,

Mobile WACh NEO: Mobile Solutions for Neonatal Health and Maternal Support
NCT04598165
INFORMED CONSENT FORM

July 23, 2021

,

KENYATTA NATIONAL HOSPITAL (KNH), UNIVERSITY of NAIROBI (UoN), and UNIVERSITY OF WASHINGTON (UW)

CONSENT FOR COHORT STUDY

Mobile WACh NEO: Mobile Solutions for Neonatal Health and Maternal Support

Investigators:

Name	Position	Department	Telephone Numbers
Jennifer Unger	Principal Investigator	Obstetrics and Gynecology, Brown University	+12063888141
John Kinuthia	Site Principal Investigator	Research & Programs, KNH	+254722799052
Grace John-Stewart	Co-investigator	Global Health, UW	+12065434278
Maneesh Batra	Co-investigator	Pediatrics, UW	+12069876556
Keshet Ronen	Co-investigator	Global Health, UW	+12065434278
Anna Hedstrom	Co-investigator	Pediatrics, UW	+12065433200
Dalton Wamalwa	Co-investigator	Pediatrics, KNH	+2540722799052
Manasi Kumar	Co-investigator	Psychiatry, UoN	+254717379687
Brian DeRenzi	mHealth Consultant	Dimagi, Cape Town, South Africa	+27796890574
Wangui Muthigani	Co-investigator	Reproductive and Maternal Health Services Unit, Kenya MOH	+254725510510
Lusi Osborn	Data Management Specialist	Ahero sub-district Hospital	+254725662840
Brenda Wandika	Study Coordinator	Mathare North City Council Clinic	+254725297691
Peninah Kithao	Assistant Study Coordinator	Kisumu County Hospital	+254722409897
Jenna Udren	Research Coordinator	Global Health, UW	+12062214156

Emergency telephone number:
Dr. John Kinuthia**:** +254-722-799-052

Key information

This is a study to understand if sending women SMS and allowing them to messages questions about their pregnancy and babies will help to improve the experiences of women and their children. Some women will receive at least one SMS per week, sometimes more. Some women will only come in for study visits. Women may want to join this study because they might receive information and support about pregnancy and infant health and they may be allowed to text with a nurse about issues they are having. If you are in this study you will not get to choose the group you are in. Women might not want to join the study because they don't want to receive messages on their phone having to do with their health and find it

,

too challenging to come in for study visits. Anyone who joins this study will provide information that may help improve health for all mothers and babies in Kenya.

If you decide to take part in the study, it should be because you really want to be a part of this study. Your care in this clinic and outside this clinic will not change because of your participation. However, you will be asked to attend 2 study visits which would occur at the same times as your normally schedules postnatal care visits. If you decide not to take part, you will not lose any services, benefits or rights you would normally have. You will still receive treatment for your pregnancy and for you in the postnatal period and care for your infant. You can choose to withdraw from the study at any time.

Researchers' statement

We are asking you to be in a research study. The purpose of this form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Pregnant women and new mothers often have questions and concerns about their pregnancy and newborns. Antenatal and postnatal clinics provide information but women may benefit from additional education and counseling during this time. Mobile phones are one way to deliver information to people about their health. Through this study we want to understand if sending information by way of mobile phones would be helpful to pregnant women and new mothers and the best way to send this information in partnership with clinics. We also want to know if being able to communicate with a nurse by SMS will help improve the health of mothers and babies Participation in this study will not affect the care you receive at this clinic. We aim to enroll 5000 women into the study.

This is what will happen if you agree to participate in this study. We will ask you to read, discuss, and sign or make your mark on this form. After this form is signed or marked, the study staff will ask you questions about you, your contact information, your family, and your pregnancy. You will be assigned to one of two groups. You cannot choose which group you will be placed in. We will also not choose your method. A computer will make this choice by chance (like flipping a coin or throwing dice). You will have the same chance of getting into either group. Once your group is randomly chosen by the computer, you will stay in that group for the entire time of the study. We cannot change your group. The two groups you may be assigned to are:

1. Control Group

If you are in the control group you will continue to receive care as usual in the clinic. You will not receive any SMS from the study. You will be asked to inform the study nurse when you have delivered your baby. You will be asked to attend follow-up visits as described at 2 and 6 weeks.

2. Two-way or interactive SMS group

If you are in the two-way or interactive SMS group you will begin receiving SMS messages from the study on your mobile phone. These SMS will contain information about general health, your delivery, your infant's health, and family planning. The messages will be delivered weekly to your phone. Two weeks before your due date, you will receive messages every day. You will be asked to inform the study nurse when you have delivered your baby. After you deliver your baby, you will receive messages every day for two weeks,

,

then every other day for 4 weeks. All messages will contain a question that asks for – but does not require – a response from you. We request that you respond to those questions. If you do not respond, you will receive a follow-up or "check-in" SMS to respond after 2 days. The "check-in SMS" will ask if you are receiving SMS and if you are well. If no response is received from you, you will still continue to receive SMS.

You will also be able to send messages with concerns or questions to the study nurse at any time although nurses will only respond during the day on weekdays. Charges associated with the messages will be paid by the study. You will not have to pay to receive or send any messages to the study nurse. You will be provided a free number to send messages to the study nurse.

In addition to the normal study procedures, we may potentially ask you to participate in an interview about your experience in the study. This interview would happen at the end of your participation. We would ask you questions about how you used the SMS messages and whether you communicated with the nurse and how you used that advice. The interview should take no more than one hour in total and you will be reimbursed similarly for you transport.

It is very important that you contact us to inform us about your delivery. We will provide you with a card with instructions on how to contact the study when deliver your baby. We will also contact you on your expected delivery date if we have not heard from you.

Study visits

The study will last until 18 weeks after your baby is born or your pregnancy ends. We will ask you to meet with the study nurse today, and at 2 and 6 weeks after your delivery. Each visit should take approximately 1 hour. At each visit we will ask you questions about you, your health, and your baby's health. We will ask you questions about your fertility plans and family planning. We will also ask you for updated information on your phone contact and where you live.

After you deliver your baby you will:

- Be asked questions about your delivery

At the each visit you will:

- Be asked questions about your experiences in the study, and with SMS messages if you receive them (only is you are in the intervention group)
- We will also ask you about your health and about the health of your infant
- We will also ask you about your mental health and if you are experiencing any mistreatment in your relationship (if you are in one).

It is very important that you come for all your scheduled clinic visits. If you are unable to make your clinic appointment, please call the clinic to make another appointment, or come to the clinic as soon as you are able. If you miss a visit with the study we will call you to remind you and reschedule.

If your infant experiences serious illness, we will schedule an additional visit with you to collect information about the illness.

Locator Information

,

At today's visit, we will collect information on how to contact you and where you live. We will use this information to contact you if you are unable to come to the clinic or we do not hear from you.

Phone calls
Also, if you have relocated or find it impossible to come into clinic at the time of your study visits we will administer the questionnaires to you over the phone.

Home visits

If you are comfortable having a home visit, we will visit your home after the first study visit to make sure we have an accurate way to contact you in case your phone contacts change.

If you do not return for your study visits, we will also conduct a home visit at the end of the study to check on you. If there is a private location, we will administer the questionnaire to you at home.

Additional Contacts
At today's visit, we collect the names and contact information for people we can contact if we are unable to get in touch with you. If we are unable to reach you via phone or home visit, we will then contact these people to find you. We will not share information about your study participation.

Permission for future contact

We would like to be able to contact you after your participation has ended to see if you would be interested in participating in future studies. You can indicate your choice about future contact at the end of this form. Agreeing to future contact does not obligate you to participate in any future study activities.

MEDICAL RECORD INFORMATION

We will ask for access to your and your baby's clinic and pharmacy records to find out more information about your pregnancy, delivery, and postpartum care. If you agree to give us access to your medical records, we will get information from the facilities where you receive antenatal and postpartum care and delivered your baby, including: any health problems, medication adherence and side effects, and your baby's health information. We will use safety checks to ensure we protect your privacy when getting your information.

RISKS, STRESS, OR DISCOMFORT

In general, whenever you share information with a research study, there are many safety checks in place to keep your information safe. However, there is a small risk that your someone outside of the study could gain access to your information. If this happened, it could be embarrassing, cause you stress and discomfort and even cause problems at home. You may experience stress or discomfort if a partner learns of your study participation. There is risk that this disclosure could result in psychological harm or even physical harm although, that would be extremely rare.

You may become embarrassed or worried when we ask personal questions about you or your infant.

SMS: Receiving information by your mobile phone is generally safe, but it is possible that other people could see the SMS we send you. If you are in the intervention group, meaning the

,

group that receives messages, you may receive information about preparing for your delivery, ANC appointments, your health, infant health and family planning. In situations where phones are shared or stolen, someone you don't know could see the text messages and learn something about you. If you send sensitive questions or information over SMS, we recommend that you delete sensitive SMS you send from your phone.

ALTERNATIVES TO TAKING PART IN THIS STUDY

There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies that we know about. **Whether or not you decide to participate in this research study, you can continue to receive your mother-child health care at this clinic.**

Your participation is voluntary

- You do not have to be in this study if you do not want to.
- You may withdraw from the study or refuse to answer any of the questions asked at any time without loss of benefit or penalty.
- If you are in the SMS group, you can stop receiving SMS at any time without loss of benefit or penalty.

BENEFITS OF THE STUDY

By participating in the study, you will contribute to our understanding of how to deliver education and counseling to help women, babies and their families. It will also help by providing information that can be used to improve services to ensure more women attend clinic visits, get help with their delivery, and are provided with family planning options. It may help keep babies healthy or get them medical attention when they need it. Only if you are assigned to the intervention group you may personally benefit from receiving information and advice about delivery planning, encouragement and counseling about family planning and, assessment of and advice about your infant's health. You may also personally benefit from being able to ask questions to a nurse about your infant's health, family planning and labor and delivery.

SOURCE OF FUNDING

The study team and/or the Kenyatta National Hospital and University of Washington are receiving financial support from the National Institutes of Health in the United States.

OTHER INFORMATION

Your participation is voluntary

- You do not have to be in this study if you do not want to.
- You may decide not to answer any question or stop being in the study without losing your regular medical care.
- If you are in the SMS group, you can decide not to receive SMS without losing your regular medical care.

Reasons why you may be withdrawn from the study

You may be removed from the study without your consent for the following reasons:

- The research study is stopped or cancelled
- The study staff feels that participating in the study would be harmful to you

Costs to you

There is no cost to you for participation in the study. Routine clinical care and services will not be provided by the study. However, you will continue to receive your care and treatment at the MCH clinic.

,

Reimbursement
You will receive Ksh 400.00 for your transportation costs and effort at each scheduled visit.

CONFIDENTIALITY OF RESEARCH INFORMATION

Confidentiality
We will keep your identity as a research subject confidential. Your responses to questions will be kept private. There are exceptions to this particularly for your safety. When we assess participants mental well-being, if we identity that you are at risk of self-harm or have very bad depression, we will disclose this information to you. We will also refer you to a qualified medical provider that can help you with your mental health and we will disclose that information to the medical provider. We will not publish or discuss in public anything that could identify you. Your medical information that you share will be identified by a code number. All of your information, including the link between your name and code number will be kept in a secure location. Once the study is completed, the link between your identifier and research data will be destroyed after the records retention period by law. Any publication of this study will not use your name or identify you personally. However, study team may share identifiable information about you in the case the study team becomes aware of possible harm to yourself or others.

Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is still possible that someone could find out you were in this study and could find out information about you.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- *a member of the federal government who needs it in order to audit or evaluate the research;*
- *individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;*
- *the federal Food and Drug Administration (FDA), if required by the FDA;*

state or local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others

<u>The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.</u>

,

A description of this clinical trial will be available on http://www.clinicaltrials.gov., as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

A copy of your consent form will be scanned directly into your electronic study record and kept in a locked cabinet.

Problems or Questions
If you ever have any questions about this study or think you may have been harmed by participating you should contact Dr. John Kinuthia.

If you have questions about your rights as a research participant, you should contact the Kenyatta National Hospital Ethics and Research Committee, at 2726300 Ext. 44102.

Printed name of study staff obtaining consent Signature Date

If you do NOT want us to contact you in the future about additional studies please mark below:
☐ I do NOT want to be contacted in the future for additional studies.

Participant's statement
Participant literacy: ☐ literate ☐ illiterate

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the *Kenyatta National Hospital Ethics and Research Committee, at 2726300 Ext. 44102*. I will receive a copy of this consent form.

Printed name of participant Signature or thumbprint of participant Date

If the potential participant cannot read the form herself, a witness (not a staff member who obtained the consent) must have been present during the entire consent process and must sign here:

I, the witness, was present while all information in this consent form was read to the potential participant. All questions were answered. The individual has agreed to take part in the research.

___
Witness Name Witness Signature
Date

Copies to: Researcher
Subject
Participant's Study Record