

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
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ClinicalTrials.gov ID: NCT02037087

Study Identification

Unique Protocol ID: newborn2013

Brief Title: The Impact of Prenatal Short Messages (SMS) on Maternal and Newborn Health

Official Title: The Impact of Prenatal Short Messages on Maternal and Newborn Health

Secondary IDs:

Study Status

Record Verification: April 2016

Overall Status: Completed

Study Start: September 2013

Primary Completion: October 2015 [Actual]

Study Completion: March 2016 [Actual]

Sponsor/Collaborators

Sponsor: Harvard School of Public Health

Responsible Party: Principal Investigator

Investigator: Yanfang Su [yanfang su]

Official Title: ScD

Affiliation: Harvard School of Public Health

Collaborators: Xi'an Jiaotong University College of Medicine

Oversight

FDA Regulated?: No

IND/IDE Protocol?: No

Review Board: Approval Status: Approved

Approval Number: 1/18/2013

Board Name: IRB, Medical School

Board Affiliation: Xi'an Jiaotong University

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Data Monitoring?: Yes

Plan to Share Data?:

Oversight Authorities: China: Ministry of Health

Study Description

Brief Summary: It is hypothesized that delivering short messages (SMS) to pregnant women can improve maternal and newborn health outcomes. This pilot offers mothers-to-be in rural China free daily short messages (SMS) via cell phone. The aim is to advise them on (a) good household prenatal practices (GHPP) and (b) care seeking (CS) in order to improve the quality of life for mothers and newborns.

Detailed Description: Factorial quasi-randomization is utilized to compare two groups of interventions (i.e., GHPP and CS) as well as to compare these individual interventions with a combination of the interventions. It is also possible that distinct treatments have interaction effects, and we plan to test for this. Policymakers are interested in using different strategies to enhance neonatal health. For example, the bank of SMS developed by our team is a combination of several components: reminders for regular checkups, information on GHPP, and information on CS. From a policy perspective, the evaluation of the full bank of SMS may be sufficient for the government to decide whether or not to scale up the full bank of SMS. However, to understand maternal behavior and, for policy purposes, to understand which components in the bank of SMS should be scaled up, it is important to disentangle which component contributes most to final neonatal health. Taken together, are all the components of the bank of SMS effective in changing maternal behavior and enhancing neonatal health? Which mechanisms are at play, good household prenatal care, care seeking in pregnancy, or both?

Conditions

Conditions: Short Message Service
Text Messaging

Keywords: Short Message Service
newborn health
maternal behavior
good household pregnancy practice
care seeking

Study Design

Study Type: Interventional

Primary Purpose: Other

Study Phase: N/A

Intervention Model: Factorial Assignment

Number of Arms: 4

Masking: Single Blind (Subject)

Allocation: Randomized

Endpoint Classification: N/A

Enrollment: 4467 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Good household prenatal practice (GHPP) The GHPP arm receives SMS messages regarding knowledge on nutrition, labor, non-medical pain management, breastfeeding, and depression. This	Behavioral: Good household prenatal practice Knowledge on nutrition, labor, non-medical pain management, breastfeeding and depression

Arms	Assigned Interventions
arm also receives messages delivered to the control group.	
Experimental: Care seeking (CS) The CS arm receives SMS messages which include danger-sign recognition and reminders for government-subsidized projects. This arm also receives messages delivered to the control group.	Behavioral: Care seeking • Danger-sign recognition • Reminders for government projects
Experimental: Full bank of SMS This arm receives the SMS messages delivered to the GHPP, CS and control group.	Behavioral: Full bank of SMS • Danger-sign recognition • Reminders for government projects • Knowledge on nutrition, labor, non-medical pain management, breastfeeding and depression
No Intervention: Control Control group receives SMS messages regarding: <ul style="list-style-type: none"> • Reminders of prenatal visits and certified skilled attendance of labor (status quo); • Fetal development in different gestational stages. The three experimental groups receive the control messages as well.	

Outcome Measures

Primary Outcome Measure:

1. Newborn health

[Time Frame: the first month after birth] [Safety Issue: No]

Newborn health is measured by appropriateness of weight for gestational age.

Secondary Outcome Measure:

2. Neonatal Adverse Outcome Indicator (NAOI)

[Time Frame: the first month after birth] [Safety Issue: No]

The NAOI focuses on measuring severe neonatal morbidity.

3. Actual number of prenatal visits over expected visits

[Time Frame: In the duration of pregnancy, an expected average of 9 months] [Safety Issue: No]

4. Uptake of government-subsidized programs

[Time Frame: In the duration of pregnancy, an expected average of 9 months, and 1 month after birth]

[Safety Issue: No]

This outcome is measured by the following metrics:

1. Duration of folic acid
2. Uptake of infant vaccinations

5. C-section rate

[Time Frame: child birth] [Safety Issue: No]

6. Maternal health

[Time Frame: Child birth and 1 year after birth] [Safety Issue: No]

Maternal health is measured by change of perception in general health and postpartum depression.

7. Near-miss

[Time Frame: In the duration of pregnancy, an expected average of 9 months, and childbirth] [Safety Issue: No]

The near-miss focuses on measuring severe maternal morbidity.

8. Psychological outcomes

[Time Frame: In the duration of pregnancy, an expected average of 9 months] [Safety Issue: No]

Attitudes, personal norms, self-efficacy, social desirability, intentions, plans, susceptibility, expectations, and severity

Eligibility

Minimum Age: 18 Years

Maximum Age: 45 Years

Gender: Female

Accepts Healthy Volunteers?: No

Criteria: There were two inclusion criteria: Local pregnant women must 1) own a cell phone in the household, and 2) visit a MCHC for antenatal care during pregnancy.

Contacts/Locations

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References

Citations:

Links:

Study Data/Documents: