks and anemia during pregnancy. Consult your doctor and consume 0.4 mg of folic acid tablet daily.	Folic acid rozana lene ki tajweez ki jati hai kyunke hamal ke pehle 12 hafton me folic acid bachay ki reerh ki hadi me kharabiyon ko rokhta hai aur hamal ke dauran khoon ki kami se bachata hai. Aap apnay doctor se mashwara karein aur rozana 0.4 mg folic acid ki goli khayein.
If women did not consume folic acid at all	Start taking folic acid regularly. It is recommended that folic acid should be consumed daily during the first 12 weeks to prevent neural tube defects and throughout pregnancy to prevent anemia.	Aap baqaidagi se folic acid lena shuru karein. Ye tajweez kia jata hai ke aap folic acid rozana khayein takey pehle 12 hafton me bachay ki reerh ki hadi me kharabiyon ko roka ja sakey aur hamal ke dauran khoon ki kami se bacha ja sake ge.

Figure 3: Examples of push messages in English and Roman Urdu

English	Roman Urdu
Folic acid is essential for preventing neural tube defects (malformations of the brain and spinal cord) and anemia during pregnancy.	Folic acid hamal ke doran bache ki reerh ki hadi ki kharabiyon ko aur maa ko khoon ki kami se bachata hai
Iron supplements are prescribed during pregnancy to prevent iron deficiency.	Hamal ke doran khoon ki kami se bachne ke liye iron ki goliyan di jati hain.
Take iron tablets with meals to increase absorption.	Iron ki goliyon ko khane ke saath ya khane ke foran baad lein takey yeh jism me behter jazb hosakey.
Tea and coffee prevent iron absorption and should not be consumed with/after iron supplements.	Iron ki goli ko chai ya coffee ke saath ya is ke foran baad na lein, yeh iron ko jism me jazb hone se roktey hain.
Take calcium supplements as advised. Inadequate calcium intake during pregnancy may increase the risk of preterm labor and high blood pressure.	Calcium ki goliyan doctor ki tajweez ke mutabiq rozana istemal karein. Hamal ke doran jism me nakafi calcium waqt se pehle bache ki padaish ka baais ban sakta hai aur khoon ke dabao ko barha sakta hai
Vitamin D supplements prevent its deficiency and support healthy bone development in the baby.	Vitamin D ke supplements ki madad se is ki kami se bacha ja sakta hai aur bachay ki sehat mand hadiyon ki tashkeel mein madad milti hai.

Study procedure

Intervention group

The trial was implemented by an RA with over 9 years of experience in antenatal research, along with a doctoral scholar specializing in maternal nutrition and public health. Participants in the intervention group were instructed to download and install the "PurUmeed Aaghaz" app, with specific guidance provided for Android and iPhone users. Subsequently, web portal accounts were created for each woman using their first and last names, and login credentials were provided for app access. The RA provided a detailed orientation of the app and subsequently activated the baseline questionnaire through the web portal, assisting participants in completing it. Upon questionnaire submission, personalized recommendations were generated within the app for the participants to read. Completed questionnaires were accessible in a non-editable format under each visit, allowing women to review them at their convenience.

Non-intervention group

Women randomized to the non-intervention group provided their history on paperless data collection questionnaires developed on Microsoft Access. Details were meticulously recorded, and the questionnaire was thoroughly reviewed for completeness at each contact. After completing the questionnaire, women received face-to-face counseling regarding supplement use from an RA or a doctoral scholar.

Follow-ups

Data, including micronutrient consumption, were collected at five time points spaced six (+/- 1) weeks apart: at enrollment (baseline) and 6, 12, 18, and 24 weeks afterward. These assessments aimed to monitor any improvements in micronutrient intake. Within the app, women can access and

compare their results from previous visits and obtain a summary to print or email to their obstetrician for further support in antenatal care. Access to the app remained available to the intervention group for six months or 24 weeks following enrollment, after which access was deactivated via the web portal.

Micronutrient supplement use counseling

Pregnant women in both groups were advised to follow the WHO guidelines for daily oral intake of folic acid (0.4 mg) and iron (30-60 mg) [60], calcium (1500-2000 mg), and vitamin D3 (200 IU) [61]. The only difference between the groups was the mode and frequency of counseling: the intervention group received counseling through the mHealth app during each follow-up, supplemented by up to three push messages per week. In contrast, the non-intervention group received face-to-face counseling during each follow-up.

Study outcome

The primary outcome of the study was a 30% relative improvement in adequate micronutrient intake of folic acid, iron, calcium, and vitamin D and cumulative supplement use score (CSUS) 24 weeks after initiation of the PurUmeed Aaghaz compared to the non-intervention group. For each supplement, a score of 0 meant daily use, 1.5 meant consumption for 4-6 days, and 3 meant consumption for 0-3 days over the past week. CSUS was the sum of scores across four supplements and ranged from 0 to 12, where 0 indicated highly adequate, and 12 indicated highly inadequate consumption [53].

Data collection

A comprehensive and structured questionnaire was developed and used for data collection after pretesting on 10% of the sample, administered by an RA and doctoral scholar on the mobile app for the intervention group, and a paperless questionnaire for the non-intervention group. Information

about sociodemographic characteristics (age, education, and occupation of self and spouse and household income) and obstetrics history (gravida, history of nausea, vomiting, and antiemetic use) was collected through face-to-face interviews. We also collected information on lifestyle behaviors such as a history of smoking (self and spouse), substance use, and consumption of home-cooked food, snacks, and sugary beverages. The supplement use history evaluated the frequency of consumption of each micronutrient (folic acid, iron, calcium, and vitamin D) over the past week. Anthropometric measurements (weight and height) were obtained from medical records to calculate body mass index (BMI). A subset of participants (every fourth woman) was systematically invited for a free assessment of serum folate, ferritin, calcium, and vitamin D levels at the laboratory of AKUH at baseline (enrollment-T0) and end line (24 weeks-T4). Women were considered deficient if their hemoglobin levels were <11 gm/dl, folate <2.6 ng/ml, ferritin <10 ng/ml, calcium <8.6 mg/dl, and vitamin D ≤20 ng/ml. Data collection was conducted in the clinic's waiting area while ensuring participants' privacy.

Data management and quality assurance

The research team received training focusing on the operation and functionality of both the mobile app and the web portal. Subsequently, RA received a rigorous three-day hands-on training on the study protocol, data collection tools, mobile app, and web portal, ensuring proficiency in account creation, activating questionnaires, push messages delivery, and app navigation. Periodic training sessions (monthly for the first four months, followed by quarterly sessions thereafter) and weekly meetings were held throughout the study to address concerns and to provide ongoing support.

On-site data collection underwent regular checks for accuracy and completeness. Data from the mobile app was instantly saved on the web portal in real time, with backups by the DHRC team on the server. Data from the non-intervention group was securely stored on a laptop in the password-protected folder. Study materials, including consent forms and randomization envelopes, were

prepared in advance. Additionally, a tracking document was created on MS Excel to monitor follow-up details. If a woman was lost to follow-up, her account on the web portal was deactivated after confirming via phone.

Ethical considerations

The study received approval from the Ethics Review Committee (Reference number: 0757) and the clinical trials unit of Aga Khan University. Participating women provided written informed consent at enrollment. The app was secured with a login ID and password for the intervention group. The web portal access was restricted to the research team. Confidentiality of all collected data was strictly maintained, and analysis was conducted anonymously for research purposes only.

Statistical analysis

Data from both groups were imported into and analyzed using STATA version 14, following data cleaning, labeling, and coding. Quantitative variables such as age and CSUS were reported as mean ± SD, while categorical variables such as education, occupation, income, nausea, vomiting, and supplement scores were described as frequencies and percentages. The booking height and weight were utilized to calculate BMI and categorized using the cutoff for the Asian population [62]. Income was the only variable with missing data points (32%) and was addressed using multiple imputations. The baseline characteristics of the two groups were compared using t-tests or chi-square/fisher exact tests, as appropriate.

The improvement in each micronutrient supplement was determined by subtracting the proportion scoring adequate at T0 from T4 and dividing the difference by T0. Similarly, the change in CSUS was calculated by subtracting the mean CSUS at T0 from T4 and dividing it by the baseline mean. The times the intervention group improved (or did not) compared to the baseline were calculated by dividing the percentage of change by 100.

Biochemical assessments for each study group were compared from T0 to T4 using a proportion test, with differences and 95% CIs reported. Additionally, repeated measures ANOVA for binary outcomes evaluated differences in biochemical tests between study groups over time, including interaction effects, and reported the corresponding p-values.

Random effects univariate and multivariable linear regression for panel data with robust standard errors were used to assess the efficacy of the intervention on CSUS. The panel settings utilized the time of each follow-up and the unique study ID of each participant. Results included unadjusted and adjusted Beta (β) coefficients with 95% CIs. Similarly, random effects univariate and multivariable binary logistic regression for panel data, with robust standard errors, were used to assess the effect of the intervention on the sufficiency of each supplement. For this purpose, we combined the scores of adequate (0) and intermediate (1.5) to generate a category of sufficient intake (scores 0 (daily) +1.5 (4-6 days)), while a score of 3 indicated insufficient use. The categorization was done because very few women scored intermediate at baseline, with numbers reducing to zero at 24 weeks. Results were reported as unadjusted and adjusted odds ratios (OR) with corresponding 95% CIs.

In univariate analysis, variables with a p-value <.25 were considered for inclusion in the multivariable model. The adjusted analysis was conducted using a stepwise approach and variables with p-values <.05 were considered significant. Confounders such as vomiting and lifestyle habits were assessed using the 10% rule of change in estimates (β or OR), and the variance inflation factor evaluated multicollinearity among independent variables. Models were adjusted accordingly in the presence of confounders. The analysis followed the intention-to-treat principle.

Results

Among 306 pregnant women enrolled, we observed insignificant differences in the baseline sociodemographic characteristics, obstetric history, anthropometric assessment, and lifestyle habits between the intervention and non-intervention groups (Table 1).

Table 1: Baseline characteristics of the study participants

Characteristics	Intervention (n=153) n (%)	Non-intervention (n=153) n (%)	p-value
Sociodemographic characteristics			
Age (years) mean ± SD	28.7 ± 4.3	28.1 ± 4.1	.162[a]
Age (years)			
<25	22 (14.4)	26 (17.0)	
25-34	117 (76.5)	117 (76.5)	.184[b]
≥35	14 (9.1)	10 (6.5)	
Education, self			
Up to high school	34 (22.2)	33 (21.6)	.890[b]
University	119 (77.8)	120 (78.4)	
Occupation, self			
Employed	50 (32.7)	54 (35.3)	.629[b]
Unemployed	103 (67.3)	99 (64.7)	
Education, spouse			
Up to high school	10 (6.5)	15 (9.8)	.297[b]
University	143 (93.5)	138 (90.2)	
Occupation, spouse			
Employed	153 (100.0)	153 (100.0)	>.999[b]
Unemployed	0	0	
Monthly household income (PKR)			
<100,000	92 (60.1)	103 (67.3)	.191[b]
≥100,000	61 (39.9)	50 (32.7)	
Obstetric history and anthropometry			
Gravida			
Primi	69 (45.1)	65 (42.5)	.645[b]
Multi	84 (54.9)	88 (57.5)	
History of nausea	107 (69.9)	106 (69.3)	.901[b]
History of vomiting	86 (56.2)	82 (53.6)	.646[b]
History of antiemetic use	58 (37.9)	51 (33.3)	.403[b]
Body Mass Index (Kg/m^2)			
Underweight (<18.5)	10 (6.5)	14 (9.2)	
Normal (18.5-22.9)	45 (29.4)	45 (29.4)	.687[b]
Overweight/obese (≥23)	98 (64.1)	94 (61.4)	
Lifestyle habits			
Substance use, self	0 (0)	5 (3.3)	.060[b]
Smoker, spouse	30 (19.6)	31 (20.3)	.886[b]
Daily intake of homecooked meals			
Up to two	39 (25.5)	37 (24.2)	.791[b]
Three	114 (74.5)	116 (75.8)	
Weekly intake of:			
Savory snack	81 (52.9)	85 (55.6)	.646[b]
Sweet snacks	113 (73.9)	116 (75.8)	.693[b]
Readymade meals	87 (56.9)	82 (53.6)	.565[b]
Carbonated beverages	74 (48.4)	69 (45.1)	.567[b]
Packaged juices	49 (32.0)	56 (36.6)	.399[b]

Tea	93 (60.8)	95 (62.1)	.814[b]
Coffee	10 (6.5)	10 (6.5)	>.999[b]

[a]t-test for independent sample

[b]chi-square or Fisher exact test

Micronutrient supplement use at baseline and end line

Out of 306 women, 232 (75.8%) completed the study, with 107 (70%) in the intervention group and 125 (81.7%) in the non-intervention group. At baseline, folic acid was the most adequately consumed supplement for both groups. However, the proportion of daily iron users was higher in the non-intervention group, while the proportion of daily calcium users was significantly greater in the intervention group. Vitamin D use was almost similar. After 24 weeks, the intervention group showed significant improvement in daily iron and vitamin D use, while folic acid improvement was comparable, and calcium use improved more in the non-intervention group (Table 2).

Table 2: Micronutrient supplement use at baseline (T0) and end line (T4)

Micronutrients	**Baseline (T0)**			**End line (T4)**			**Improvement in adequacy T4 –T0**	
	Intervention (n=153)	**Non-intervention (n=153)**		**Intervention (n=107)**	**Non-intervention (n=125)**		**Intervention**	**Non-intervention**
	n (%)	**n (%)**	**p-value**	**n (%)**	**n (%)**	**p-value**		
Folic acid								
Adequate	124 (81.0)	121 (79.1)		104 (97.2)	121 (96.8)			
Intermediate	4 (2.6)	6 (3.9)	.834[a]	1 (0.9)	0 (0)	.544[a]	20%	22.4%
Inadequate	25 (16.3)	26 (17.0)		2 (1.9)	4 (3.2)			
Iron								
Adequate	12 (7.8)	36 (23.5)		102 (95.3)	91 (72.8)			
Intermediate	0 (0)	2 (1.3)	<.001[a]	0 (0)	0 (0)	<.001[a]	11.2 times	2.1 times
Inadequate	141 (92.2)	115 (75.2)		5 (4.7)	34 (27.2)			
Calcium								
Adequate	47 (30.7)	9 (5.9)		71 (66.4)	112 (89.6)			
Intermediate	2 (1.3)	1 (0.6)	<.001[a]	0 (0)	1 (0.8)	<.001[a]	1.2 times	14.2 times
Inadequate	104 (68.0)	143 (93.5)		36 (33.6)	12 (9.6)			
Vitamin D								
Adequate	31 (20.3)	37 (24.2)		86 (80.4)	69 (55.2)			
Intermediate	2 (1.3)	6 (3.9)	.232[a]	1 (0.9)	1 (0.8)	<.001[a]	3 times	1.3 times
Inadequate	120 (78.4)	110 (71.9)		20 (18.7)	55 (44.0)			
CSUS mean± SD[a]	7.72 ± 3.05	7.87 ± 2.66	.654[b]	1.79 ± 2.46	2.54 ± 2.30	.017[b]	-76.7%	-67.7%

[a]p-value from chi-square/fisher exact test

[b]p-value from t-test

Biochemical assessment of micronutrients at baseline and end line

After 24 weeks, anemia decreased by 5% in the intervention group but increased by 22% in the non-intervention group, with a significant interaction observed between study groups and the time period. Folate deficiency was not observed in either group. Serum levels of ferritin, calcium, and vitamin D did not show reflective improvements at the end line in either group. In fact, ferritin and calcium deficiencies were augmented in the non-intervention group (Table 3).

Table 3: Biochemical assessment of micronutrients at baseline and end line

Biochemical tests	Intervention			Non-intervention			p-value[b]		
	Baseline (T0) n (%)	End line (T4) n (%)	Difference (T4-T0)[a]	Baseline (T0) n (%)	End line (T4) n (%)	Difference (T4-T0)[a]	Study groups	Time	Interaction[c]
Anemia (Hb <11 gm/dl)	6 (28.6)	n=21 5 (23.8)	-0.05 (-0.31, 0.22)	10 (37.0)	n=27 16 (59.3)	0.22 (-0.04, 0.48)	.117	.371	.027
Folate deficiency (<2.6 ng/ml)	0 (0)	n=15 0 (0)	-	0 (0)	n=21 0 (0)	-			
Low ferritin (<10 ng/ml)	2 (13.3)	n=15 3 (20.0)	0.07 (-0.20, 0.33)	6 (27.3)	n=22 8 (36.4)	0.09 (-0.18, 0.36)	.221	.353	.886
Hypocalcaemia (<8.6 mg/dl)	2 (11.8)	n=17 2 (13.3)	0.02 (-0.21, 0.25)	3 (15.8)	n=19 11 (57.9)	0.42 (0.14, 0.70)	.009	.057	.057
Vitamin D deficiency (≤20 ng/ml)	6 (46.1)	n=13 7 (53.8)	0.08 (-0.31, 0.46)	17 (80.9)	n=21 17 (80.9)	0 (-0.24, 0.24)	.015	.711	.711

[a]Proportion test

[b]p-value for repeated measures ANOVA

[c]Interaction between study groups and time

Efficacy of intervention on the sufficiency of supplement use and cumulative supplement use score

Both unadjusted and adjusted analyses showed marginally higher, but statistically non-significant, odds of sufficient folic acid use in the intervention group. The intervention group showed significant improvement in sufficient use of iron and vitamin D as well as mean CSUS compared to the non-intervention group. On the other hand, the non-intervention group demonstrated significantly higher

odds of sufficient calcium use (Table 4).

Table 4: Unadjusted and adjusted analysis of the efficacy of the intervention on sufficiency of supplement use

Micronutrient supplements	Unadjusted		Adjusted	
	OR / β (95% CI)	p-value	aOR / β (95% CI)	p-value
Folic acid	1.06 (0.59, 1.92)[a]	.845	1.14 (0.63, 2.07)[c]	.659
Iron	1.24 (0.98, 1.56)[a]	.077	1.41 (1.06, 1.89)[d]	.020
Calcium	0.65 (0.52, 0.81)[a]	<.001	0.62 (0.47, 0.81)[e]	<.001
Vitamin D	1.83 (1.42, 2.36)[a]	<.001	1.97 (1.51, 2.57)[f]	<.001
CSUS	-0.23 (-0.60, 0.14)[b]	.230	-0.40 (-0.79, -0.01)[g]	.043

[a]Odds ratio (OR)
[b]Beta coefficient (β**)**
[c]OR adjusted for age, education, vomiting, gravida, smoking among spouses, and intake of savory snacks
[d]OR adjusted for age, occupation, vomiting, BMI, smoking among spouses, and intake of savory snacks and carbonated beverages
[e]OR adjusted for vomiting, gravida, smoking among spouses, and intake of carbonated beverages and coffee
[f]OR adjusted for vomiting, gravida, smoking among spouses, and intake of carbonated beverages
[g]β adjusted for age, occupation, vomiting, smoking among spouses, and intake of home-cooked meals, savory snacks, and carbonated beverages
Note: The non-intervention group is taken as a reference
Note: Panel settings included the time of each follow-up and participant ID.

Discussion

Principal results

The personalized mHealth intervention- PurUmeed Aaghaz - showed significant improvement in micronutrient supplement use among pregnant women, particularly for iron and vitamin D.

Comparison with prior work

Folic acid was the most frequently used supplement, with around 80% of women already taking it before the intervention, aligning with guidelines recommending its use in preconception and early pregnancy to reduce neural tube defects [63]. This usage is consistent with higher adherence observed among Dutch (85.4% and 90.8%) [41, 64], Australian (79%) [65], and Iranian women (54.5%) [66]. Conversely, in Pakistan, only 33.4% and 38.3% of women received IFA during their

last pregnancy [22, 67]. Evidence suggests that women aware of folic acid usage benefits during pregnancy are 25 times more likely to use it than those who are not [68]. Therefore, counseling pregnant women as early as the first trimester is essential to improve adherence and ensure better health outcomes.

Improvement in folic acid use remained sustained until the end line in both groups. This is consistent with other studies examining the impact of mHealth on folic acid supplementation. For instance, an RCT by Van Dijk et al. found no significant difference in folic acid use among Dutch women receiving personalized and tailored coaching through the mHealth app compared with those without personalized interaction [64].

On the contrary, a Dutch survey reported a 56.3% improvement in folic acid use among pregnant women using the Smarter Pregnancy app after six months, though it lacked a comparison group [41]. Additionally, a cluster randomized trial found that women using the PRENACEL app, which included weekly text messages and provider interaction, were more likely to receive a folic acid prescription compared to routine ANC (83% vs. 75.9%) [69].

The comparable improvement in folic acid adequacy between the groups underscores the need for further investigation into mHealth interventions, particularly in populations with lower folic acid use. The insignificant difference may be due to a wider awareness of folic acid's role in early pregnancy to prevent NTDs. This awareness likely led to prevalent folic acid use at baseline before implementation of the intervention, limiting room for improvement. Further, this could be attributed to the higher educational status and urban residence of our participants, as poor adherence to folic acid usage has been observed in rural and less educated women [67].

The positive role of mHealth intervention was evident in significantly improving daily iron supplementation. These findings are consistent with previous research, which shows that digital health interventions have the potential to improve iron supplement uptake. Although the improvement in iron usage in a Kenyan study was marginally different (91.6% in the intervention

group compared to 87.4% in the control group) [70], this improvement was comparable in the Indian population (81% vs. 69%). Further, the prevalence of anemia was less prevalent in the intervention group than in the control group (36% vs. 45%) [71]. SMS reminders versus usual care have also been reported to improve compliance with iron tablets consumption (94% versus 66%). However, each group observed a significant decrease in hemoglobin and ferritin levels [72].

Evidence from various studies supports the effectiveness of mHealth interventions in improving iron supplementation. For instance, in India, a government mandated maternal care via mHealth led to a more significant increase in iron tablet consumption from baseline to end line (25.3%) compared to traditional care (14.3%) [73]. Similarly, Sontakke et al. demonstrated that mobile phone call reminders combined with standard care resulted in higher compliance (85.8%) compared to standard care alone (77.5%) [74]. In Malaysia, a cluster-randomized trial showed that the MyPinkMom intervention, which included six infographic videos, significantly improved attitudes toward adherence to iron supplementation over routine counseling [75]. Additionally, a study in Liberia revealed that mobile phone tele-reminders significantly increased the likelihood of completing monthly iron and folic acid supplementation (≥28 days) (aOR: 5.0; 95% CI: 1.29-19.42) than those who did not receive reminders [76].

In our study, though iron supplement use improved significantly in the intervention group, it was not concomitantly reflected in improvement in ferritin levels. This may be due to the fact that iron supplementation without simultaneous dietary improvement may not be sufficient to improve iron stores, especially for women who begin pregnancy with insufficient iron reserves. Additionally, iron supplementation only during pregnancy may not provide enough window of opportunity to fully replenish depleted iron levels, which may require several months to do so if daily iron dosage is not adjusted according to the body weight and baseline ferritin levels.

Unlike folic acid and iron, there is limited research on mHealth interventions for improving calcium

supplement compliance in LMICs. Existing studies are predominantly from developed countries, where calcium deficiency is relatively less prevalent. In Pakistan, 32.7% of pregnant women experience calcium deficiency, exacerbated by physiological changes during pregnancy and linked to hypertensive disorders [77]. Given the poor nutritional status of women in Pakistan, calcium supplementation is vital to support fetal development and maintain maternal well-being. Contrary to our findings, a cluster RCT in a remote highland region of Vietnam demonstrated a significant increase in calcium supplement use from 60.2% to 91.5% in the group receiving SMS reminders, while the control group saw a decrease from 84.2% to 76.9% [78].

In contrast, we observed significant improvement in calcium supplement use by 24 weeks in the non-intervention group (89.7%) compared to the intervention group (50.6%). However, despite this significant improvement in calcium supplement use, there was a notable increase in hypocalcemia over the study period in the non-intervention group compared to the intervention group. This could be due to the fact that calcium supplementation was not potentially supported by the intake of calcium-rich foods, and there was a co-existing vitamin D deficiency as well. The modest improvement in calcium supplement use observed after mHealth intervention in our population indicates a need to refine and strengthen our messages and recommendations, emphasizing the critical role of calcium supplementation and appropriate diet during pregnancy.

Our findings indicate that mHealth intervention could be a valuable way of addressing widely prevalent vitamin D deficiency among WRA and pregnant women in LMICs, particularly in Pakistan, where digital health interventions targeting vitamin D supplement use are scarce. A significant improvement over 24 weeks in vitamin D supplementation (from 20.3% to 80.4%) compared to the non-intervention group (from 24.2% to 55.2%) was, however, not reflected in improvement in vitamin D levels.

Strengths and limitations

Our study represents a pioneering effort in Pakistan to evaluate the efficacy of an mHealth

intervention in promoting supplement use during pregnancy. By enrolling women in the first trimester and following them until the third trimester, we obtained comprehensive data on supplement use throughout pregnancy. Secondly, employing an RCT design ensured unbiased allocation of participants to study groups, enhancing the robustness of our findings.

However, certain limitations must be acknowledged while evaluating our findings. Participants were recruited from antenatal clinics of a tertiary care hospital based on specific eligibility criteria, potentially limiting the generalizability of our findings to the broader population. Nonetheless, these stringent inclusion criteria were essential to address our research objective. Additionally, a considerable proportion of women refused participation in the study, likely due to its implementation coinciding with the onset of the COVID-19 pandemic. The pandemic caused many women to avoid visiting clinics, and those who did visit were reluctant to consent or participate in the study.

Furthermore, many women switched hospitals to those closer to their homes due to the ongoing lockdown, resulting in a lost to follow-up, despite our attempts to support scheduling and retention. We acknowledge potential sociodemographic differences between women who participated in the study and those who declined, which may affect the study's findings. In addition, the RA and PhD scholar performed participant recruitment and data collection, which could introduce information bias. However, we ensured that the lack of blinding did not affect outcome assessment by stringently following the study protocol.

Moreover, in the RCT, the mHealth intervention offered tailored recommendations and thrice-weekly push messages to enhance engagement beyond standard antenatal care. Typically, women in routine antenatal settings receive only brief counseling with minimal focus on diet and micronutrients, which may reduce compliance. The intervention has the potential to be implemented outside of RCTs, enabling women to fill out screening questionnaires for personalized recommendations. Additionally, the push messages can be automated, underscoring the benefits of integrating such interventions into routine care.

Conclusion and implications

During the first trimester of pregnancy, women attending tertiary care hospital do not consume iron, calcium, and vitamin D supplements adequately. Our personalized mHealth intervention improved usage of all four micronutrient supplements, though significant improvements were observed for iron and vitamin D supplements, even after adjustment of covariates. However, the non-intervention group displayed higher odds of adequacy for calcium intake. Biochemical assessments of a subset of women revealed no improvement in serum levels of ferritin, calcium, and vitamin D over time. In fact, deficiencies in iron and calcium worsened in the non-intervention group. No folate deficiency was observed among the participants.

Inadequate nutrient intake before and during pregnancy, combined with increased nutritional requirements and metabolic demands, can contribute to or exacerbate micronutrient deficiencies. With the rising mobile phone and internet usage in Pakistan, mHealth interventions offer promise as an effective tool for improving micronutrient supplement utilization during pregnancy, overcoming the limitations of conventional counseling methods. Future research should consider exploring the effect of digital health interventions across diverse populations and target various health behaviors among pregnant women to further enhance maternal and fetal health outcomes.

Authors' contributions

Study was conceptualized by RN, KV, NM and SS. The study methodology was developed by RN, KV and SS. The study implementation on field and data management were performed by KV. Data analysis was performed by KV with the support of IA. The initial and revised manuscript drafts were prepared by KV and critically reviewed by RN, NM and IA. The study funding was acquired by RN, and NM. RN provided supervision for all aspects of the study. All the authors reviewed and approved the final version of the manuscript.

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Conflicts of Interest

None declared

Abbreviations

AKUH: Aga Khan University Hospital

aOR: adjusted odds ratio

BMI: body mass index

CSUS: cumulative supplement use score

LBW: low birth weight

LMICs: low and middle-income countries

mHealth: mobile health

PTB: preterm birth

RCT: randomized controlled trial

WHO: World Health Organization

WRA: Women of reproductive age

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Supplementary Files

Multimedia Appendixes

Unadjusted and adjusted analysis of the efficacy of the intervention on the cumulative supplement use score (CSUS) and sufficiency of folic acid, iron, calcium and vitamin D.
URL: http://asset.jmir.pub/assets/6012884f40085e857980c9f4d3719700.doc

CONSORT (or other) checklists

e-Consort checklist.
URL: http://asset.jmir.pub/assets/e1108f5f3c4e865968ca5f881774320a.pdf