Antenatal Care Health Education Intervened by Social Networking on Mobile Phone Compared with Usual Care to Improve Maternal and Neonatal Outcomes: Randomized Controlled Trial

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Background: Although there is a little evidence of social media, especially short message service or SMS, enhancing maternalneonatal outcomes, clinical trials with social audio-video networking improving their maternal-neonatal outcomes have not been investigated yet.

Objective: To determine whether antenatal-health education through audio-video social network about severe obstetric symptoms can provide earlier management and better maternal-neonatal outcomes.

Materials and Methods: Using an open-label randomized controlled trial, the difference of the rate of preterm birth, neonatal respiratory distress syndrome (RDS), stillbirth, and perinatal mortality between the control group of routine antenatal health education and the intervention group with audio-video social networking about severe obstetric symptoms was analyzed. Between April 2015 and July 2018, the investigator randomly assigned 1,160 antenatal women in the control (n=558) and the intervention groups (n=602). Data from 832 participants (control n=400, intervention n=432) were available for analyses.

Results: The intervention group had an inconclusively non-significant difference in the rate of preterm birth when compared with the control group (8.1% versus 11%), odds ratio (OR) 0.8 (95% confidence interval (CI) 0.5 to 1.2); p=0.260 with the statistical power of 0.26. However, the rate of neonatal RDS was significantly lower in the intervention group than in the control group with statistical significance (0.9% versus 3.8%), OR 0.3 (95% CI 0.1 to 0.9); p=0.028. There was a significant difference in labor pain duration before admission between the intervention and the control groups (121.7 \pm 95.3 versus 139.2 \pm 7.0 minutes), coefficient –17.7 (95% CI –31.4 to –4.0); p=0.011.

Conclusion: Antenatal health education through audio-video social networking was found to significantly lower the rate of the neonatal RDS, which was the result of a significant shorter labor-pain time. The shorter labor-pain time plays a role in the early management of preterm birth and low birth weight.

Keywords: Social networking, Mobile phone, Antenatal care, Health education, Maternal outcome, Neonatal outcome, Preterm birth

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In 2013, about 6.3 million under-5-year-old children died around the world, 52% died from infectious disease, and 44% died during the infant period. The three major causes of death consisted of a complication of preterm birth (15%), pneumonia (15%), and delivery complication (10%). A decrease in pneumonia, diarrhea, and measles lowered the number of deaths to about 3.6 million children compared with those in year 2000. Extrapolating the upward trend for congenital anomalies, preterm birth, and neonatal sepsis, an estimated 4.4 million under-5-year old children will die in 2030⁽¹⁾.

The proportion of preterm birth and main neonatal morbidity with respiratory distress syndrome (RDS),

stillbirth, and perinatal death in women delivering from 28 to 36 weeks' gestation were a significant outcome in a randomized controlled trial (RCT). Preterm birth occurred in nearly 9.6% as worldwide incidence and about 11.1% in South-East Asia. Preterm birth was one of the three apparent causes of neonatal mortality, which 15% died from preterm birth complications such as RDS, intraventricular hemorrhage, necrotizing enterocolitis, and sepsis⁽²⁾.

Factors associated with preterm birth consisted of maternal age 35 years or older, single status, lowsocioeconomic, low education, previous preterm birth, and maternal-fetal complications⁽³⁾. Social media is a modern technology and includes short message service or SMS⁽⁴⁾. It is defined as sharing among personal exchange and virtual communications through diversities of presentation like blogs, wikis, podcasts, forums, message boards, review, opinion sites, and social networking⁽⁵⁾. A systematic review demonstrated a low-to moderate-quality evidence showing that SMS notification and multimedia message service (MMS) on a mobile phone could increase the standard of antenatal care (ANC) visit with lower cost than mobile phone call⁽⁶⁾.

The benefits of mobile health (mHealth), social or transmedia, and multiplatform media for increased survival rate of under-5-year old children in low- or middle-income countries are still controversial⁽⁷⁾. An RCT in Zanzibar, East Africa demonstrated that antenatal women who received SMS and called back to personnel in primary healthcare for health education and ANC schedule would deliver with skilled midwife⁽⁸⁾.

Current studies indicate that mobile's SMS intervention in antenatal women could raise the numbers of ANC attendance to four or more visits according to the World Health Organization (WHO) recommendation and reduce the perinatal mortality⁽⁹⁾. An RCT using SMS and phone call between mother and healthcare personnel were associated with a lower rate of perinatal mortality to improve neonatal health, especially in low resource settings⁽¹⁰⁾.

Social networking on a mobile telephone rapidly develops with free application, internet, and coverage to almost all age group, gender, occupation, and socioeconomics⁽¹¹⁾. In addition, mobile phone's social networking has also been progressively used in the daily life of both healthcare personnel and women attending ANC clinic. LINE is a popular freeware application for instant communications on electronic devices.

Moreover, women may be empowered in

decision making on health from learning by the internet to enhance confidence in questioning healthcare personnel and get information to manage various conditions⁽¹²⁾. However, there is inadequate evidence that indicated the effect of social networking, especially audio-video media to enhance maternal-neonatal outcomes.

Therefore, health education through LINE application of antenatal women concerning serious complications like pain, bleeding, water breaking, and fewer fetal movement may encourage patients to visit the hospital as early as possible. Early diagnosis of premature labor provides expected early management and better maternal-neonatal health.

The purpose of the present study was to indicate whether social audio-video networking about severe complications via a mobile phone would enhance the maternal-neonatal outcomes.

Materials and Methods Ethics approval

Ethical approval number: 5/2558 for the present study was obtained from Nopparatrajathanee Hospital Research Ethics Board, Nopparatrajathanee Hospital.

The study was registered in the clinical trials registry of ClinicalTrials.gov Identifier: NCT02371213.

Study design and participants

An open RCT with the parallel assignment was conducted at Nopparatrajathanee Hospital between April 2015 and July 2018, with an intervention of antenatal health education with mobile phone's social audio-video networking in a LINE application. One thousand one hundred-sixty Thai pregnant-woman of 18 years or older who attended the ANC clinic and with either the participant or husband or relative using the mobile phone with social networking application enrolled in this study.

The exclusion criteria consisted of participant who is known by another person in the different intervention arm (contamination), cannot be assessed on well-being regarding privacy, had a delivery failure, or misunderstood social media.

Randomization

Participants were randomly assigned a 1:1 ratio to either the social-networking intervention group or the usual ANC control group by simple randomization with a computer-generated random number (Rand's Million Random Digits). The original procedure of this randomization method was done and started at the 354th random number on page 127 of Rand's Million Random Digits for each assigned group to complete the 1,160 enrolled participants.

Allocation concealment

Central telephone allocation with sequentially numbered-sealed-opaque envelopes was used to ensure that each assigned intervention or control group would not be revealed until research assistants at ANC clinic completing the eligibility screening of participants and gave them the study information before they decided to participate in the study and signed the informed consent.

Procedures

Gestational age was assessed from the fetal measurement before the mid-second trimester. At randomization, participants in the intervention arm were given social audio-video networking on the mobile phone with a routine ANC group-health education. The intervention was audio-video media about serious complications such as pain, vaginal bleeding, water breaking, or fewer fetal movement. It was watched through a social networking application on the mobile phone by participant from the first ANC visit four times monthly and four times every two weeks.

Routine ANC group-health education was defined as two-time standard ANC group-health educations provided by a registered nurse who was research assistant giving the first time before 28 weeks' gestation with information about maternity role, physical, mental changes, ominous signs to see doctors, sanitation, and medication. The second time after 32 weeks' gestation about the counting of fetal movement, delivery preparation, alteration of the body near delivery, the distinction between true and false labor pain, abnormal symptoms to see doctors, steps of delivery service in the hospital, a method of delivery, and breathing exercise for labor pain relief. Preterm labor is determined as a regular uterine contraction resulting in changes in the cervix start before 37 weeks including effacement and dilation⁽¹³⁾.

Management of preterm labor consists of terbutaline, a beta2-adrenergic receptor agonist or nifedipine or magnesium sulphate as a tocolytic to delay preterm labor for up to 48 hours and steroid administration to the mother to treat fetal lung maturity and reduce complications of prematurity⁽¹⁴⁾. Intrapartum group B streptococcal infection prophylaxis is administered to women with unknown culture status who are in preterm labor

with a considerable risk of impending delivery or who have preterm premature rupture of membrane (PROM), rupture of membranes for 18 hours or more, or intrapartum fever⁽¹⁵⁾.

The data on maternal-neonatal outcomes were collected at the labor room, postpartum ward and neonatal care unit. The primary outcome was the rate of preterm birth at less than 37 weeks of gestation. Labor pain time, vaginal bleeding time, and PROM time before admission were collected for analysis of factors associated with preterm birth. The secondary outcomes consisted of the rate of neonatal RDS having breathing disorder that affects newborns, the rate of stillbirth as a baby born with no signs of life at or after 28 weeks of gestation, and the rate of perinatal death which refers to the number of stillbirths and neonatal deaths within seven days after birth.

Sample size

The sample size was calculated and based on a proportion of preterm birth before 37 weeks of gestation accounting for 11.8% in the control group (Nopparatrajathanee Hospital, 2014), and a decrease in spontaneous preterm birth by 40% in the intervention group. The investigator determined that a sample size of 1,160 participants (580 per group) would provide a power of 80% to detect a 40% relative reduction in the primary outcome from a baseline rate of 11.8%, with a 2-sided type I error of 0.05.

Recruitment

A research nurse screened women attending ANC clinic at the first visit. The women who met eligibility criteria would be informed with the study information sheet. When they understood the study information and the process of participation, they signed the consent form. The research nurse performed recruiting and enrolling participants into the study.

Data management

The present study collected data on case record form that conformed to the outcomes of the study. Sources of necessary data were collected from the ANC participants whereas primary and secondary outcomes were gathered from the labor room, the postpartum ward, and the neonatal care unit. Data processing were done by double entry, data cleaning and checking before analyses.

Data analysis

Demographic data showed with mean and standard deviation. Difference test of continuous data

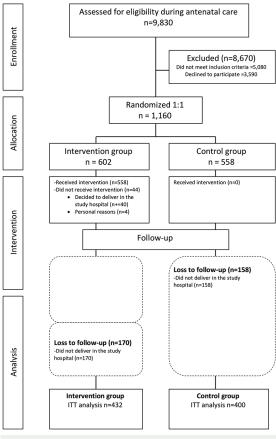


Figure 1. Flow diagram of the study following the CONSORT guidelines.

ITT=intention-to-treat analysis

between two groups was analyzed with independent Student t-test in case of normal distribution or Wilcoxon rank sum test for non-normal distribution and test of difference of ratio data with Fisher's exact test.

Comparison between the intervention group and the control group of the primary outcome was used odd ratio 95% confidence interval (CI). Logistic regression models were used to control confounding effects between odds ratio (OR) of the intervention group and co-variables. The p-values of less than 0.05 (2-sided) were regarded as statistically significant. The analysis was performed by "intention-to-treat" (ITT) principle.

Results

Nine thousand eight hundred thirty antenatal women were screened for eligibility, 5,080 women did not meet the inclusion criteria, and 3,590 declined to participate. One thousand one hundred sixty participants were randomly attributed to either the intervention group (n=602) or the control group (558). During the conduct of the study, 110 participants from the intervention group were non-adherent because of quitting LINE application (n=92), miscarriage (n=8), moved out (n=5), quitting network (n=2), cancelled phone (n=2), and medical reason (n=1). One hundred ten participants in the intervention group and 158 in the control group dropped out because they did not deliver in the study hospital. Therefore, 832 participants were included in the ITT analysis (432 participants in the intervention group and 400 participants in the control group (Figure 1).

Maternal characteristics did not show significant difference between intervention and control groups at their mean age $(27.1\pm6.4 \text{ versus } 27.8\pm7.0 \text{ years})$, gestational age at the first ANC $(15.3\pm7.7 \text{ versus})$ 14.3 ± 6.9 weeks), living with a partner (96.6%) versus 95.6%), nulliparity (36.9% versus 34.9%), employment during pregnancy (73.1% versus 74.0%), secondary school or higher (91.6% versus 88.8%), four or more ANC visits (100% versus 99.8%), previous preterm birth (0.7% versus 2.2%), and medical complication (2.5% versus 2.1%). The neonatal characteristics in both groups did not differ on their gestational age at birth $(38.2\pm1.8 \text{ versus } 38.0\pm2.1$ weeks), cesarean section (30.6% versus 33.8%), birth weight $(3,132.0\pm470 \text{ versus } 3,083.1\pm521.8 \text{ g})$ and low birth weight (8.6% versus 8.8%) (Table 1). The rate of neonatal RDS was significantly lower in the intervention group than that in the control group with statistical significance (0.9% versus 3.8%), OR 0.3 (95% CI 0.1 to 0.9); p=0.028.

The intervention group had an inconclusively non-significant difference in the rate of preterm birth when compared with the control group (8.1%)versus 11%), OR 0.8 (95% CI 0.5 to 1.2); p=0.260. The secondary outcomes of the rate of stillbirth and perinatal death showed no significant difference between both groups. Neonatal RDS was significantly associated with preterm birth, OR 10.2 (95% CI 2.7 to 38.1); p=0.001, and low birth weight, OR 7.9 (95%) CI 2.1 to 29.8); p=0.002, which were adjusted with factors of preterm birth, low birth weight, small for gestational age, cesarean section, and PROM. There was a significant difference in labor pain time before admission between the intervention and the control groups (121.7±95.3 versus 139.2±7.0 minutes), coefficient (coef.) -17.7 (95% CI -31.4 to -4.0); p=0.011, but both groups did not differ at vaginal bleeding time (112.8±165.0 versus 108.5±162.5 minutes), coef. -0.4 (95% CI-22.3 to 21.4); p=0.969

Table 1. Maternal and neonatal characteristics in the intervention and control groups

	Intervention (n=602) n (%)	Control (n=558) n (%)	p-value
Maternal characteristics			
Maternal age (years); mean±SD	27.1±6.4	27.8±7.0	0.112
Gestational age at the first antenatal care (weeks); mean±SD	15.3±7.7	14.3±6.9	0.078
Marital status: living with a partner	539 (96.6)	496 (95.6)	0.432
Nulliparity: yes	206 (36.9)	181 (34.9)	0.525
Employment during pregnancy: yes	408 (73.1)	384 (74.0)	0.782
Secondary school or higher: yes	511 (91.6)	461 (88.8)	0.150
Mobile owner: yes	525 (94.1)	-	-
Antenatal care four or more visits: yes	558 (100)	518 (99.8)	0.482
Previous preterm birth: yes	3 (0.7)	9 (2.2)	0.080
Medical complication: yes	10 (2.5)	9 (2.1)	0.442
Neonatal characteristics	(n=432)	(n=400)	
Gestational age at birth (weeks); mean±SD	38.2±1.8	38.0±2.1	0.378
Mode of delivery			
Cesarean section	132 (30.6)	135 (33.8)	0.335
Non-cesarean section	300 (69.4)	265 (66.2)	-
Birth weight (g); mean±SD	3,132.0±470.0	3,083.1±521.8	0.388
Low birth weight (less than 2,500 g)	37 (8.6)	35 (8.8)	1.000

Table 2. Comparison of the rate of preterm birth, neonatal respiratory distress syndrome, stillbirth, and perinatal death in the intervention and control groups

Rate	Intervention (n=432)	Control (n=400)	p-value	OR (95% CI)	Delta	p1	p2	Power	Actual alpha
_	n (%)	n (%)							
Preterm birth	35 (8.1)	44 (11.0)	0.260	0.8 (0.5 to 1.2)	-0.0290	0.1100	0.0810	0.26	0.04
Neonatal RDS	4 (0.9)	15 (3.8)	0.028*	0.3 (0.1 to 0.9)	-0.0282	0.0375	0.0093	0.73	0.03
Stillbirth	0 (0.0)	3 (0.75)	0.111	-	-0.0007	0.0075	0.00671	0.01	0.01
Perinatal death	0 (0.0)	3 (0.75)	0.111	-	0.0032	0.0075	0.0107§	0.03	0.01

OR=odds ratio; CI=confidence interval; p1=the estimated proportion of outcomes in the control group; p2=the proportion of outcomes in the intervention group; delta=difference of proportions between p1 and p2; RDS=respiratory distress syndrome

* Statistically significant difference by logistic regression adjusted with factors of age, marital status, parity, occupation, education, gestational age at the first antenatal care, previous preterm birth, premature rupture of membrane and severe preeclampsia

[¶] Stillbirth rate and [§] perinatal mortality rate applied from published study in case of zero number of intervention group⁽¹⁶⁾

and PROM time before admission $(21.5\pm85.1 \text{ versus} 26.3\pm108.9 \text{ minutes})$, coef. -3.7 (95% CI -17.0 to 9.6); p=0.583 (Table 2).

Three hundred sixty-four participants in the intervention group received, understood, and satisfied the antenatal health education with social audio-video networking by mobile phone (95.9%, 97.8%, and 97.5%, respectively). Social media with antenatal health education disturbed the privacy of

the participants in 6.9%.

Discussion

Observed data only for the validity of the result was preferred to analyze to a moderate degree (28%) of missing data. However, randomization and allocation of both groups may be affected. Power analysis was applied for power and actual alpha to indicate a true or false negative result. Antenatal health education intervention with social audio-video networking on a mobile phone demonstrated a significantly lower rate in the neonatal RDS. Most participants received, understood, satisfied, and accepted the disturbed privacy about social video-audio media. On the other hand, the study's intervention resulted in an inconclusively non-significant difference in the proportion of preterm birth because there was too low statistical power to conclude such a result.

Therefore, the addition of more statistical power by enrolling more participants in increasing sample size could indicate a true statistical significance. The RCT showed that the result of SMS about abnormal symptoms for antenatal women after 28 weeks of pregnancy until delivery did not differ in pregnancy outcome except more satisfied, more confident, and less anxious compared with the control group⁽¹⁷⁾.

The rate of neonatal RDS was lower in the intervention than in the control group because a significant difference of shorter time of labor pain to delivery room probably provided early management of preterm birth and low birth weight infant, which are significantly associated with neonatal RDS⁽¹⁸⁾. Nevertheless, an RCT does not support the use of vaginal progesterone pessaries in women with a history of a previous spontaneous preterm birth to reduce the risk of neonatal RDS or other neonatal and maternal morbidities relate to preterm birth⁽¹⁹⁾.

The main strength of the present study is one of the first RCTs of antenatal health education with social audio-video networking on a mobile phone that improves the neonatal outcome of RDS. Another strength of the present study is the exclusion of foreign participants who mostly had insufficient socialmedia communication. The remaining strength of the study includes the power analysis for the validity in concluding whether there was a truly significant difference between the intervention and the control groups.

The present study had some potential limitations. First, the open-label method of the trial could have affected medical decision makings, such as inhibition of preterm labor or continuing labor. Second, the single-center nature of the trial and the high rate of loss of follow-up made these findings lack of the external generalizability. Third, long duration of the enrollment and follow-up made more missing data from loss of follow-up and delivery at other hospitals, and fourth, missing data affected randomization and lowered the power of the study. Multi-center RCT can improve the limitations of medical decision making, loss of follow-up, randomization, and the statistical power of the study.

Conclusion

Antenatal health education with social audiovideo networking on a mobile phone lowers the rate of neonatal RDS. Multi-center blinded clinical trials should be conducted in a further study including promotion of adherence strategies to enhance motivation for regular participants and give an appropriate statistical power.

What is already known on this topic?

Mobile's SMS intervention in antenatal women could raise the numbers of ANC attendance to four or more visits according to WHO recommendation and decline in perinatal mortality. An RCT using SMS and phone call between mother and healthcare personnel were associated with a lower rate of perinatal mortality to improve neonatal health, especially in low resource settings.

What this study adds?

Antenatal health education with social audiovideo networking on a mobile phone lowers the rate of neonatal RDS.

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Conflicts of interest

The author declares no potential conflicts of interest concerning the research, authorship, and publication of this article.

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