Mobile Health Intervention to Improve Perinatal Continuum of Care in Guatemala

Informed consent form for midwife participants

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NCT02348840

Emory University
Verbal Consent to be a Research Subject

Title: Mobile Health Intervention to Improve Perinatal Continuum of Care in Guatemala

Principal Investigator: Gari Clifford

Sponsor: National Institutes of Health

Investigator-Sponsor: N/A

Study-Supporter: N/A

Introduction

You are being asked to participate in a medical research study. Here we are going to tell you more about the study.

After hearing about it, you can decide to partipate or not. It is your choice. If you decide to participate, and then later don't want to anymore, you can quit.

Deciding to not participate will not affect your relationship with Wuqu' Kawoq in anyway. In other words, you will not be penalized for not participating.

About the Study

This study is trying to figure out if cell phones can help midwives like you in their work. The phones will help you collect information about your patients who are pregnant.

This information will help improve your work. It will also help improve sharing patients with other health workers, like the ones who work with Wuqu' Kawoq.

How might this sharing work? Imagine that you had a patient who needed to be referred to the hospital. Or imagine that you had a sick newborn baby. The phone would allow you to get help from doctors and nurses.

What will We Do?

In this study we will work with 50 midwives like you. We will teach you how to use a cell phone that comes with some special tools. These tools can measure the blood pressure, oxygen level, and heart rate of your patients. They can also measure the heart rate of the baby.

Midwives like you who participate will care for patients like always. However, you will also use this new device at the same time. You will collect basic health information. You will also collect the blood pressure of each mother and the heart rate of each mother and the baby.

Based on the information you collect, the cell phone will provide you with advice. For example, it might tell you that the baby's heart rate is not normal and that help is needed.

This information will also be sent by the phone to doctors or nurses at Wuqu' Kawoq. They will be able to provide additional help to you.

The project will last about 12 months. During the first 6 months, 25 midwives will get the cell phone. Which 25 get it will be chosen at random. This means that only half of you will use the phone during the first 6 months. During the second 6 months, all of you will use the cell phone.

The cell phone and the special tools that come with it are simple and well tested. They are not experimental. They are all tools that can already be bought in special stores.

Risks to You

If you agree to participate in the study, your visits with your patients will take longer. This is because you will have to use the cell phone in each visit. We think this will make each visit 15 or 20 minutes longer than it normally would be.

Benefits

You will not receive any direct rewards for participating in the study. You will be able to use new cell phone tools in the care of your patients.

You will also receive new support from Wuqu' Kawoq doctors and nurses. This support may help you provide more care to your patients.

Payment

You will not be paid any money for participating.

Security

Emory and Wuqu' Kawoq are the two groups that are running the study. They will keep all records about the study private, in keeping with laws.

In the study we will record personal information about patients. We will not record any personal information about midwives. Your name or other information will not be used in any reports about the study.

Agreeing to Participate

If you agree to participate in the study, we assume that this will be until the study ends, unless you say differently.

Taking back your Participation

If you agree to participate, but then later you want to take it back, you can at any time. If you want to do this, you can contact the people running the study.

The main person who you should contact is Dr. Peter Rohloff. You can reach him by calling Wuqu' Kawoq's office at +502 50005833. If you know how to use email, you can also email him at: peter@wuqukawoq.org.

Leaving the Study

You can leave the study without penalty.

If you leave the study before it ends, we may have some final requests for you. For example, we may need to visit you to recover the cell phone or other equipment you were given.

The people running the study can also ask you to leave the study at any time, for any reason. This might happen most often if they think it is better for you not to participate. For example, this could happen if the study changes in some way that makes it hard for you to participate.

Contact Information

Contact Dr. Peter Rohloff at +502 50005833:

- if you have any questions about this study or what your role is
- if you think you have been injured because of participating
- or if you have any questions or doubts or complaints about the study

Contact the Emory Institutional Review Board at +1 404-712-0720 or irb@emory.edu:

- if you have questions about your rights while participating
- if you have any questions or doubts or complaints about the study
- We also have a survey that you can complete online, if you have access, to tell us about your experience at http://www.surveymonkey.com/s/6ZDMW75.

Consent

Please print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent to keep.

_____
Signature of Subject

_____
Name of Subject

_____ _____
Signature of Person Conducting Informed Consent Discussion Date Time

_____
Name of Person Conducting Informed Consent Discussion