Original Paper

The Impact of a Maternal Education Program Through Text Messaging in Rural China: Cluster Randomized Controlled Trial

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Abstract

Background: In recent years, attempts have been made to use mobile phone text messaging (short message service, SMS) to achieve positive results for a range of health issues. Reports on the impact of maternal education programs based on this widely available, inexpensive, and instant communication tool are sparse.

Objective: This study aimed to explore the impact of a maternal education program through text messaging.

Methods: We conducted a cluster randomized trial in a remote region in the Chinese province of Hunan between October 1, 2011, and December 31, 2012. We used county as the unit of randomization (a total of 10 counties), with half of the counties randomly allocated to the intervention arm (with maternal education material adapted from the World Health Organization being delivered by text messaging to village health workers and pregnant women alike) and the other half to the control arm (normal care without text messaging). Data on maternal and infant health outcomes and health behaviors were collected and compared between the 2 arms, with maternal and perinatal mortality as the primary outcomes.

Results: A total of 13,937 pregnant women completed the follow-up and were included in the final analysis. Among them, 6771 were allocated to the intervention arm and 6966 were allocated to the control arm. At the county level, the mean (SD) of maternal mortality and perinatal mortality rate were 0.0% (0.1) and 1.3% (0.6), respectively, in the intervention arm and 0.1% (0.2) and 1.5% (0.4), respectively, in the control arm. However, these differences were not statistically significant. At the individual level, there were 3 maternal deaths (0.04%) and 84 perinatal deaths (1.24%) in the intervention arm and 6 maternal deaths (0.09%) and 101 perinatal deaths (1.45%) in the control arm. However, the differences were again not statistically significant.

Conclusions: Adequate resources should be secured to launch large-scale cluster randomized trials with smaller cluster units and more intensive implementation to confirm the benefits of the text messaging–based maternal education program suggested by this trial.

Trial Registration: ClinicalTrials.gov NCT01775150; https://clinicaltrials.gov/ct2/show/NCT01775150 (Archived by WebCite at http://www.webcitation.org/74cHmUexo)

Introduction

Background

Although maternal and infant death rates in China are not as high as those in some developing countries [1], they are still very high, about 300 per 100,000 deliveries for maternal mortality and 40 per 1000 births for infant mortality in remote areas. Many of these maternal and infant deaths may be avoidable if mothers/local health workers can learn how to better detect and manage pregnancy complications. The World Health Organization (WHO)'s Promotion of Perinatal Care Program [2] contains teaching aids and texts for maternity care education. These WHO materials have been validated and widely implemented in many regions worldwide, with varying levels of success.

In recent years, attempts have been made to use mobile phone text messaging (short message service, SMS) to achieve positive results for a range of health issues including treatment management and adherence [3-5], quality of life and well-being assessment [6], weight management [7,8], suicide prevention [9], smoking cessation [10], and other public health issues [11,12]. Attempts have also been made to use mobile phone text messaging to address issues related to maternal and child health, including interventions to support postabortion contraception [13], infertility treatment [14], prevention of mother-to-child HIV transmission [15], pregnancy nutrition intervention [16], management of gestational diabetes [17], adherence to postpartum care [18], lactation management [19], and infant feeding [20]. Although the overarching goal of mobile phone text messaging seeks to promote behavioral changes in both health care providers and the target population of interest, text messaging interventions evaluated to date have met with varying degrees of success [11,12].

Reports on the impact of maternal education programs based on this widely available, inexpensive, and instant communication tool in low- and middle-income countries are sparse. To our knowledge, none of the studies have yet tried to integrate WHO's maternity care education material with text messaging as a local maternal and infant health promotion tool in remote rural areas in China. In a systematic review, Amoakoh-Coleman et al identified 19 studies (10 intervention studies and 9 descriptive studies) of mobile health (mHealth) on various maternal and child health issues; they found that none of these studies attempted to integrate the WHO education materials in the education program and none of these studies directly assessed the effect of mHealth on maternal and neonatal mortality [21]. Mobile phones are popular in China (more than 50% of the population has a mobile phone) and accessible (with wireless networks spanning most remote areas), and mobile phone text messaging is affordable (<5 cents per message), making China an opportune place to implement a large-scale maternal education program using this text messaging–based health communication tool.

Objective

To obtain the empirical data needed to explore this cost-effective novel health promotion opportunity, we designed a cluster randomized trial to evaluate the potential benefits of implementing the WHO maternal education program using text messaging in a remote area in China. We chose a cluster randomized trial because it could be implemented in large scale at a lower cost and it might help to reduce contamination [22].

Methods

Ethical Approval, Trial Registration, and Reporting

We obtained approval from the Ottawa Hospital Research Ethics and Confidentiality Committee before commencing the proposed study (REB # 2011467-01H). We registered this trial in the ClinicalTrials.gov Protocol Registration System (registration number: NCT01775150). We followed the Consolidated Standards of Reporting Trials 2010 statement: extension to cluster randomized trials [23] in the reporting of the trial.

Study Region

This study was conducted in the northwestern region of the Chinese province of Hunan, a mountainous area comprising about 5 million residents. Basic maternity care in this area is provided by village health workers. There are several unique features that make the northwestern region of Hunan province the ideal location for a cluster randomized trial to evaluate the impact of a maternal health education program. First, the authority governing the whole region agrees to participate in this study, so that no further negotiation with local authorities is needed. As a result, possible bias introduced by selective participation is reduced [22]. Second, the region is quite homogeneous, thereby increasing the chance of obtaining a balanced randomization result. Third, half of the village birth attendants in the region have no formal training, and the other half have inadequate or outdated training [24]. Therefore, there is room for improvement through the proposed maternal education program. Fourth, although the region is not well developed, penetration of mobile phone is high (>70%), rendering an education program relying on health communications by mobile phone feasible.

Development of the Health Education Tool

On the basis of the WHO education materials, we developed a health education tool with mobile phone text messaging for village health workers and pregnant women alike. The original WHO education materials are written documents with both electronic and paper versions [2]. These documents are comprehensive, with 28 education modules on details regarding various maternity care including safe motherhood, parenthood, concept of risk and appropriateness for prenatal care visits and testing, labor and delivery, postpartum care, and breastfeeding.

Although the WHO education tool is well founded and validated, it is developed in English and is too long and too detailed to be sent by text messaging effectively. To make it a user-friendly,

text messaging–based tool acceptable by village health workers and pregnant women in the study region, it needs to be translated into Chinese and to be shortened and modified. First, we formed a multidisciplinary expert panel comprising a maternity care specialist, a midwife, 2 epidemiologists, a psychologist, and a nutrition scientist. The expert panel made decisions on every step of the translation and modification of the WHO education materials. Second, the original English version of WHO education materials was translated into Chinese by 2 researchers independently. Third, the 2 Chinese translation versions were compared with the original English version by the expert panel. The expert panel revised the inconsistent and inaccurate items to reach the final version of the translated Chinese version. The translated Chinese version was then shortened and modified by the expert panel. Finally, the 28 modules of the original WHO educational materials were packaged into 4 periods: first trimester, second trimester, third trimester, and postpartum. For postpartum, materials were packaged for maternal care and baby care separately. For each period, up to 7 text messages with specific educational instructions were included. The main contents of the text messages are displayed in Multimedia Appendix 1 (details available upon request). In addition, a few modifications were made to suit the local culture and lifestyle. For example, with respect to nutrition items, beef and dairy products were replaced with high-protein foods such as pork, fish, chicken, and egg, which are frequently consumed by local people in the region. The whole process followed a previously developed protocol that included rigorous and accurate translations and appropriate appraisal.

Sample Size

In the original design, we planned to use village as the unit of randomization. The sample size calculation determined that we required 1130 villages (565 villages for each arm) and 10 births per village for the 12 months of the trial (11,300 total births) to achieve 90% power to detect a relative reduction of 30% in the primary outcome (maternal and perinatal death rates) from a control arm rate of 4% using a 2-sided test at the 5% level of significance [22]. These calculations were based on an assumed intraclass correlation of 0.02 for the villages. With a reduction of 30% as the acceptable magnitude of effect for consideration by researchers and/or policy makers, the available study sample is sufficient to answer the study question.

Recruitment of Study Participants and Randomization

Due to logistical difficulties and budget constraints, we could not use village as the unit of randomization for the cluster trial and we had to use county instead. We, therefore, selected 10 counties in the region and randomly allocated half of the counties to the intervention arm (with text messaging instructions to be sent by county maternal and child health bureaus) and the other half to the control arm (routine care with no text messaging). An independent statistician unrelated to this trial generated the random allocation sequence, and the investigator in charge (RHX) allocated the 10 participating counties to the intervention arm and the control arm accordingly. Village health workers in the 10 participating counties were requested to monitor women of reproductive age who planned to have a baby during the study period, and once a woman was

confirmed to be pregnant, she was considered eligible for this study and was recruited into the study by the village health worker. However, any woman who was unable to read or access text messaging through her own phone or her husband's or family member's phone was excluded. Recruitment was started on October 1, 2011, and ended on August 31, 2012.

Delivery of Educational Material

We worked with local mobile phone carriers and maternal and child health bureaus of the intervention counties to install the adapted WHO education material into their wireless telecommunication systems. Text messages containing education materials were delivered to village health workers and pregnant women in the 5 intervention counties according to the pregnancy period recorded by staff at county maternal and child health bureaus.

Data Collection

Data on mothers' residence (rural vs urban), gravidity, parity, pregnancy risk status (according to the Chinese national guideline), prenatal visit, prenatal screening, syphilis test, hepatitis B test, folic acid supplementation, mode of delivery, obstetric hemorrhage, maternal death, infant sex, birth weight, perinatal death, thyroid test, phenylketonuria test, and hearing test were collected from study participants by village health workers using the data collection form developed by the research team. Data were collected at the beginning of the diagnosis of pregnancy and in the 42 days postpartum (to meet the definition of maternal death).

Statistical Analysis

We first compared the distribution of baseline characteristics and then compared maternal and infant outcomes between the 2 arms. Cluster-level analyses proceeded after comparing means and medians of maternal and infant outcomes as proportions for each cluster to ensure that cluster proportions were approximately normally distributed. We then compared mean differences of the maternal and infant outcomes between the 2 arms using a standard unweighted t test. Supplementary analysis at the individual level was also performed. In the analysis at the individual level, random effects logistic regression analysis was used. To account for clustering by county, the county was specified as a random effect. To adjust for the small number of clusters, the Kenward-Roger method was used [25]. Odds ratio and 95% CI were expressed as the effect measures, using the control arm (no text messaging) as the reference. The analysis was adjusted for the following baseline characteristics: gravidity, parity, rural residence, household income, high-risk pregnancy status, and infant gender.

Results

Participants

Between October 2011 and August 2012, a total of 25,236 pregnant women were recruited into the study (13,332 in the intervention arm and 11,904 in the control arm). Of these, 13,937 (55.2%) women completed the follow-up and were included in the final analysis. Among them, 6771 women were in the intervention arm and 6966 in the control arm. Most of

the remaining 11,299 pregnant women excluded from the final analysis did not complete pregnancy before the study closing date (December 31, 2012), rather than being lost to follow-up (Figure 1).
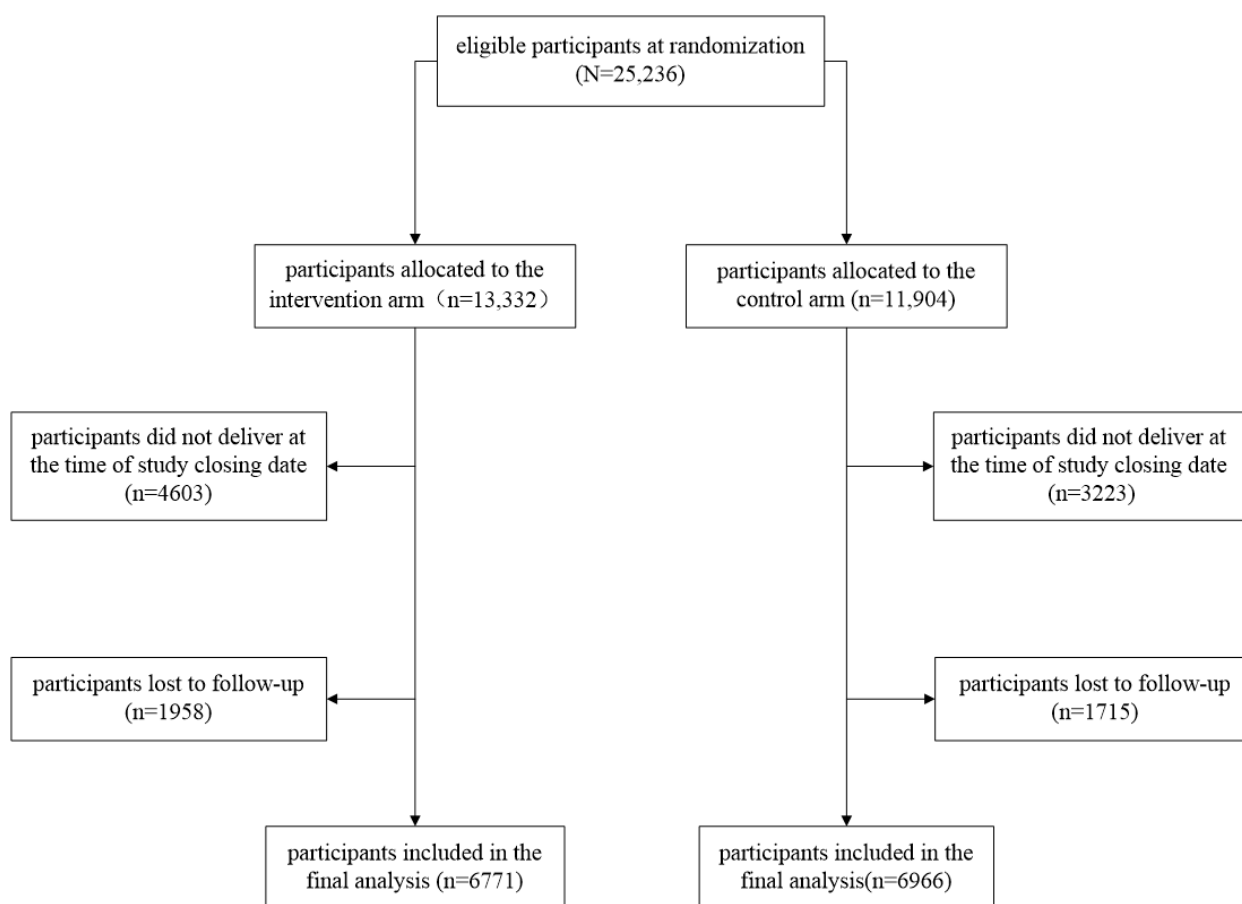
Baseline Characteristics

Table 1 shows the baseline characteristics of the study population. The study region is a typical rural area of China, with the majority (>90%) of the residents living in rural areas. Maternal and infant baseline characteristics between the 2 arms were generally comparable (Table 1).

As means and medians of county-specific outcome measures were very similar (data available upon request), we did not take log transformations of the data but used t tests to compare outcomes between the 2 arms at the county level.

Figure 1. Flowchart of study participants of the text messaging trial in Hunan, China.

Table 1. Comparison of maternal and infant characteristics between the intervention and control arms at the individual level, Hunan, China, 2011-2012.

Characteristics	Intervention arm (N=6771), n (%)	Control arm (N=6966), n (%)
Gravidity		
>1	3285 (48.52)	3478 (49.93)
1	3486 (51.48)	3488 (50.07)
Parity		
>1	3883 (57.35)	4316 (61.96)
1	2253 (33.27)	2039 (29.27)
Rural resident	6388 (94.34)	6389 (91.72)
High-risk pregnancy	2488 (36.75)	2841 (40.78)
Fetal gender		
Female	3057 (45.15)	3639 (52.24)
Male	3684 (54.41)	3304 (47.43)

Table 2. Comparison of maternal and infant outcomes between the intervention and control arms at the county level, Hunan, China, 2011-2012.

Outcome	Intervention arm, % mean (SD)	Control arm, % mean (SD)	Percentage mean difference (95% CI)	P value (based on t test)
Early pregnancy visit	94.8 (2.3)	95.0 (1.1)	0.2 (−5.8 to 6.2)	.94
Prenatal screening	52.5 (12.7)	41.3 (14.3)	−11.2 (−30.9 to 8.5)	.23
Syphilis test	93.2 (7.1)	96.8 (3.3)	3.6 (−4.5 to 11.6)	.34
Hepatitis B test	94.9 (5.4)	98.3 (1.8)	3.4 (−2.4 to 9.3)	.21
Folic acid supplementation	75.6 (13.6)	78.4 (6.3)	2.7 (−12.8 to 18.2)	.69
Cesarean delivery	37.4 (6.8)	42.8 (16.0)	5.4 (−12.5 to 23.3)	.50
Obstetric hemorrhage	0.7 (0.5)	1.2 (0.8)	0.5 (−0.5 to 1.4)	.32
Maternal death	0.0 (0.1)	0.1 (0.2)	0.1 (−0.1 to 0.3)	.47
Perinatal death	1.3 (0.6)	1.5 (0.4)	0.1 (−0.6 to 0.9)	.66
Birth weight <2500 g	3.0 (0.5)	3.7 (2.1)	0.6 (−1.6 to 2.9)	.54
Birth weight >4000 g	1.5 (0.6)	1.6 (0.6)	0.1 (−0.8 to 1)	.80
Thyroid test	86.5 (10.2)	88.1 (5.0)	1.7 (−10.1 to 13.4)	.75
Phenylketonuria test	86.4 (10.2)	88.2 (4.9)	1.8 (−9.9 to 13.5)	.73
Hearing tests	2.3 (0.9)	2.1 (0.9)	−0.2 (−1.5 to 1.1)	.69

Table 3. Comparison of maternal and infant outcomes between the intervention and control arms at the individual level, Hunan, China, 2011-2012 (adjusted for gravidity, parity, residence, household income, high-risk pregnancy status, and gender of infant).

Outcomes	Intervention arm (N=6771), n (%)	Control arm (N=6966), n (%)	Crude odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Early pregnancy visit	6308 (93.16)	6644 (95.38)	0.99 (0.98-1.00)	0.99 (0.99-1.00)
Prenatal screening	3291 (48.6)	2381 (34.18)	1.34 (1.28-1.39)	1.25 (1.21-1.31)
Syphilis test	6121 (90.4)	6625 (95.11)	0.98 (0.97-0.98)	0.98 (0.97-0.99)
Hepatitis B test	6229 (92)	6767 (97.14)	0.97 (0.96-0.98)	0.98 (0.97-0.99)
Folic acid supplementation	4733 (69.9)	5431 (77.96)	0.93 (0.91-0.95)	0.92 (0.90-0.93)
Cesarean delivery	2488 (36.75)	2927 (42.02)	0.88 (0.84-0.92)	0.95 (0.91-0.98)
Obstetric hemorrhage	47 (0.69)	77 (1.11)	0.64 (0.45-0.92)	0.42 (0.22-0.80)
Maternal death	3 (0.04)	6 (0.09)	0.52 (0.13-2.10)	__a
Perinatal death	84 (1.24)	101 (1.45)	0.96 (0.72-1.27)	0.73 (0.50-1.06)
Birth weight <2500 g	196 (2.9)	210 (3.02)	0.98 (0.81-1.19)	1.20 (0.97-1.47)
Birth weight >4000 g	97 (1.43)	105 (1.51)	0.97 (0.74-1.28)	1.01 (0.76-1.36)
Thyroid test	3977 (58.74)	4156 (59.66)	0.96 (0.95-0.98)	0.96 (0.95-0.98)
Phenylketonuria test	3911 (57.76)	4162 (59.75)	0.96 (0.95-0.98)	0.96 (0.95-0.98)
Hearing test	3935 (58.12)	3989 (57.26)	0.97 (0.95-0.98)	0.97 (0.95-0.99)

[a]Not estimable.

County Level Comparison

Table 2 compares outcomes between the 2 arms at the county level. Mean (SD) maternal mortality rates were 0.0% (0.1) and 0.1% (0.2), respectively, in the intervention arm and control arm. The corresponding means (SD) for the perinatal mortality rate were 1.3% (0.6) and 1.5% (0.4), respectively, in the intervention arm and control arm. However, these differences were not statistically significant (Table 2).

Individual Level Comparison

Table 3 displays results of analysis at the individual level. Of the 6771 participants, there were 3 maternal deaths (0.04%) and 84 perinatal deaths (1.24%) in the intervention arm, and of the 6996 participants, there were 6 maternal deaths (0.09%) and 101 perinatal deaths (1.45%) in the control arm. However, the differences were not statistically significant. For secondary outcomes, cesarean delivery (2488/6771, 36.75% cesarean deliveries) and obstetric hemorrhage (47/6771, 0.7% hemorrhage

cases) rates were significantly lower in the intervention arm than those in the control arm (2927/6966, 42.02% cesarean deliveries and 77/6966, 1.11% hemorrhage cases), both statistically and clinically (Table 3). No important differences between the 2 arms for other outcomes were observed (Table 3).

Discussion

Principal Findings

Our cluster randomized trial in a rural area in Hunan, China, found that it was feasible to deliver maternal education materials by text messaging through a mobile phone to village health workers and pregnant women simultaneously. The results did show some reduction in maternal mortality (3/6771, 0.04%) and perinatal mortality (84/6771, 1.24%) in the intervention arm as compared to the control arm (maternal death rate: 6/6996, 0.09% and perinatal death rate: 101/6996, 1.45%). For secondary outcomes, the rates of cesarean delivery and obstetric hemorrhage were lower in the intervention arm than those in the control arm, both statistically and clinically. This is also expected, as educated women should be better prepared; therefore, the need for cesarean delivery and the incidence of obstetric hemorrhage should be reduced. Although the observed associations between maternal education and maternal and infant outcomes were weak and not demonstrable after taking the cluster effect into consideration, these preliminary results are encouraging and deserve further investigation.

Strengths and Limitations

To our knowledge, this is the first study that evaluated the impact of WHO's maternity care education materials for local maternity care education in the remote rural area in China with text messaging. Through mobile phone–based text messaging, we are able to deliver the education materials to a large number of village health workers and pregnant women instantly. The cluster randomized trial is the appropriate design to assess the effect of a maternal education program, as it can be implemented with high efficiency and reduce the chance of contamination [22].

There are several reasons that may explain why our study failed to find an impact of a promising education tool delivered by an efficient method. First, because of implementation difficulties and budgetary constraint, we had to use the county as the unit of randomization. Originally, we planned to use villages as the units of randomization. We realized later that this would have made the trial cost prohibitive: with limited funding, we had to negotiate with local carriers for free text messaging service for this project, which the carriers agreed to only at the county level. There were also logistical considerations: villages lacked the manpower and expertise to deliver education material through text messaging. For these reasons, it was not feasible to use smaller units for randomization. As there were only 10 clusters (counties), we elected to use a more robust cluster-level method of analysis. A disadvantage of analysis at the cluster level is that there could be a loss in power because of data aggregation at the county level. Second, only about half of the recruited women were included in the final analysis. Most of the women were excluded not because they were lost to follow-up but

because they had not yet delivered at the time of study termination (again because of budgetary constraints). The loss to follow-up is unlikely to introduce bias because both the intervention and control arms terminated at the same time. However, the substantial loss of study subjects resulted in lower power. Third, because of limited funding, we were not able to vigorously promote, implement, and monitor the maternal education program. For example, we did not track whether or not the village health workers and pregnant women received the text messages, actually read the messages, and if they found the text messages helpful. We did not have the capacity to provide additional assistance to the village health workers and pregnant women if they had difficulties understanding the messages or how to apply them to their own situations. As a result, the program may have not been implemented to the maximum extent possible, thus limiting its impact. Previous studies have suggested that to ensure the success of text messaging–based interventions, efforts should be made to intensively engage with the targeted population [19,20]. Fourth, we have based power calculation on maternal and perinatal mortality rates that were published more than 10 years ago [1]. Maternal and infant health has been improved substantially in the past decade in China, including rural areas [26], which further limited the study power of this trial.

Implications

Much of the mortality and morbidity in developing countries may be attributable to avoidable risk factors such as unhealthy diets, poor personal hygiene, unsafe delivery by birth attendants, and unintentional injuries; almost all these factors are modifiable [27-29]. For example, postpartum hemorrhage has been identified as one of the most important causes of maternal death in developing countries [27]. On the other hand, evidence generated from clinical investigations, mostly from the industrialized countries, has demonstrated that active management of the third stage of labor can substantially reduce the incidence of severe postpartum hemorrhage [30]. It is, therefore, reasonable to infer that if deliveries in developing countries were managed in the same manner as in industrialized countries, maternal deaths related to postpartum hemorrhage in these countries could be largely prevented. As another example, higher perinatal mortality in developing countries can be attributed in part to the lack of access to high-quality perinatal care for at-risk mothers, fetuses, and newborns [31-33]. Due to the emergent nature of the management of obstetric and neonatal complications and due to the difficulties in transferring at-risk mothers to nearby medical centers in a timely fashion in remote rural areas, instantly accessible information by mobile phone text messaging could provide a helpful tool for village health workers to manage obstetric and neonatal complications locally.

The mobile phone text messaging–based health education tool has been advocated by researchers and health organizations alike [11,12]. The scope and extent of use of this tool with respect to important population health issues have been expanded rapidly, with various trials being designed or launched on repeat suicidal episodes prevention [34], type 2 diabetes prevention [35], detection and management of hypertension in indigenous people [36], diabetes self-management in low- or middle-income countries [37], secondary prevention of coronary

heart disease and diabetes [38], and increasing acceptability and use of effective contraception among young women [39]. However, the impact of such a tool in reducing maternal and infant mortality and severe morbidity in low- and middle-income countries such as China has not yet been well documented. The key reason may be lack of rigorous evaluations from randomized trials, and it is crucial to evaluate its beneficial effects using cluster randomized trials.

Although our cluster randomized trial failed to find a statistically significant impact of the maternal education program delivered by text messaging through mobile phone on improved maternal and infant health and health behaviors, the advantages of text messaging in the field of maternal education should not be overlooked. It is able to deliver precisely packaged material to a massive population at a low cost. To send text messages to a massive population through a mobile phone, the senders need to work with local carriers. Therefore, these types of text messages were usually created and distributed by authoritative sources. On the other hand, messages delivered through social media platforms such as Facebook or WeChat, which could be distributed by anyone in the self-established social groups without scrutiny by experts, were often incorrect or even misleading. There is a general agreement that we need rigorous regulations, protocols, and ethical guidelines to correctly apply new technologies (mobile phone apps and text messages included) in the health care environment. Poorly validated information, often created by nonexperts, and a lack of updated data have been mentioned as concerning issues related to health smartphone apps. As such, authors urge different strategies that will provide higher quality evidence for smartphone apps' effectiveness and contents. This means that nonscientific or not evidence-based information spreading by text messages could be potentially dangerous to patients. Moreover, smartphones are needed to use social media platforms, which are often not affordable for people in remote areas.

Conclusions

In summary, a cluster randomized trial in a rural area in Hunan, China, suggests that it is possible to deliver maternal education material through text messaging to a massive population at a low cost. Although this exploration trial failed to demonstrate a statistically significant reduction of maternal and perinatal mortality or change in health behavior by maternal education through text messaging, several lessons learned from this exercise could help in the design and execution of future cluster randomized trials evaluating this intervention on maternal and infant health and other health issues. First, the choice of cluster unit for randomization requires balanced consideration. On the one hand, using smaller units such as villages is more efficient in terms of statistical analysis and study power. On the other hand, using larger units such as counties is much easier in the implementation of the trial at a much lower cost. However, using a larger unit of cluster will sacrifice statistical efficiency and study power. Second, to ensure the success of this type of intervention, vigorous promotion, implementation, and monitoring are needed. Finally, refined design considerations such as spreading the text messages after a small face-to-face meeting to explain the goals of text messaging intervention; developing a follow-up source to be sure the women can read and understand the received text messages; using images, videos, or other types of media format that may make the key concepts easier to understand; and assistance for those who may be in need could strengthen the intervention.

Authors' Contributions

RHX, HT, and SWW conceptualized and designed the study; RHX, HT, MT, QD, DK, YL, and SWW made major contributions in the acquisition of data and analysis and interpretation of the data; RHX drafted the paper; SWW, HT, MT, and DK critically reviewed and revised the paper; all authors approved the final version of the manuscript. Each author certified that he or she had participated sufficiently in the work to believe in its overall validity and to take public responsibility for appropriate portions of its content.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The main contents of text messages sent to the health care providers and the women in Hunan, China during the four periods.

[PDF File (Adobe PDF File), 18KB-Multimedia Appendix 1]

Multimedia Appendix 2

CONSORT-EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 3MB-Multimedia Appendix 2]

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References

1. WHO. World Health Organization. 2005. Make every mother and child count URL: http://www.who.int/whr/2005/whr2005_en.pdf [accessed 2018-12-05] [WebCite Cache ID 74RTzYNt3]

2. Chalmers B, Mangiaterra V, Porter R. WHO principles of perinatal care: the essential antenatal, perinatal, and postpartum care course. Birth 2001 Sep;28(3):202-207. [Medline: 11552969]

3. Badawy SM, Thompson AA, Kuhns LM. Medication adherence and technology-based interventions for adolescents with chronic health conditions: a few key considerations. JMIR Mhealth Uhealth 2017 Dec 22;5(12):e202 [FREE Full text] [doi: 10.2196/mhealth.8310] [Medline: 29273573]

4. Cooper V, Clatworthy J, Whetham J, Consortium E. mHealth interventions to support self-management in HIV: a systematic review. Open AIDS J 2017 Nov 21;11:119-132 [FREE Full text] [doi: 10.2174/1874613601711010119] [Medline: 29290888]

5. Moore DJ, Jain S, Dubé MP, Daar ES, Sun X, Young J, et al. Randomized controlled trial of daily text messages to support adherence to preexposure prophylaxis in individuals at risk for human immunodeficiency virus: the TAPIR study. Clin Infect Dis 2018 May 02;66(10):1566-1572. [doi: 10.1093/cid/cix1055] [Medline: 29228144]

6. Rincon E, Monteiro-Guerra F, Rivera-Romero O, Dorronzoro-Zubiete E, Sanchez-Bocanegra CL, Gabarron E. Mobile phone apps for quality of life and well-being assessment in breast and prostate cancer patients: systematic review. JMIR Mhealth Uhealth 2017 Dec 04;5(12):e187 [FREE Full text] [doi: 10.2196/mhealth.8741] [Medline: 29203459]

7. Griffin JB, Struempler B, Funderburk K, Parmer SM, Tran C, Wadsworth DD. My quest, an intervention using text messaging to improve dietary and physical activity behaviors and promote weight loss in low-income women. J Nutr Educ Behav 2018 Jan;50(1):11-18. [doi: 10.1016/j.jneb.2017.09.007] [Medline: 29325657]

8. Job JR, Fjeldsoe BS, Eakin EG, Reeves MM. Effectiveness of extended contact interventions for weight management delivered via text messaging: a systematic review and meta-analysis. Obes Rev 2018 Apr;19(4):538-549. [doi: 10.1111/obr.12648] [Medline: 29243354]

9. Berrouiguet S, Larsen ME, Mesmeur C, Gravey M, Billot R, Walter M, HUGOPSY Network, et al. Toward mHealth brief contact interventions in suicide prevention: case series from the suicide intervention assisted by messages (SIAM) randomized controlled trial. JMIR Mhealth Uhealth 2018 Jan 10;6(1):e8 [FREE Full text] [doi: 10.2196/mhealth.7780] [Medline: 29321126]

10. Noonan D, Silva S, Njuru J, Bishop T, Fish LJ, Simmons LA, et al. Feasibility of a text-based smoking cessation intervention in rural older adults. Health Educ Res 2018 Feb 01;33(1):81-88. [doi: 10.1093/her/cyx080] [Medline: 29309599]

11. Bogoch II, Lundin J, Lo NC, Andrews JR. Mobile phone and handheld microscopes for public health applications. Lancet Public Health 2017 Aug;2(8):e355 [FREE Full text] [doi: 10.1016/S2468-2667(17)30120-2] [Medline: 29253476]

12. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management. Epidemiol Rev 2010;32:56-69 [FREE Full text] [doi: 10.1093/epirev/mxq004] [Medline: 20354039]

13. Smith C, Ly S, Uk V, Warnock R, Edwards P, Free C. Process evaluation of a mobile phone-based intervention to support post-abortion contraception in Cambodia. Contracept Reprod Med 2017 May 01;2:16 [FREE Full text] [doi: 10.1186/s40834-017-0043-8] [Medline: 29201421]

14. Ronen K, Unger JA, Drake AL, Perrier T, Akinyi P, Osborn L, et al. SMS messaging to improve ART adherence: perspectives of pregnant HIV-infected women in Kenya on HIV-related message content. AIDS Care 2018 Apr;30(4):500-505 [FREE Full text] [doi: 10.1080/09540121.2017.1417971] [Medline: 29254362]

15. Fairbanks J, Beima-Sofie K, Akinyi P, Matemo D, Unger JA, Kinuthia J, et al. You will know that despite being HIV positive you are not alone: qualitative study to inform content of a text messaging intervention to improve prevention of mother-to-child HIV transmission. JMIR Mhealth Uhealth 2018 Jul 19;6(7):e10671 [FREE Full text] [doi: 10.2196/10671] [Medline: 30026177]

16. Huda TM, Alam A, Tahsina T, Hasan MM, Khan J, Rahman MM, et al. Mobile-based nutrition counseling and unconditional cash transfers for improving maternal and child nutrition in Bangladesh: pilot study. JMIR Mhealth Uhealth 2018 Jul 18;6(7):e156 [FREE Full text] [doi: 10.2196/mhealth.8832] [Medline: 30021707]

17. Rasekaba T, Lim K, Blackberry I, Gray K, Furler J. Telemedicine for gestational diabetes mellitus (TeleGDM): a mixed-method study protocol of effects of a web-based GDM support system on health service utilization, maternal and fetal outcomes, costs, and user experience. JMIR Res Protoc 2016 Aug 09;5(3):e163 [FREE Full text] [doi: 10.2196/resprot.6044] [Medline: 27507708]

18. Himes KP, Donovan H, Wang S, Weaver C, Grove JR, Facco FL. Healthy beyond pregnancy, a web-based intervention to improve adherence to postpartum care: randomized controlled feasibility trial. JMIR Hum Factors 2017 Oct 10;4(4):e26 [FREE Full text] [doi: 10.2196/humanfactors.7964] [Medline: 29017990]

19. Martinez-Brockman JL, Harari N, Pérez-Escamilla R. Lactation advice through texting can help: an analysis of intensity of engagement via two-way text messaging. J Health Commun 2018;23(1):40-51. [doi: 10.1080/10810730.2017.1401686] [Medline: 29236569]

20. Litterbach EK, Russell CG, Taki S, Denney-Wilson E, Campbell KJ, Laws RA. Factors influencing engagement and behavioral determinants of infant feeding in an mHealth program: qualitative evaluation of the growing healthy program. JMIR Mhealth Uhealth 2017 Dec 18;5(12):e196 [FREE Full text] [doi: 10.2196/mhealth.8515] [Medline: 29254908]

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21. Amoakoh-Coleman M, Borgstein AB, Sondaal SF, Grobbee DE, Miltenburg AS, Verwijs M, et al. Effectiveness of mHealth interventions targeting health care workers to improve pregnancy outcomes in low- and middle-income countries: a systematic review. J Med Internet Res 2016 Aug 19;18(8):e226 [FREE Full text] [doi: 10.2196/jmir.5533] [Medline: 27543152]

22. Donner A, Klar N. Design and analysis of cluster randomization trials in health research. United States: John Wiley & Sons Inc; 2000.

23. Campbell MK, Piaggio G, Elbourne DR, Altman DG, CONSORT Group. CONSORT 2010 statement: extension to cluster randomised trials. Br Med J 2012 Sep 04;345:e5661. [doi: 10.1136/bmj.e5661] [Medline: 22951546]

24. Annual report on the maternal and child health status in Hunan. Hunan: Hunan Ministry of Health; 2001.

25. Kenward MG, Roger JH. Small sample inference for fixed effects from restricted maximum likelihood. Biometrics 1997 Sep;53(3):983-997. [Medline: 9333350]

26. Xi B, Zhou C, Zhang M, Wang Y, Xu L. Maternal and child mortality in China. Lancet 2014 Mar 15;383(9921):953-954. [doi: 10.1016/S0140-6736(14)60481-5] [Medline: 24629296]

27. Graham WJ. Now or never: the case for measuring maternal mortality. Lancet 2002 Feb 23;359(9307):701-704. [doi: 10.1016/S0140-6736(02)07817-0] [Medline: 11879885]

28. World Health Organization. Geneva: WHO; 1985 Nov. Prevention of maternal mortality: report of a WHO interregional meeting URL: https://tinyurl.com/y7pm7bru [accessed 2018-12-07] [WebCite Cache ID 74TtUscFS]

29. World Health Organization. Reducing risks, promoting healthy life. Geneva: WHO; 2002. URL: https://www.who.int/whr/2002/en/ [accessed 2018-12-07] [WebCite Cache ID 74Tty7QvH]

30. WHO recommendations for the prevention and treatment of postpartum haemorrhage. Geneva: World Health Organization; 2012. URL: https://tinyurl.com/yd9mrkpd [accessed 2018-12-05] [WebCite Cache ID 74RUwpOcZ]

31. Conde-Agudelo A, Belizán JM, Díaz-Rossello JL. Epidemiology of fetal death in Latin America. Acta Obstet Gynecol Scand 2000 May;79(5):371-378. [Medline: 10830764]

32. Langhoff-Roos J, Larsen S, Basys V, Lindmark G, Badokynote M. Potentially avoidable perinatal deaths in Denmark, Sweden and Lithuania as classified by the Nordic-Baltic classification. Br J Obstet Gynaecol 1998 Nov;105(11):1189-1194. [Medline: 9853768]

33. Sheiner E, Hallak M, Shoham-Vardi I, Goldstein D, Mazor M, Katz M. Determining risk factors for intrapartum fetal death. J Reprod Med 2000 May;45(5):419-424. [Medline: 10845177]

34. Larsen ME, Shand F, Morley K, Batterham PJ, Petrie K, Reda B, et al. A mobile text message intervention to reduce repeat suicidal episodes: design and development of reconnecting after a suicide attempt (RAFT). JMIR Ment Health 2017 Dec 13;4(4):e56 [FREE Full text] [doi: 10.2196/mental.7500] [Medline: 29237584]

35. Muralidharan S, Mohan V, Anjana RM, Jena S, Tandon N, Allender S, et al. Mobile health technology (mDiab) for the prevention of type 2 diabetes: protocol for a randomized controlled trial. JMIR Res Protoc 2017 Dec 12;6(12):e242 [FREE Full text] [doi: 10.2196/resprot.8644] [Medline: 29233806]

36. Yeates K, Campbell N, Maar MA, Perkins N, Liu P, Sleeth J, et al. The effectiveness of text messaging for detection and management of hypertension in indigenous people in Canada: protocol for a randomized controlled trial. JMIR Res Protoc 2017 Dec 19;6(12):e244 [FREE Full text] [doi: 10.2196/resprot.7139] [Medline: 29258978]

37. Abaza H, Marschollek M. SMS education for the promotion of diabetes self-management in low & middle income countries: a pilot randomized controlled trial in Egypt. BMC Public Health 2017 Dec 19;17(1):962 [FREE Full text] [doi: 10.1186/s12889-017-4973-5] [Medline: 29258499]

38. Huo X, Spatz ES, Ding Q, Horak P, Zheng X, Masters C, et al. Design and rationale of the Cardiovascular Health and Text Messaging (CHAT) study and the CHAT-Diabetes Mellitus (CHAT-DM) study: two randomised controlled trials of text messaging to improve secondary prevention for coronary heart disease and diabetes. BMJ Open 2017 Dec 21;7(12):e018302 [FREE Full text] [doi: 10.1136/bmjopen-2017-018302] [Medline: 29273661]

39. McCarthy OL, Osorio CV, Makleff S, Huaynoca S, Leurent B, Edwards P, et al. An intervention delivered by app instant messaging to increase acceptability and use of effective contraception among young women in Bolivia: protocol of a randomized controlled trial. JMIR Res Protoc 2017 Dec 18;6(12):e252 [FREE Full text] [doi: 10.2196/resprot.8679] [Medline: 29254910]

Abbreviations

mHealth: mobile health
SMS: short message service
WHO: World Health Organization

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