

Randomized Controlled Trial (RCT) of SMS Messages to Pregnant Women in Peru: WAWARED RCT

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Abstract

Background: Pregnancy-related complications continues to be unacceptable high, especially in low resource countries. Antenatal Care (ANC) could be an effective intervention. However, still most pregnant women in the developing world go to only one-or less than the recommended ANC visits during their whole pregnancy, so there is a need of strategies to improve ANC attendance. Digital technologies represent an innovative approach to increase ANC attendance. Within the Project WAWARED: “Getting connected for better maternal and child health”, we included a Randomized Controlled Trial (RCT) to evaluate the impact of the introduction of individually tailored SMS messages to pregnant women in Peru. The objective of this paper is to present the results of the WAWARED RCT and examine the effects of SMS messages in ANC visits, behavioral outcomes, maternal and neonatal outcomes.

Methods: The WAWARED system sent automatic SMS messages according to gestational age and any specific pathology registered in the Electronic Medical Records (EMR). ANC appointment reminders were sent, and additional educational messages were also sent to the intervention group until the end of the pregnancy. 651 participants were randomized to the intervention group and the control group respectively.

Findings: Pregnant women who received SMS messages were 6% more likely to attend more than 6 ANC visits and 25% more likely to attend the visits on time. This effect was modified by education, since all the effect was seen in women with secondary or higher education. There was no significant difference in the rates of Low Birth Weight (LBW) between groups.

Conclusions: SMS sent to pregnant women had a significant effect in increasing the number of ANC visits and these effects were more evident in women with more education, but it was also possible that the introduction of the EMR helped to improve the number of ANC in both control and intervention groups.

Introduction

Pregnancy-related complications continues to be unacceptable high, especially in low resource countries. The World Health Organization (WHO) estimates that every day at least 830 women die from preventable causes related to pregnancy and childbirth [1,2]. Globally, countries have agreed on a target under the Sustainable Development Goal 3 to reduce global maternal mortality to less than 70 per 100 000 births by 2030, with

no country having a maternal mortality rate of more than twice the global average [3]. Since most causes of maternal deaths are preventable, there is an urgent need for effective interventions. Antenatal Care (ANC) could be an effective intervention since it provides a platform for health promotion, prevention, screening, and diagnosis of diseases and is an opportunity to provide the social and psychological support that women need for a healthy pregnancy [4]. However, although early ANC visits have the potential to avoid pregnancy-related complications; still most

pregnant women in the developing world go to only one or less than the recommended ANC visits during their whole pregnancy, so there is a need of strategies to improve ANC attendance [5,6].

Mobile phones are becoming one of the most important ways to communicate and keep in touch. Short Message Services (SMS) have been used for behavioral change in disease prevention, in disease management and to increase patient attendance to outpatient clinics [7-11]. For maternal care, studies have shown that most pregnant women (even in developing countries) have access to SMS and have interest in receiving messages with educational information [12-14]. However, there are no robust evidence on the impacts of these interventions on maternal health outcomes. Within the Project WAWARED: "Getting connected for a better maternal and child health", funded by the Mobile Citizen Program of the Inter-American Development Bank, we included a Randomized Controlled Trial (RCT) to evaluate the impact of the introduction of individually tailored SMS messages to pregnant women in Peru [15]. "WAWA" is the Quechua word for baby. Quechua is the main native language of Peru. "RED" means network. The objective of this paper is to present the results of the WAWARED RCT and examine the effects of SMS messages in ANC visits, behavioral outcomes, maternal and neonatal outcomes.

Methods

The WAWARED project involved the implementation of an Electronic Medical Record System (EMR) for maternal health in the Region of Callao-Ventanilla in Peru [16]. This EMR was linked to automatic SMS messages to pregnant women tailored to their health profile and gestational age which was evaluated through a RCT which is presented in this manuscript.

Development of SMS and the automated text message system

SMS development was informed by behavioral change theory [17,18]. Following the methodology used by other studies, we took several steps for developing the messages using formative research [19] and validating them; addressing the technology to send SMS, and piloting the system [20,21].

1. Focus groups and in-depth interviews to address needs and to define content, format and design SMS messages:

We performed focus groups with pregnant women to identify their

2. needs and frequency of SMS. At the beginning we proposed SMS aimed to increase adherence to ANC visits: "appointment reminders". During the focus groups women shared their needs of having other additional types of messages: "educational messages" i.e. importance of hand washing; "motivational messages" i.e. "You are doing well with your pregnancy! Good job!"; "nutritional messages" and "special messages" according to diseases. Furthermore, participants

told us that they would like to receive the messages 3 times a week (Monday, Wednesday and Saturday) at 9:00 am. At the end of this step we decided to design the four different types of messages. In addition, we conducted in depth interviews with pregnant women to understand the reasons why they go or do not go to their ANC visits. With this information we crafted the contents of the appointment reminders and motivational messages. All the other messages were created reviewing national guidelines and recommendations regarding ANC [21]. Additional in-depth interviews were performed with health providers involved in ANC to explore the information that were already given during ANC visits and to get their suggestions on the content of the draft SMS. Health providers were very in agreement with the types of messages we decided to work on.

3. **Validation of the SMS:** We perform additional focus groups with pregnant women to validate the messages for completeness, cultural correctness, relevance and understandability. In addition, we conducted a focus group with midwives and authorities of the Ministry of Health to validate the final messages. At the end we had 10 motivational messages, 35 appointment reminders, 67 educational messages and 268 specific messages for the total course of pregnancy.
4. **Technological Component:** We received a number of free text messages from a local telephone company and we used their SMS platform to distribute messages to women with cell phones having them as providers.
5. **Providers.** For women with cell phones from other companies, we used the Tropo company services. Tropo (<https://www.tropo.com>) is a provider of communication services, specialized in mass messaging and connectivity with SMS.
6. **Pilot testing:** We developed a pilot study to test the automated text messaging system, including 92 pregnant women.

Trial Design and participants

We conducted the RCT to evaluate the SMS involving the 15 health centers and 1 hospital from the Ventanilla/Callao health network. Eligible participants were pregnant women, at least 18 years old, with 20 weeks' gestation or less coming to one of the health centers or the hospital for her first ANC visit, reporting ability to read, having a cell phone and being interested to participate in the study. In Peru, incoming SMS are free of charge, so participants did not incur in any costs.

Sample Size

Sample size calculations were based on percent of pregnant women (60%) who attended at least 6 ANC visits during their pregnancy in the region of Callao in previous years [22,23]. With 651 women in each arm, using $\alpha = 0.05$ and presuming 12% loss

to follow-up, we estimated achieving 80% power to detect a difference of at least 8% in the proportion of women coming to at least 6 ANC visits on time.

Randomization

All the health centers located in Ventanilla-Callao had an operational EMR for maternal care started through the WAWARED project. For the RCT we introduced a module on the EMR for eligibility to participate. The randomization lists were established before initiating the study. In addition, the randomization used permuted block design, with blocks of four subjects to maintain the adequacy of randomization.

For all pregnant women coming to her first ANC, the EMR identified those with at least 18 years old, with 20 weeks' gestation or less and with a cell phone. The computer screen showed this message inviting women to participate in the study: "We have a system that we want to evaluate for appointment reminders, preventive and motivational messages for pregnant women, would you be interested in participating in the investigation?". If the woman was interested, the health provider (usually a professional midwife) read the verbal informed consent showed in the screen with the woman, assess other eligibility criteria and the agreement was documented in the computer as a yes. The mobile phone number was rechecked and information about the mobile phone provider was added. Each woman was randomized to either receive or not the SMS messages automatically by the system. Health providers were not informed of the assignment of the participant.

Intervention

After the automatic randomization, the system started to send SMS messages according to gestational age and any specific pathology registered in the EMR. ANC appointment reminders were sent every Monday and the day before the scheduled appointment. Furthermore, every Wednesday and Saturday, additional educational messages suggesting healthy foods, vitamin intake reminders, hygiene practices or messages specific to recorded diseases were also sent to the treated group until the end of the pregnancy (week 40).

Measure of Outcomes

Most of the data analyzed came from the EMR (attendance to ANC, birth weight, and hemoglobin levels). Additionally, at the end of the pregnancy women from the intervention and control groups were interviewed to collect data on food intake and reported adherence to iron/folic acid in the last week of pregnancy (exit questionnaire). The interview took approximately 10 minutes.

Analysis:

1. Primary outcome:

The primary outcome of the RCT was the percentage of pregnant women who attended at least 6 ANC within the whole pregnancy

period. In addition, we also assessed the percentage of pregnant women who attended at least 6 ANC on time (at the scheduled date) within the pregnancy period.

2. Secondary outcomes:

Secondary outcomes included behavioral responses in terms of feeding habits and intake of iron/folic acid. SMS included recommendations of healthy food items that should be eaten and discouragements suggesting the avoidance of certain items. We build two different indexes measuring the incidence of both recommended and not recommended food items within each woman's diet measured through an exit questionnaire. To do so, we computed indicator variables for each food item taking the value of one if the woman reported consumption of the item; while zero otherwise. Then, for each indicator variable, we computed the mean and the standard deviation of the control group. After this, to each food item indicator of the entire sample (both treated and control women), we applied a standardization by subtracting the control group mean and dividing by the control group standard deviation. Finally, we averaged the standardized indicators for both recommended and not recommended food items to obtain both indexes. These indexes are expressed in standard deviations with respect to the control group. That is, the indexes have zero mean and unity standard deviation for the control group; so that the differences in the average of the indexes between treated and control groups are expressed in standard deviations of the distribution of control women. To measure behavioral changes in terms of iron/folic acid intake, we consider the percentage of pregnant women who reported taking all their doses on time during the last week of pregnancy.

Finally, we included as secondary outcomes the percentage of women who were found anemic (hemoglobin level below 11) at the end of pregnancy (maternal outcome) and the percentage of newborns with low birth weight (below 2,500 grams) (neonatal outcome).

3. Statistical analysis:

We used Stata/SE v14.1 (Stata Corp., College Station, TX, USA) for analysis. All tests were two-sided with a significance level of 5%.

Descriptive statistics for both groups were calculated including demographic characteristics. Categorical variables were summarized using the number and proportion of patients, while continuous variables were presented using the mean and the Standard Deviation (SD).

The primary and secondary outcomes were examined using the intention-to-treat principle. For categorical outcomes, we compared the proportions between intervention and control groups using relative risk regression adjusted for woman's age, distance

from the household to the health center, woman’s educational attainment and occupation with a log link and clustered error variance at the health center level. For continuous outcomes, we compared the mean between intervention and control groups using multivariate regression adjusted for woman’s age, distance from the household to the health center, woman’s educational attainment and occupation with clustered error variance at the health center level.

In addition, as this intervention required the ability to read and understand SMS messages, we considered an analysis of possible effect modification by stratifying the sample by the woman’s educational attainment (women without secondary education vs women with completed secondary education or higher). Educational attainment intends to capture not only the ability to read and understand the SMS, but also the awareness of the potential benefits of ANC.

Ethical Considerations

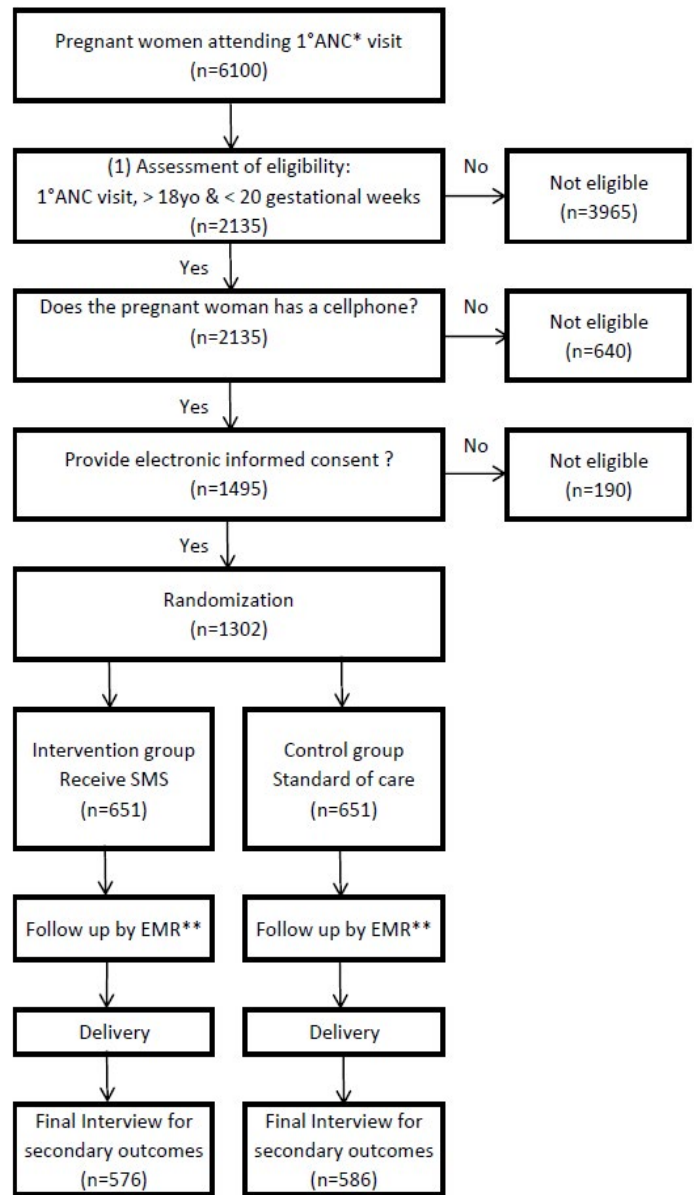
All participants provided electronic verbal consent as described before. The study was approved by ethical review committees of the Universidad Peruana Cayetano Heredia (IRB number 56864) and the Regional Health Directorate of Callao, Peru.

RESULTS

Study Participants

There were 6100 women who attended the health establishments in Ventanilla for first ANC visit between 2012-2013. Only 2135 of the participants met the initial eligibility criteria (first ANC visit, 18 years or older, and less than 20 weeks of pregnancy). From them, 1,495 had a cellphone and 1,302 (87%) agreed to participate in the study. 651 participants were randomized to the intervention group and the control group respectively. All the participants were followed throughout their gestational period. At the end of the follow-up, 576 (88%) of the intervention group and 586 (90%) of the control group had their exit questionnaire. (Figure 1).

Most maternal characteristics were balanced between study arms at baseline. The only difference was in the proportion women reporting as their occupation being students between the control (9.8%) and the intervention (6.3%) groups (p=0.01) (Table 1).



*ANC= Antenatal care
**EMR= Electronic Medical Record

Figure 1: Enrollment, randomization and patient flow.

	Treated n (%) (n=576)	Control n (%) (n=586)	p
<i>Sociodemographic Characteristics</i>			
Age, mean (sd)	25.75 (6.42)	25.58 (6.64)	0.60
Born in Lima	233 (43.07)	254 (45.44)	0.46
Highest education			
None	20 (3.47)	33 (5.63)	0.08
Primary	170 (29.51)	191 (32.59)	0.38
Secondary	278 (48.26)	259 (44.20)	0.24
Post-secondary	108 (18.75)	103 (17.58)	0.55
Occupation			
Housewife	439 (76.75)	432 (73.97)	0.28
Employed	97 (16.96)	95 (16.27)	0.71
Student	36 (6.29)	57 (9.76)	0.01
Civil status			
Single	96 (16.67)	98 (16.72)	0.83
Married	65 (11.28)	83 (14.16)	0.29
Not married but living with partner	415 (72.05)	405 (69.11)	0.25
Weeks of pregnancy, mean (sd)	12.01 (4.62)	11.73 (4.37)	0.16
First pregnancy	243 (42.19)	268 (45.73)	0.16
Anemic (hemoglobin level <11)	118 (21.26)	133 (23.50)	0.24
<i>Household Characteristics</i>			
Total household income (USD)*, mean (sd)	287.00 (86.4)	280 (91.6)	0.29
Distance to health center (meters), mean (sd)	929.65 (968.22)	895.12 (898.59)	0.48

Table 1. Baseline Characteristics of Participants

Antenatal Care Visits

Regarding ANC visits, we found significant differences between intervention and control groups. In the intervention group, 499 of 576 (86.6%) pregnant women attended to 6 or more ANC visits compared to 482 of 586 (82.3%) in the control group [Relative Risk (RR) 1.06, 95% Confidence Interval (CI) 1.01 – 1.11, P=0.03]. When the comparison relates to attend to 6 or more ANC visits **on time**, in the intervention group, 134 of 575 (23.3%) did so, compared to 108 of 582 (19.6%) in the control group (RR 1.25, 95% CI 1.06-1.48, P=0.01) (Table 2).

	RR (95%CI)	p
<i>Antenatal care</i>		
Attend ≥ 6 prenatal controls	1.06 (1.01 - 1.11)	0.03
Attend ≥ 6 prenatal controls on time	1.25 (1.06 - 1.48)	0.01
<i>Behavioral outcomes</i>		
Recommended food index (in the last week)	0.06 (0.02 - 0.09)	0.01
Non-recommended food index (in the last week)	-0.05 (-0.12 - 0.02)	0.12
Took iron on time (last week)	1.05 (0.97 - 1.13)	0.25
<i>Birth and maternal health outcomes</i>		
Low birth weight (<2500)	0.98 (0.68 - 1.40)	0.91
Anemic (hemoglobin level <11)	0.97 (0.76 - 1.23)	0.8

Table 2: Treatment Effects.

Behavioral Outcomes

The mean of the recommended food index in the intervention group is 0.06 higher compared to the control group [95% CI 0.02 - 0.09, P=0.01]. There was not statistical difference in the mean non-recommended food index between intervention and control groups. We did not find any difference between intervention and control groups in relation to reported iron intake in the last week (P=0.25)

Maternal and Neonatal Outcomes

At the end of the pregnancy, 98 of 460 (21.3%) in the intervention group had anemia compared to 106 of 476 (22.3%) in the control group (RR 0.97, 95% CI 0.76-1.23, P=0.80). Surprisingly the levels of anemia at the end of pregnancy for both

groups were similar to the levels at baseline (Table 1). There was no significant difference in the rates of low birth weight (LBW) between groups. LBW was found in 27 of 576 (4.7%) of newborns from the intervention group compared to 28 of 586 (4.8%) in control group (RR 0.98, 95% CI 0.68-1.40, P=0.91) (Table 2).

Treatment Effects by Educational Attainment

In the stratified analysis by level of education we found a significant effect on the group that has secondary or higher education in the following variables: Attend to 6 or more ANC visits (RR 1.06, 95% CI 1.01-1.12, P=0.01); attend to 6 or more ANC visits on time (RR 1.25, 95% CI 1.02-1.53, P=0.03); higher recommended food index (RR 0.06, 95% CI 0.01-0.11, P=0.03); and took iron on time (RR 1.09, 95% CI 1.01-1.18, P=0.03) (Table 3).

	None or primary (n=414)	Secondary or Higher (n=748)
	RR (95%CI)	RR (95%CI)
	P	P
Antenatal care		
Attend ≥6 prenatal controls	1.01 (0.92 - 1.10) 0.91	1.06 (1.01 - 1.12) 0.01
Attend ≥6 prenatal controls on time	1.23 (0.83 - 1.90) 0.276	1.25 (1.02 - 1.53) 0.03
Behavioral outcomes		
Recommended food index (in the last week)	0.05 (-0.01 - 0.12) 0.12	0.06 (0.01 - 0.11) 0.03
Non-recommended food index (in the last week)	-0.10 (-0.26 - 0.07) 0.22	-0.03 (-0.08 - 0.03) 0.29
Took iron on time (last week)	0.99 (0.83 - 1.19) 0.94	1.09 (1.01 - 1.18) 0.03
Birth and maternal health outcomes		
Low birth weight (<2500)	1.28 (0.55 - 3.02) 0.57	0.85 (0.45 - 1.60) 0.62
Anemic (hemoglobin level <11)	1.10 (0.71 - 1.72) 0.43	0.90 (0.71 - 1.14) 0.36

Table 3: Treatment Effects by Educational Attainment.

Discussion

The RCT showed that pregnant women who received SMS messages were 6% more likely to attend more than 6 ANC visits and 25% more likely to attend the visits on time. The other important finding is that the effect was modified by education, since all the effect was seen in women with secondary or higher education. No significant difference in the rates of Low Birth Weight (LBW) between groups was found.

One of the most commonly documented uses of mHealth is the one-way text-message and phone reminders to encourage follow-up appointments. A systematic review and meta-analysis on the impact of text-based electronic notifications on improving clinic attendance included 26 articles, none included ANC [24]. The review showed that patients who received notifications were 23% more likely to attend clinic visits compare to those who received no notification. Our results are similar to a system implemented in Kenya where a mobile phone SMS-based system was used to track pregnancy and maternal and child outcomes [25]. The authors concluded that implementation of mobile-phone systems at the community level could contribute to improving emergency obstetric and neonatal care. In Zanzibar, an intervention, based on a mobile phone text message and voucher component contributed to improve the health of the newborns [26].

The WHO, in a 2016 document, recommended increasing the number of “contacts” or ANC visits from 4 to 8, to better assess mothers and babies and to improve the support and communication between healthcare providers and pregnant women [4,27]. We used the indicator of more than 6 ANC visits for this study, following the current Peruvian National Guidelines. However, we added the analysis of equal of more than 8 ANC and found a significant difference between the intervention and control arm (RR 1.18, 95% CI 1.06-1.33, P=0.003).

It is interesting to note that reviewing reports from the Ventanilla region from previous years, only 60% of pregnant women completed more than 6 ANC visits. But during the study in the control group we documented that around 85% of the pregnant women had more than 6 ANC. Although SMS were sent only to the intervention group, as part of the study, we implemented the EMR for both intervention and control groups. It is possible that just the use of EMR in our study, allowed providers to better register data, to schedule visits directly from the EMR and to have a better follow up of patients, resulting in improving their adherence to the clinic visits for both intervention and control groups. EMRs in general have shown to be promising as facilitators for health care improvement. A recent state-of-the-art review found that the most commonly emphasized process improvement associated with EMR relates to improved efficiency of time-consuming or error-

prone tasks [28]. Nevertheless, reduction of missed appointments has been associated with the introduction of EMRs tools [29].

In relation to iron intake, we did not find any effect in the prevention or reduction of anemia in our population. One interesting observation is that the level of anemia found in this group of pregnant women, was relatively low (21.3%-23.5%) compare to the prevalence of anemia in general population of pregnant Peruvian women (27.9%) [30]. A very similar situation happened with another secondary outcome, LBW. The prevalence of LBW in our study was lower (4.8%) than that of the general population in Peru (8.2%) [31]. One explanation could be related to the inclusion criteria we used for the recruitment of pregnant women, including only those women coming before 20 weeks of gestation to their first ANC. These women could be selected women, those more concerned about their health and with better nutritional practices and healthier lives and therefore had lower levels of anemia and LBW. In addition, to be able to detect any effect on anemia or LBW we would have needed a larger sample size and we calculated our sample size based on the number of ANC visits, which really was our main outcome of interest.

Successful reading comprehension requires the ability to analyze, synthesize, and evaluate information [32], and these abilities could be acquired when finishing secondary studies. Reading comprehension in Peru has been found to be related with socio-cultural factors and gender [33]. A population like ours, with no secondary studies could have had limitations on their reading comprehension and difficulties to understand the content of the SMS despite they could read them, and this could explain why most of the positive effect of the messages was seen in women with secondary education or more. The provision of information can influence people's behavior only when they are able to process the new information [34].

Conclusion

In our study, SMS had a significant effect in increasing the number of ANC visits and these effects were more evident in women with more education, but it was also possible that the introduction of the EMR helped to improve the number of ANC in both control and intervention groups. We did not find significant differences in relation to iron intake, anemia or LBW, but the study was not powered for these secondary outcomes.

WAWARED (EMR and SMS) continued to be used in the Ventanilla-Callao network of health centers and it was implemented in the other health networks of Peru. In December 2015, an agreement with the Peruvian Ministry of Health (MINSA) was subscribed to transfer the WAWARED system for national implementation. In 2017, a directive from the Ministry of Health (Ministerial Resolution N° 021-2017/MINSA) established the use of the WAWARED system in health care establishments at the

national level. The implementation started progressively in 2017, and by 2018, more than 1000 MINSA health facilities are using the system nationally and the implementation continues. WAWARED is a clear example of a successful and sustainable collaboration between academia, the national and regional governments and an international developing financing agency.

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