IGHID 12309 - BEDSIDE IMPROVEMENT OF RESUSCITATION THROUGH MHEALTH FEEDBACK (BIRTH STUDY)

NCT Number: NCT05963516

Document Date: 05/24/2023

Kinshasa School of Public Health and the University of North Carolina at Chapel Hill
Midwife Consent to Participate in a Research Study

Consent Form Version Date: v1.0 May 24, 2023
UNC IRB Study: 23-0267
Title of Study: IGHID 12309 – Bedside Improvement of Resuscitation Through mHealth feedback (BIRTH)
Principal Investigator: Eric Mafuta
Principal Investigator Institution: Kinshasa School of Public Health
Principal Investigator Phone number: 081 031 89 18
Funding Source and/or Sponsor: National Institute of Child Health and Human Development, Doris Duke Charitable Foundation, Laerdal Global Health

---

Concise Summary

The purpose of this study is to improve resuscitation care and newborn outcomes by helping you learn from your care. In this study, you will use a mobile health tool called the Liveborn app to receive feedback on your resuscitation care. The Liveborn app communicates via Bluetooth with a battery-operated heart rate meter called NeoBeat. The Liveborn app is not FDA approved. NeoBeat is CE marked in the European Union.

Your participation in this study will last approximately 20 months. As a participant, you will attend resuscitation training and practice your bag-mask ventilation skills once weekly with a manikin. You will also use the Liveborn app to receive feedback either *during* or *after* a resuscitation according to your facility's randomized assignment.

It is possible that your resuscitation care will improve through participation in this study. There are minimal risks to your participation, most notably a small risk of breach of confidentiality and a risk of social embarrassment from receiving feedback.

What are some general things you should know about research studies?

You are being asked to participate in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, at any time, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. If you decide not to participate or if you decide to leave the study before it is done, this will not affect your relationship with the researcher, your employer, the Kinshasa School of Public Health or the University of North Carolina at Chapel Hill.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about participation in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to improve resuscitation care and newborn outcomes by helping you learn from your care using the Liveborn app. The Liveborn app is a mobile health tool that allows an observer to document key events during a resuscitation. The Liveborn app connects with a battery-operated heart rate meter called NeoBeat to detect the newborn's heart rate. The Liveborn app uses the information from the observer and NeoBeat to provide audio-visual feedback during a resuscitation. The Liveborn app also uses this information to help you debrief after a resuscitation.

You are being asked to be in the study because you provide newborn resuscitation care at a health facility participating in this study.

Are there any reasons you should not be in this study?

There are no reasons why you should not be in the study other than personal preference.

How many people will take part in this study?

Approximately 150 nurse midwives and 25,000 babies from multiple institutions will take part in this study.

How long will your part in this study last?

Your participation in this study will last approximately 20 months. As a participant, you will attend two or three trainings over the course of the study that will last up to one day each. You may also be asked to participate in a focus group discussion. The rest of your participation will occur during your regular work hours.

What will happen if you take part in the study?

At the start of this study, you will complete a demographic survey and attend a training that will take approximately one full day. At this training, you will review how to resuscitate newborns according to the Helping Babies Breathe curriculum. You will learn how to use a heart rate meter called NeoBeat for newborns who need resuscitation. You will also learn how to use the Liveborn app.

Throughout the study, you will practice your bag mask ventilation skills with a manikin once weekly for approximately 15 minutes during your regular time at work. You will also place NeoBeat on newborns who need resuscitation. You may be asked to observe the resuscitation care of your colleagues using the Liveborn app.

Your facility will be assigned by chance, like flipping a coin, to one kind of feedback from the Liveborn app: 1) audio-visual feedback during resuscitation or 2) debriefing after resuscitation. You will receive training in how to use the feedback from Liveborn according to your facility's assignment. You will use the Liveborn app for feedback during the intervention phase of the study when you care for newborns at birth. You will complete a survey about your experience with the Liveborn app towards the end of the study.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. You may benefit from being in this study as your resuscitation care for newborns could improve. It is also possible you will not benefit from this study.

What are the possible risks or discomforts involved from being in this study?
There is small risk of breach of confidentiality with participation in this study. We will minimize this risk by assigning you a study identification number that we will use instead of your name for all information we collect.

There is also a risk of social embarrassment from receiving feedback during or after a resuscitation with the Liveborn app. This risk is no more than the risk of receiving feedback from a supervisor. We will minimize this risk by training you and your colleagues in how to create a safe and supportive environment for feedback.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

How will information about you be protected?
We will protect all information we collect about you by assigning you a study identification number. This identification number will be linked to your name on a study log. The study log will be kept in a secure, locked location. Only authorized research staff will have access to the study log. All data collected about you during this study, including demographic surveys, observations with the Liveborn app will contain your identification number instead of your name.

Participants will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, the Kinshasa School of Public Health and the University of North Carolina at Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of these Schools, research sponsors, or government agencies for purposes such as quality control or safety.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, or because the entire study has been stopped. If you withdraw or are withdrawn from this study, all data collected up until the point of withdrawal will be retained.

Will you receive anything for being in this study?
You will not receive anything for being in this study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if we learn about new findings or information during the study?
If we learn about new information during the study that could affect your willingness to continue participating, we will provide this information to you.

What will happen if you are injured by this research?
The only known risks to participating in this research are a small risk of breach of confidentiality and a risk of social embarrassment.

However, all research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill and the Kinshasa School of Public Health have has not set aside funds to pay you for any such injuries, illnesses, or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study-related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. He will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

Who is sponsoring this study?
This research is supported by National institute of Health, Doris Duke Charitable Foundation, Eunice Kennedy Shriver National Institute of Child Health and a monetary gift donation from Laerdal Global Health. In addition, Laerdal Global Health will be providing some personnel, such as Co-Investigators, to work on this project. If you would like more information, please ask the researchers listed in the first page of this form.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study, or if you have complaints or concerns about the study, or if a research-related injury occurs, you should contact the researcher listed on the first page of this form.

ClinicalTrials.gov Registration
A description of this clinical trial will be available on www.clinicaltrials.gov, as required by United States 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 website at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Kinshasa School of Public Health Institutional Review Board at 081 50 46 570.

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent