

**Evaluation of an mHealth SMS dialogue strategy to meet women's and couples'
postpartum contraceptive needs in Kenya (Mobile WACH XY):
A randomized controlled trial**

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Abstract

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Objective: To evaluate the effect of a two-way SMS intervention on postpartum contraceptive use among individual women and couple dyads.

Methods: Mobile WACH XY was an unblinded randomized controlled trial conducted in two public county hospitals in western Kenya. Pregnant, HIV-negative women at least 14 years of age with estimated gestational age ≥ 28 weeks who had access to a mobile phone, were able to read and respond to SMS, and intended to remain in the area until trial completion were included. Women were randomly assigned (1:1) to receive two-way SMS or control (no SMS). Prior to randomization, partnered women had the option to refer male partners; if referred, study staff approached men for enrollment. Family planning (FP)-focused SMS messages were delivered weekly from enrollment to 6 months postpartum, and the SMS platform enabled SMS dialogue with a nurse. Follow up visits occurred at 6 and 14 weeks and 6 months postpartum. The primary outcome, self-reported highly effective contraceptive (HEC) use at 6 months postpartum, was compared between groups by the χ^2 test, and Poisson regression with robust standard errors was used in adjusted analysis.

Results: We enrolled 260 women (130 to each group), and 254 women were included in the analysis. Median maternal age was 23 (IQR 20-26.5), and 198 women (76.2%) were partnered, of whom 153 referred male partners for trial inclusion. Of these, 103 men were enrolled. At 6 months postpartum, 69.9% women who received two-way SMS were using HEC, compared with 57.4% in the control group. In an analysis adjusted for baseline differences in education, parity, and desire for future children, the adjusted risk ratio for HEC use was 1.26, 95% CI 1.04-1.52, $p=0.02$.

Conclusions: This two-way SMS intervention focused on FP education and counseling led to increased HEC use at 6 months postpartum among women and couples in Kenya.

INTRODUCTION

Addressing high unmet need for contraception among postpartum women in low- and middle-income countries is a research and programmatic priority in family planning.^{1,2} Demographic and health survey (DHS) data from 2004-2013 estimate that 65% of women in East and Southern Africa who gave birth in the prior year were not using contraception despite not wanting a pregnancy in the next two years.³ In Kenya, unmet need for limiting and spacing pregnancies within the first 2 years postpartum was prospectively estimated at 57%.⁴ Recognizing the missed opportunities for improving sexual and reproductive health (SRH) as well as child health outcomes,⁵ the FP2020 global initiative has identified postpartum family planning (FP) within one year of delivery as a critical component of global FP strategy.⁶

Postpartum women have specific FP needs that may not be well-served by traditional FP programs. Social norms and practices surrounding the resumption of sexual activity after delivery, as well as pregnancy risk perception during lactation and prior to resuming menses, are important drivers of postpartum FP use and continuation.⁷⁻⁹ Contraceptive side effect and safety concerns,^{8,9} low postpartum visit attendance,¹⁰ and concern about partner disapproval¹¹ are also cited as barriers to meeting postpartum women's FP needs. The majority of postpartum women in Kenya initiate short-acting methods,^{4,12} and method switching and discontinuation are common.¹³ A recent study found that while 49% of postpartum women in a Nairobi cohort initiated a contraceptive method by 6 months of delivery, almost half discontinued within 12 months of initiation.¹² Antenatal FP counseling has had inconsistent effects on FP use after delivery.^{2,7} Furthermore, while male partners are known to play a critical role in reproductive decision-making^{14,15} and there is great global interest in strategies to engage them in FP,¹⁶ few FP programs have successfully incorporated men. Qualitative research from Kenya highlights both men's and women's desire for men to be included in FP education, as well as widespread male resistance to FP and its negative impact on women's contraceptive choices.^{17,18} There is an urgent need for tailored and innovative strategies to meet women's FP needs postpartum.

Interventions using mobile health (mHealth) technologies, including short message service (SMS), have shown promise in a variety of contexts in resource-limited settings, such as improvements in infant HIV testing rates¹⁹ and antiretroviral adherence in HIV care.²⁰ While mHealth approaches are increasingly used in global FP and SRH programs, there is limited evidence of efficacy.²¹ A trial in Cambodia demonstrated increased post-abortion contraceptive uptake among women who received a mobile phone intervention²²; another randomized

evaluation of a widely disseminated, FP-focused SMS program in Kenya showed no effect on contraceptive use.²³ While data on the use of SMS for postpartum contraceptive education and counseling is lacking, mHealth approaches could be a valuable adjunct to facility-based care. In light of the specific barriers facing postpartum women's contraceptive access, an interactive and tailored program that allows for SMS dialogue with a health care provider (two-way SMS) and real-time support for questions and concerns may be useful. The Mobile Wach XY trial aimed to evaluate the effect of two-way SMS on postpartum contraceptive use.

METHODS

Study design

Mobile WACH XY was an unblinded randomized controlled trial (RCT) implemented at two Kenyan Ministry of Health hospitals in the Nyanza region of western Kenya, Ahero sub-County Hospital and Bondo County Hospital. These facilities serve a predominantly low-income, rural population and provide a wide range of antenatal and maternal child health care services. In 2014, unmet need for family planning among married women in the study region was estimated at 23.3%, the second-highest in the country.²⁴ This study was approved by the institutional review boards at the Kenyatta National Hospital/University of Nairobi (Ethics and Research Committee) and the University of Washington (Human Subjects Division).

Participants

Female participants were recruited from antenatal clinics by study nurses at each facility and screened with a tablet-based questionnaire. Eligible women were at least 14 years of age; pregnant with an estimated gestational age of ≥ 28 weeks; able to read and respond to SMS themselves or with assistance in English, Kiswahili, or Dholuo; reported daily access to a mobile phone using the Safaricom network; planned to remain in the study area for 6 months postpartum; reported HIV negative status; and were not participating in another research study. HIV-infected women were excluded due to an ongoing mHealth study at the same facilities implementing an SMS intervention specific to this population.²⁵ Women signed written consent forms at enrollment, which were available in English, Kiswahili, and Dholuo. The informed consent process emphasized that SMS content would provide overt FP information and counseling, and that end user privacy concerns should be considered prior to enrollment.

After signing informed consent, but prior to randomization, women were asked about their partnership status. If partnered, participants were given the opportunity to refer their male partners for recruitment into the trial. Male partners of women allocated to the two-way SMS Intervention, if enrolled, would also receive SMS. Male partner referral was voluntary and not required for continued study participation. Each referred partner was contacted via phone by male study staff and home visits were arranged; enrollment occurred in the community setting.

Randomization

Women were randomly assigned (1:1) to either two-way SMS or control (no SMS) groups using random block randomization. A statistician with no other study involvement prepared sequentially numbered, sealed, opaque envelopes containing allocation assignments, which were distributed to each site. Study participants and staff could not be masked to group allocation, due to the nature of the intervention. Male partners were enrolled within 3 weeks of randomization and were allocated to the same SMS group as their female partners.

Procedures

All women received standard antenatal and postnatal care as offered at the facility, but the control group did not receive SMS. Women in the two-way SMS intervention registered their mobile phone numbers in the Mobile WACH SMS delivery system and received a brief orientation to the intervention at the enrollment visit. The Mobile WACH platform is a human-computer hybrid communication system designed at the University of Washington that enables automated sending of SMS as well as SMS dialogue between participants and study clinicians; it has been previously used in other trials and is described in detail elsewhere.²⁵ The online system, hosted on a secure server, allows study clinicians to view and answer SMS messages, manage study visit dates and participant-specific details such as delivery date or FP method choice, and track retention activities. Participants indicated their language of choice (English, Kiswahili, or Dholuo), a preferred name for their personalized messages, and a preferred day of the week (Sunday through Thursday) and time to receive automated messages. Study nurses demonstrated that sending SMS to the study short code was free of charge through Safaricom, and explained that nurses were available to respond to messages only on weekdays during business hours and that the SMS system should not be used for urgent medical needs. Women were able to discontinue SMS at any time by sending the message “stop” to the study short code.

The Theory of Planned Behavior²⁶ was used to guide message development; FP message content was refined and the Mobile WACH SMS platform adapted from the findings of formative pre-RCT focus group discussions with women and men. Automated SMS were structured to contain a health education message, and each message ended with an actionable piece of advice or a question designed to promote interaction and SMS dialogue with the study nurse. Automated message content centered around postpartum FP, and included information about available methods and their hierarchy of effectiveness, postpartum pregnancy risk, contraceptive safety during lactation, anticipatory guidance about side effects, community misperceptions about contraceptive risks, and dual protection against sexually transmitted infections and pregnancy.

Automated messages were sent once weekly from enrollment until 6 months postpartum: message content corresponded to participants' gestational age in pregnancy, or week postpartum after delivery. Approximately one-third of messages were focused on general perinatal support and encouragement, healthy pregnancy and postpartum care, and promotion of exclusive breastfeeding. Women whose male partners were referred for the trial received messages tailored for couple dyads. The messages were personalized for both members of the couple and used couple-specific language around communication. If the male partner was ultimately not enrolled, the couples-specific messaging was sent to the female partner only. When postpartum women or couples indicated initiation of a contraceptive method, they switched into method-specific automated messaging, which was designed to support continuation and real-time side effect management related to the chosen method. Once enrolled in the study, male partners' phone numbers were also registered in the SMS delivery system. Male partners of women in the two-way SMS group received the same messages as their female partners (those tailored for couples), and were able to send messages to the study nurse as well. The study nurse was able to forward questions from one partner to the other, and reply to one or both members of the couple, as appropriate.

Study nurses administered a tablet-based baseline survey to all participants at enrollment. Women received a home visit within two weeks of the first study visit, to enable future follow up in case of inability to contact by phone. All participants were asked to notify the study team when they delivered, either by calling/sending an SMS to a study administration mobile number (control and intervention group), or by sending an SMS to the study short code (intervention group only). Study nurses called each participant 2 weeks after delivery (if the delivery date was known), or 2 weeks after the estimated delivery date to confirm delivery and

contact information. Study visits at the facility were scheduled at 6 and 14 weeks and 6 months postpartum, corresponding with the infant immunization schedule. At each study visit, study nurses administered a tablet-based survey. FP use and date of initiation were ascertained by self report. If a participant stated an intention to start a contraceptive method that day at the clinic, but had not yet initiated at the time of the study visit, she was not considered a contraceptive user at that time point. If a participant missed a 6-week or a 6-month study visit, she received a phone call 2 weeks after the scheduled visit in an attempt to reschedule. In the case of a missed 6-month study visit, if the participant could not be reached by phone, study staff visited the home and completed the final study visit at home. Study staff were trained to avoid any clinical interaction or counseling at study visits, home visits, and during phone calls for retention purposes. Study staff instead referred participants to non-study facility clinicians or, if allocated to two-way SMS, to communicate with the study nurse via SMS. Male partners were surveyed at enrollment and at 6 months postpartum in the community setting.

Outcomes

The primary outcome of the trial was current self-reported use of a highly effective contraceptive (HEC) method at 6 months postpartum. Highly effective methods were defined as modern methods available in Kenya with a <10% typical use failure rate: permanent contraception (male or female), contraceptive implant, copper intrauterine device (IUD), injectable contraception (depot medroxyprogesterone acetate), and oral contraception. Any contraceptive use was defined as use of a barrier, calendar, lactational amenorrhea methods (at visits prior to 6 months postpartum) or HEC methods. Secondary outcomes included self-reported HEC use, any contraceptive method use, exclusive breastfeeding, FP satisfaction, contraceptive discontinuation by 6 months postpartum, and time to first initiation of any contraceptive method.

Statistical analysis

We had 80% power to detect a 50% increase in HEC use at 6 months postpartum in the intervention versus control group with a sample size ≥ 196 , assuming a two-sided $\alpha=0.05$ and 40% estimated baseline HEC use in the control population.²⁷⁻²⁹ To account for potential 20% attrition, we increased our sample size to 260 women.

All analyses were intention-to-treat and completed in STATA 14.2 (College Station, TX: StataCorp LP). Categorical primary and secondary outcomes were compared using the χ^2 test.

Relative risk (RR) was calculated with a RR >1 indicating higher contraceptive use in the intervention group. Poisson regression with robust standard errors was used to adjust for variables that were unbalanced between groups at baseline despite randomization. In secondary analysis of initiation of any contraceptive method, a Cox proportional hazards model was constructed to assess the relationship between the intervention and time to initiation of any contraceptive method. Probabilities of contraceptive initiation by 6 and 14 weeks and 6 months postpartum were estimated using the Kaplan-Meier method and compared using the Wald test. A test of proportional hazards demonstrated no violation of the assumption. Pre-specified subgroup analyses of the primary outcome by male partner referred or enrolled status were compared by the χ^2 test. The trial was registered with ClinicalTrials.gov, NCT02781714.

RESULTS

Study recruitment, enrollment, and retention

Between July 19 and December 6, 2016, 648 women were assessed for eligibility, 388 (59.9%) were ineligible or declined participation, and 260 (40.1%) women were enrolled (figure 1). The most common reasons for ineligibility (non-exclusive) were gestational age less than 28 weeks (46%), no daily access to a mobile phone (28%), lack of a Safaricom SIM card (12%), and receipt of antenatal care elsewhere (18%). Among enrolled women, 130 were randomized to each group. Three participants withdrew and 3 were lost to follow up prior to the first study visit; a total of 254 participants were included in the analysis. An additional 2 participants in the intervention group were lost to follow up after attending the 14-week visit. The SMS intervention was stopped on request for four women who were included in the analysis. The primary outcome analysis included the 252 women who attended the 6-month postpartum visit, for 97% overall retention. There were 2 stillbirths in each randomization group; 2 neonatal deaths occurred in the intervention group, and 3 in the control group.

Characteristics at randomization

Baseline characteristics are shown in table 1. Median age was 23 (IQR 20-26.5), and median gestational age at enrollment was 32 weeks (IQR 30-36). Most women were partnered (76.2%), and currently married (70.4%). Of 198 partnered women, 158 (79.8%) referred their male partners for inclusion in the trial, and 103 (52.0%) were enrolled. The majority had a primary school or less education (54.2%), were parous (56.5%), and had ever used a

contraceptive method (58.5%). Half (50.0%) of enrolled women considered their current pregnancies to be unintended or mistimed. The minority, 46 (17.7%) shared their phones and 97 (37.3%) reported ever having used the internet. The groups were balanced at baseline with the exception of education category, parity, and desire for another child in the future.

Outcomes

Overall contraceptive use was similar among SMS and control at each of the 3 time points in the unadjusted analysis (RR 1.00, 95% CI 0.60-1.66 at 6 weeks; RR 1.12, 95% CI 0.89-1.41, $p=0.34$ at 14 weeks; RR 1.18, 95% CI 1.00-1.38, $p=0.05$ at 6 months) (table 2). When adjusted for variables found to be unbalanced at enrollment despite randomization (education, parity, and desire for future children), the intervention group was more likely to use contraception at 6 months (adjusted RR [aRR] 1.19, 95% CI 1.01-1.41, $p=0.04$). Contraceptive users in both groups reported similarly high levels of satisfaction with their methods. HEC use at 6 and 14 weeks postpartum did not differ between groups (RR 0.77, 95% CI 0.41-1.44, $p=0.41$ at 6 weeks; RR 1.09, 95% CI 0.84-1.42, $p=0.51$ at 14 weeks). HEC use at 6 months postpartum was significantly higher among women in the SMS group (69.9%) compared with the control group (57.4%) (Relative risk [RR] 1.22, 95% CI 1.01-1.47, $p=0.04$). In the adjusted analysis, 6-month HEC use remained associated with treatment assignment (adjusted RR [aRR] 1.26, 95% CI 1.04-1.41, $p=0.02$).

Injectable contraception was the most popular method in both groups, accounting for 41.4% (53/128) of users and 23.2% of all attendees at 14 weeks and 45.5% (80/176) and 31.7%, respectively, at 6 months (figure 2). Long-acting reversible contraception use, specifically the contraceptive implant, was also high in both groups. Implant users made up 35.2% and 36.4% of overall contraceptive users (19.7% and 25.4% of all attendees) at 14 weeks and 6 months respectively. Method mix was similar between the groups at 14 weeks, but by 6 months postpartum more women in the intervention group were using the most highly effective methods. Only one repeat pregnancy was reported during study follow up; a participant in the intervention group whose baby died shortly after birth was pregnant at the 6-month visit. Most women (31.8% at 6 weeks, 57.9% at 14 weeks, and 67.7% at 6 months) reported having resumed sexual intercourse by 6 months. No participants reported LAM as their method of contraception at the 14 week or 6 month visits.

Time to first initiation of any contraception, adjusted for education, parity, and desire for future children, did not differ by group (Hazard ratio [HR] 1.31, 95% CI 0.96-1.78, $p=0.09$)

(figure 3). The probability of FP method initiation was higher in the intervention group compared with the control group by 6 months postpartum, but the difference was not statistically significant (0.74 vs. 0.65, $p=0.12$).

We performed two subgroup analyses on the primary outcome of HEC use at 6 months postpartum: the first was stratified by male partner referral status, which was determined re-randomization, and the second was stratified by male partner enrollment status (i.e. partners were ultimately enrolled after being referred) (table 3). When stratified by partner referral status, there was no statistically significant difference in HEC use at 6 months postpartum between the groups in either stratum, though among women who had not referred their male partners or were unpartnered ($n=99$) there was a trend towards more women in the SMS group using HEC (58.3% vs. 41.2%, $p=0.09$). The second subgroup analysis demonstrated an effect of the SMS intervention on HEC use at 6 months postpartum among those whose partners were not enrolled or were unpartnered ($n=152$; 62.5% vs 45.0, $p=0.03$), but not among those with enrolled partners ($n=100$; 80.4% vs. 77.6%, $p=0.73$).

Exclusive breastfeeding was similar between groups at all the time points (RR 0.97, 95% CI 0.89-1.07, $p=0.57$ at 6 weeks; RR 1.09, 95% CI 0.96-1.23, $p=0.19$ at 14 weeks; RR 1.05, 95% CI 0.78-1.41, $p=0.73$ at 6 months) (data not shown).

SMS platform use

Over the study period, the Mobile WACH platform delivered over 6800 messages to female and male participants. Female participants sent 3190 messages, the majority in response to system messages; male participants sent a total of 387 SMS. Study nurses sent a total of 1950 messages in response to participant questions. The majority (34.4%) of incoming messages from participants were FP-related, followed by the categories of antenatal (8.8%) and delivery concerns (8.7%).

DISCUSSION

In this randomized trial of a two-way family planning-focused SMS intervention using a human-computer hybrid SMS platform, HEC use at 6 months postpartum was higher among women in intervention group. Women randomized to the SMS intervention were 26% more likely to be currently using a HEC method at the 6-month time point. We observed a high level of

engagement in SMS dialogue among women and couples in the intervention arm, which mechanistically supports the efficacy of semi-automated, yet personalized, SMS for FP counseling and education in the postpartum period.

While women in the two-way SMS arm were significantly more likely to use HEC at 6 months postpartum, we did not observe an effect on HEC use at 6 weeks or 14 weeks postpartum. There was a trend towards higher use of any method at and after 14 weeks postpartum. Lack of statistical power to detect a difference at the earlier study visits due to fewer women having initiated contraception may explain these findings. Alternatively, the intervention may have had an increasing effect over time as women interacted with the system and perceived themselves to be at risk for pregnancy. We chose 6 months postpartum to measure the primary outcome of HEC use, as we considered this time point to be most clinically relevant. By 6 months, the majority of women will have ceased exclusive breastfeeding and resumed sex, and the risk of pregnancy is likely increased in comparison to earlier postpartum time points.^{3,30} Similarly, while the probability of FP initiation did not differ between the groups over time, the Kaplan-Meier curves diverged most at 6 months, which could suggest an increasing intervention effect over time.

Our findings are consistent with our earlier RCT (Mobile WACH), which used a similar but not identical SMS platform. The previous Mobile WACH RCT noted increased contraceptive use at 16 weeks among women who received SMS, however, contraceptive use was at similar and high prevalence in all RCT arms by 6 months.³¹ In addition, SMS intervention arms in the prior trial demonstrated higher rates of exclusive breastfeeding compared with control. Our first trial compared one-way “push” SMS vs. two-way SMS vs. control (no SMS) with the goal of more broadly promoting maternal child health service utilization, such as facility delivery, infant immunization, and exclusive breastfeeding, including FP use. The message content in the present study was more focused on family planning behavior. In the current study, we observed no difference in breastfeeding rates between the groups, perhaps because message content dedicated to breastfeeding was minimal in comparison to the FP content. Indeed, more than two-thirds of pre-programmed automated messages were specific to FP topics in the current study. The similarities and differences between these two RCTs suggest that frequency, number, and content of the messages matter in motivating specific behavior change.

To our knowledge, no other published studies have reported on messaging tailored for postpartum women. Our finding of increased HEC use in the intervention arm is consistent with other studies of contraceptives in non-postpartum cohorts. An RCT conducted in the United

States demonstrated improved continuation of oral contraceptive pills 6 months after initiation among women randomized to daily SMS compared with routine care (64% vs. 54%, $p=0.005$).³² An intervention in Cambodia delivering 6 interactive voice messages and phone support after abortion demonstrated increased contraceptive uptake at 4 months post-abortion compared with routine care.³³ In contrast, m4RH, a free SMS-based service that was widely marketed to the general population in Kenya and provides contraceptive information as well as a database of clinics where FP is available, did not show an effect on contraceptive use.²³ Our trial used a highly personalized, interactive SMS approach and was tailored for postpartum women; the mechanisms of effect on contraceptive outcomes in mHealth interventions likely differ based on participant context, and require additional research to direct future efforts.

Contraceptive use was higher than anticipated in our study in both trial arms. This may be due to steadily increasing contraceptive prevalence in Kenya.³⁴ Unmet need in the general Kenyan population decreased substantially and contraceptive prevalence increased from 2008 to 2014³⁴. We based our sample size calculation on recent population-based data sources from Kenya suggesting a contraceptive prevalence at 6 months postpartum in the 40-50% range,²⁷⁻²⁹ which is substantially lower than observed in our study: 64% of control group participants were using a method by 6 months. It is possible that women who agreed to participate in the study were more motivated to learn about, and initiate, FP than the general population, or that study participation in either group, regardless of SMS exposure, encouraged care-seeking behavior. Participants were asked to attend study visits in the postpartum period, which may have encouraged FP initiation simply by encouraging visits to the facilities. Additionally, while study nurses were trained to avoid clinical counseling and health information provision, referring participants instead to facility clinicians, contact with study staff may have provided unmeasured support for FP care-seeking behaviors.

While injectable contraception was the largest contributor to method mix at all time points, contraceptive implant use was unexpectedly high in both groups. Approximately 20% (35% of users) at 14 weeks and 25% (36% of users) at 6 months were using implants, in contrast to 12.4% surveyed women in the Nyanza region in the 2014 DHS.²⁴ High implant use in this postpartum population may be related to counseling about the implant as a safe method during lactation. Alternatively, the relatively long duration of use may have been particularly attractive to women during the study time period, which spanned both a 100-day government doctors' strike and the first three months of a country-wide nurses' strike. Both strikes led to unpredictable availability of services, including FP, and periods of clinic closure. Women in the

two-way SMS group frequently sent messages inquiring about whether the clinic was open; study participants may have had concerns about accessing shorter-term methods like oral and injectable contraception.

We observed a larger effect size among single women and women who did not invite their male partners or whose male partners were not enrolled, compared with partnered women whose partners were referred or enrolled. Among women with referred and/or enrolled partners, contraceptive uptake was high in both trial arms and higher than among non-partnered women or those whose partners were not referred/enrolled. This finding is consistent with our hypothesis that women who felt comfortable referring and enrolling male partners would be more likely to use contraception, in part because they know their partners to be relatively supportive of FP. These women appeared to have benefited less from the intervention than single women or those who perceive their partners to be unsupportive of FP. However, the study was underpowered to detect a difference within subgroups. Qualitative studies from the study region, including formative work for the current study, have enumerated men's concerns and misperceptions about contraceptive side effects and harms.^{17,18,35} Including men in two-way SMS programming may have a greater impact on women's method continuation over time, as contraceptive side effects are cumulatively experienced and managed.

This trial has several strengths, including high retention (97%). This was an individually randomized study of a single intervention, which allows us to attribute the significant findings to the SMS dialogue. The majority of the intervention is reproducible, as the platform is able to send pre-programmed, automated and yet personalized SMS to participants, which enhances its potential for scale-up. The two-way component of the intervention was dynamic to the needs of participants and could not be completely standardized. However, the PI regularly reviewed staff responses to participant messages for quality assurance, and worked with staff to optimize intervention consistency. Our study also has some limitations. We were unable to abstract data on FP use from clinic records and relied on self-report for the FP and other behavioral outcomes, which could result in over reporting due to social desirability bias. Health service delivery at both study facilities was interrupted by health worker strikes, which may have altered contraceptive initiation, choice, and continuation; however, these impacts would be expected to be distributed evenly between study groups. Furthermore, study visit attendance was similar between groups. Finally, our results may not be generalizable to other groups of women who do not have daily access to a mobile phone, including those of lower socioeconomic status.

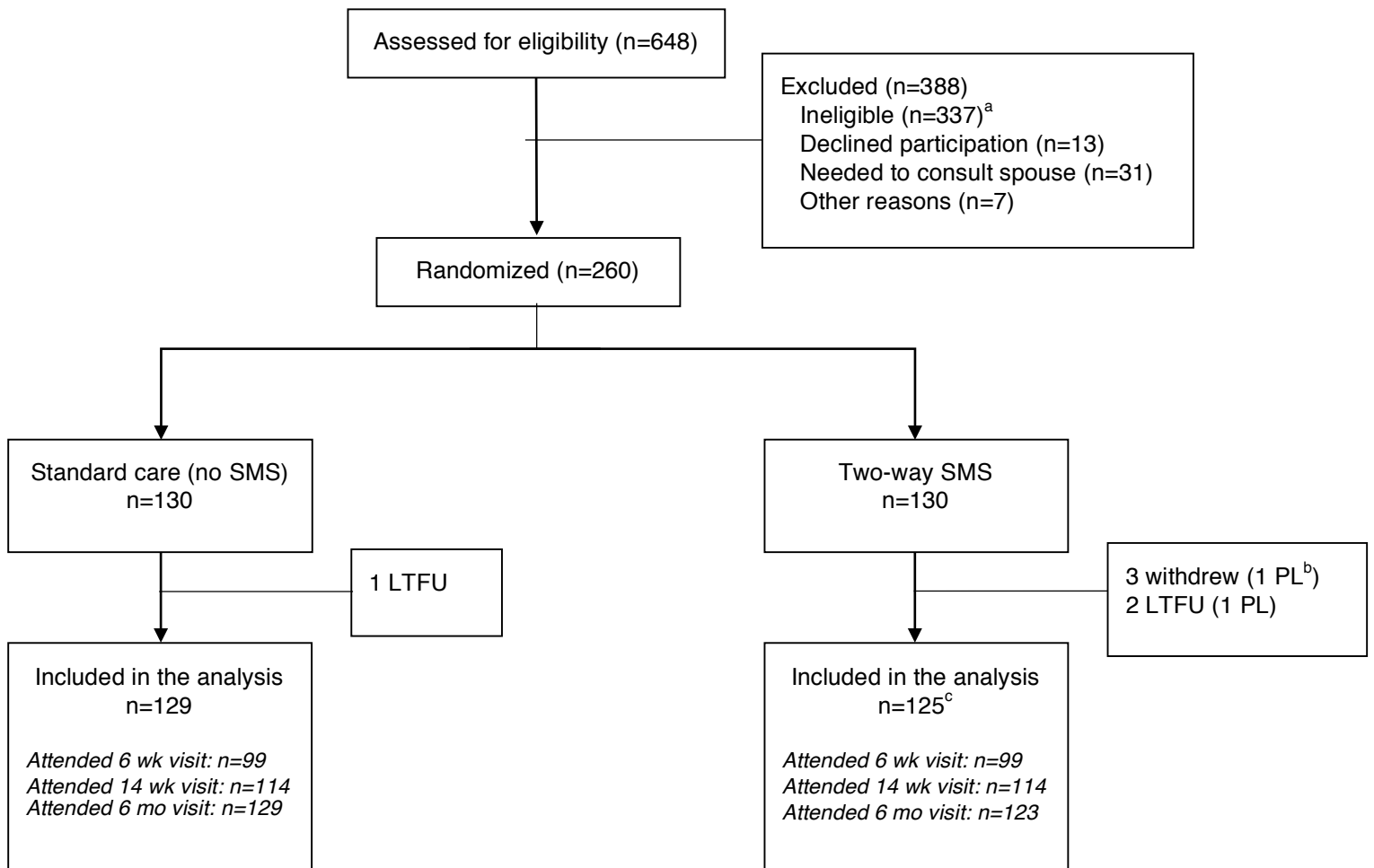
To date, few reproductive health-focused mHealth programs and interventions have rigorously evaluated their effects on contraceptive behavior and outcomes. Our findings highlight the effectiveness of a two-way SMS intervention to support contraceptive use among postpartum women and couples in Kenya—a population at high risk for unintended pregnancy. Future studies should assess the most efficacious and acceptable duration of SMS support, as it is possible that SMS dialogue with a provider may have an even larger effect on contraceptive continuation in the first 12 or 18 months postpartum than on initiation. The development of novel methods for remote data capture may allow for more accurate assessment of contraceptive practices in real time, and might be preferable to in-person study visits for evaluation of SMS interventions. Furthermore, improved satisfaction measures are needed in order to understand what women and couples want from their FP method, contextualize method discontinuation, and guide future FP programming. While our study demonstrates that the inclusion of men in a targeted FP mHealth intervention is feasible and that men engaged in the intervention, we could not reach non-referred male partners who may have had the highest need for FP education. As many men have significant influence and power in reproductive decision-making, there remains a need and demand for community-based efforts to educate and mobilize men around FP. Finally, while enthusiasm for SMS-based programming is warranted in light of increasing evidence of benefit and relatively low cost of the technology, interventions' cost-effectiveness and potential for integration into routine health care delivery must be research and implementation priorities.

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^aReasons for ineligibility (Participants could choose >1 reason, so percentages do not add up to 100%)
 Gestational age <28 weeks: 155 (46%); No daily access to mobile phone: 95 (28%); No Safaricom SIM: 40 (12%); Does not know phone number: 15 (4%); Unwilling to receive SMS: 4 (1%); Receiving antenatal care elsewhere: 60 (18%); Other research study: 31(9%); HIV+: 4 (1%); Age<14: 2 (0.5%)

^bPL: Perinatal loss (intrauterine fetal death, stillbirth, neonatal death)

^c4 participants stopped the SMS intervention on request (2 PL)

Figure 1: Trial profile

	Two-way SMS (n=130)		Control (n=130)	
Site				
Ahero sub-County Hospital, Kisumu County	62	(47.7)	62	(47.7)
Bondo County Hospital, Siaya County	68	(52.3)	68	(52.3)
Age (years)	22.5	(22-26)	23	(19-28)
Education (years)	12	(10-16)	12	(8-15)
Education*				
Less than primary	8	(6.2)	10	(7.7)
Primary completed	50	(38.5)	73	(56.2)
Secondary completed	38	(29.2)	33	(25.4)
Post-secondary	34	(26.2)	14	(10.8)
Married	90	(69.2)	93	(71.5)
Polygamous marriage	12	(9.2)	13	(10.0)
Partnered at enrollment	96	(73.9)	102	(78.5)
Referred partner ^a	80	(83.3)	78	(76.4)
Partner enrolled ^a	54	(56.3)	49	(48.0)
Length of relationship (years) ^a	3	(1-6)	3.5	(2-8)
Individual income (monthly, KSH) ^b	0	(0-5000)	400	(0-5000)
Gestational age at enrollment (weeks)	33	(31-36)	32	(30-35)
Parity*				
0 (Nulliparous)	62	(47.7)	51	(39.2)
1	39	(30.0)	30	(23.1)
2	15	(11.5)	25	(19.2)
3	7	(5.4)	10	(7.7)
4 or more	7	(5.4)	14	(10.8)
Unintended or mistimed pregnancy ^c	62	(48.1)	68	(52.7)
Ever use FP	73	(56.2)	79	(60.8)
Ever use HEC	62	(47.7)	66	(50.8)
Desires no more children ^d *	30	(23.3)	44	(34.4)
Ever discussed FP with partner ^a	74	(77.1)	81	(79.4)
Believes partner approves of FP ^a	81	(84.4)	79	(77.5)
Shares mobile phone	22	(16.9)	24	(18.5)
Using mobile phone for <1 year	17	(13.6)	16	(12.4)
Has ever used the internet	53	(40.8)	44	(33.9)

Data are n(%) or median(interquartile range). *Statistically-significant (p<0.05) differences between the groups (χ^2 test)

^aPercentages calculated based on number partnered (n=198) as denominator.

^bn=112/109 ^cn=129/129 ^dn=129/128

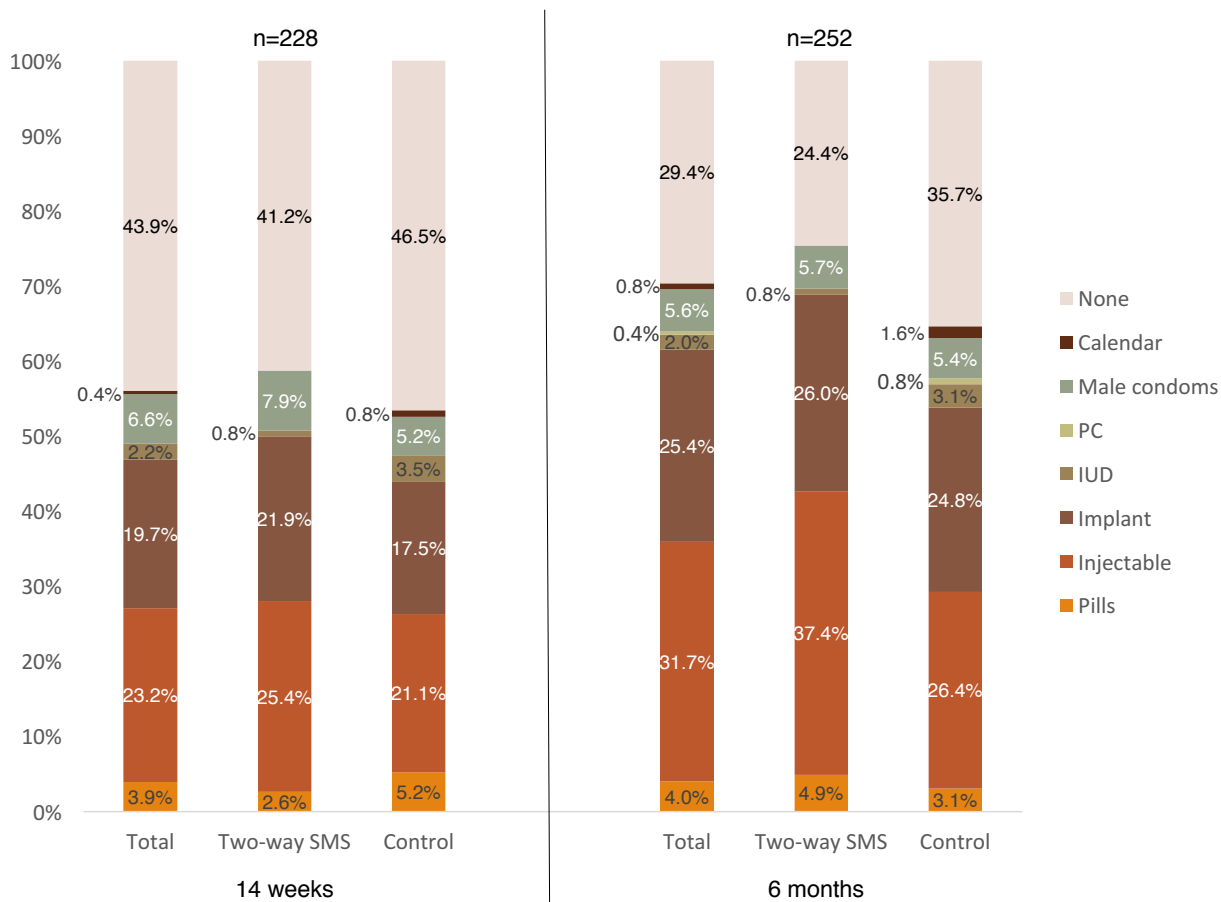
Table 1: Trial participant characteristics at baseline

	Two-way SMS	Control	RR (95% CI)	p value	aRR (95% CI)*	p value
Any method use at 6 weeks	22 (22.7)	23 (22.8)	1.00 (0.60-1.66)	0.99	1.04 (0.61-1.76)	0.89
HEC ^a use at 6 weeks	14 (14.4)	19 (18.8)	0.77 (0.41-1.44)	0.41	0.86 (0.45-1.65)	0.66
LARC/PC ^b use at 6 weeks	6 (6.2)	10 (9.9)	0.62 (0.24-1.65)	0.34	0.66 (0.22-1.95)	0.46
Any method use at 14 weeks	67 (59.3)	61 (53.0)	1.12 (0.89-1.41)	0.34	1.09 (0.86-1.38)	0.50
HEC use at 14 weeks	58 (51.3)	54 (47.0)	1.09 (0.84-1.42)	0.51	1.07 (0.81-1.41)	0.61
LARC/PC use at 14 weeks	26 (23.0)	24 (20.9)	1.10 (0.68-1.80)	0.70	1.04 (0.63-1.71)	0.89
Any method use at 6 months	93 (75.6)	83 (64.3)	1.18 (1.00-1.38)	0.05	1.19 (1.01-1.41)	0.04
HEC use at 6 months ^c	86 (69.9)	74 (57.4)	1.22 (1.01-1.47)	0.04	1.26 (1.04-1.52)	0.02
LARC/PC use at 6 months	34 (27.6)	36 (27.9)	1.00 (0.67-1.48)	0.96	0.92 (0.62-1.38)	0.70
Satisfied with method ^d at 14 weeks postpartum (n=128)	62 (91.2)	52 (86.7)	1.05 (0.93-1.19)	0.42	1.07 (0.95-1.20)	0.25
Satisfied with method with method at 6 months postpartum (n=178)	86 (94.5)	83 (97.7)	0.97 (0.91-1.03)	0.29	0.96 (0.91-1.02)	0.22

Data are n(%). ^aIncludes oral contraception, injectable contraception, implant, intrauterine device, sterilization ^bLARC: Long-acting reversible contraception (implant, intrauterine device), PC: Permanent contraception (bilateral tubal ligation). ^cPrimary outcome. ^dSatisfied or highly satisfied with method on 5-point Likert scale.

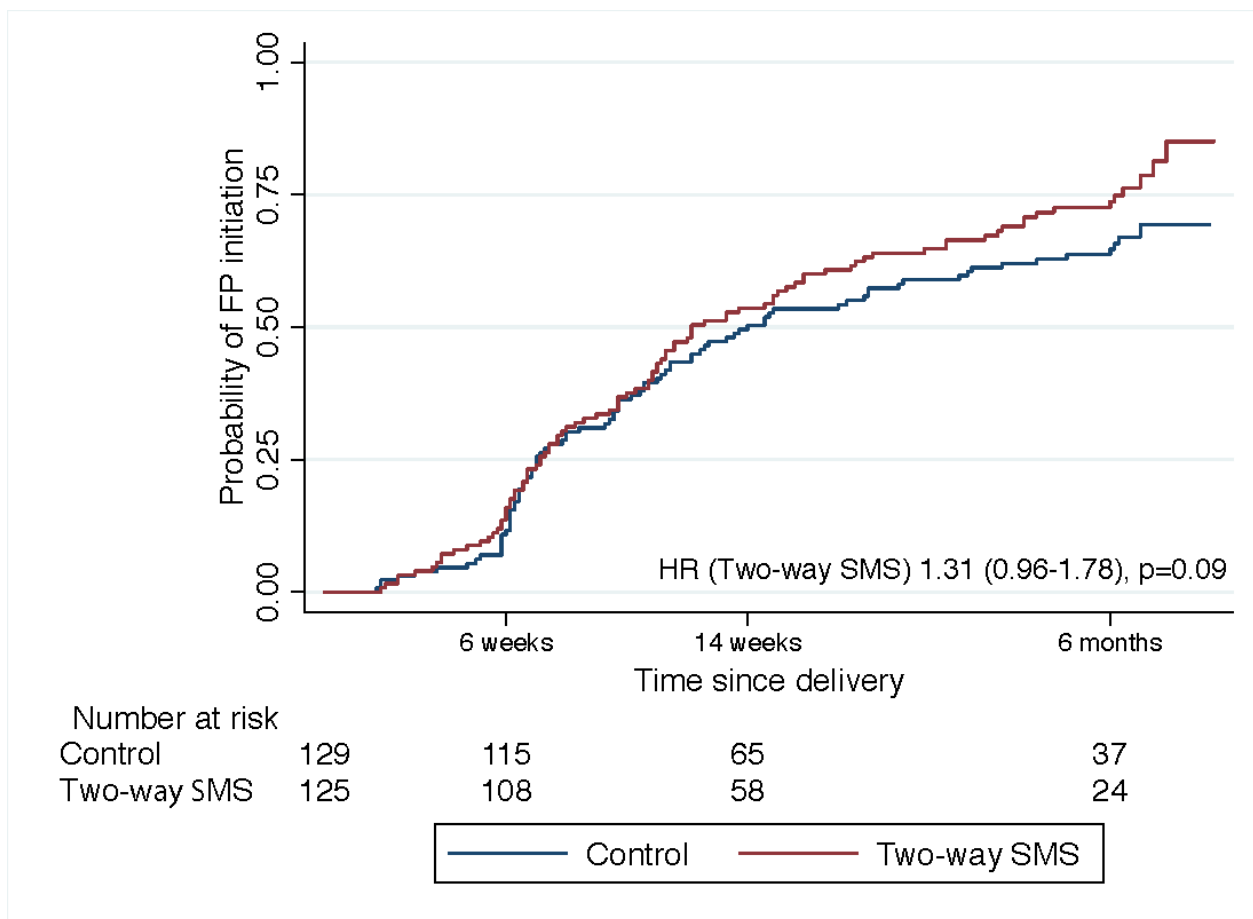
*Adjusted risk ratio (aRR) computed by Poisson regression with robust standard errors, adjusted for education category, parity, desire for future children.

Table 2: Effect of two-way SMS on contraceptive method use and method satisfaction



PC: Permanent contraception (bilateral tubal ligation)
 IUD: Intrauterine device

Figure 2: Contraceptive method mix by group at 14 weeks and 6 months



Adjusted for education category, parity, and desire for future children.

Figure 3: Probability of FP initiation over time since delivery

HEC use at 6 months postpartum	Two-way SMS	Control	RR (95% CI)	p value
Partner referred (n=153)	58 (77.3)	53 (68.0)	1.14 (0.94-1.38)	0.19
Partner not referred/no partner (n=99)	28 (58.3)	21 (41.2)	1.42 (0.94-2.13)	0.09
Partner enrolled (n=100)	41 (80.4)	38 (77.6)	1.04 (0.85-1.27)	0.73
Partner not enrolled/no partner (n=152)	45 (62.5)	36 (45.0)	1.39 (1.03-1.88)	0.03

Data are n(%).

Table 3: Subgroup analyses of HEC use at 6 months postpartum by partner referred and partner enrolled status