BOSTON MEDICAL CENTER AND THE
BOSTON UNIVERSITY SCHOOLS OF MEDICINE,
PUBLIC HEALTH AND DENTAL MEDICINE

Cover Sheet

Informed Consent for

Nthabi in Lesotho - Pilot

NCT04354168

PI Brian Jack, MD

6-3-2021

BMC and BU Medical Campus IRB
IRB NUMBER: H-40268
IRB APPROVAL DATE: 06/03/2021

PRE-TESTING – SUBJECT CONSENT FORM

Basic Information

Title of Project: Nthabi in Lesotho -

Pilot IRB Number: H-40268

Sponsor: NIH/Fogarty International Center
Principal Investigator: Brian W. Jack, MD
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Boston MA 02118

Local Study Contact: M'e Elizabeth Nkabane-Nkholongo
Local Phone Number: +266 2232 4262

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are doing the research to aid in the development of the Nthabi mobile health application in Lesotho. If you agree, you will be asked to use the Nthabi mobile application for a two-week period and provide feedback on any technical issues, like system crashes or lags that you encounter.

The main risks of being in the study are potential loss of confidential health information and the discussion of sensitive health topics. You will find more information about risks later in this form.

You might benefit from being in the study because there is a possibility that the information your hear might prompt you to make changes that may improve your overall health. You will find more information about benefits later in this form.

Purpose The purpose of this study is to help in the development of a health information technology (mobile application) tool aimed at improving the health of young Basotho women.

The findings of the usability testing will help us address any technical issues prior to a larger study that will be conducted with up to 200 participants.

What Happens In This Research Study

Who will be in the research study? You will be one of approximately 10 subjects to be asked to participate in this study.

Where will the research study take place? This research will take place over the phone.

How long is participation in the research study? 2 weeks.

What will happen next? If you agree to participate, research staff will collect basic contact and sociodemographic information. You will work with research staff to create a username and password to be able to login to the Nthabi mobile application. Once research staff create your account, you will be asked to download the Nthabi mobile application onto your Android smartphone and you will log in.

What happens during the research study with the Nthabi system? The Nthabi system includes information on 5 health topics- HIV, TB, Family Planning, Folic Acid, and Healthy Diet. Nthabi is a conversational agent, which is a simulated counselor that mimics face-to-face interactions. The Nthabi system is also interactive and you will be asked to respond to her questions and be provided with educational information. We encourage you to use the Nthabi application at least three times a week for about 20 minutes for the next two weeks. During your use of the Nthabi mobile application, we will track the number of minutes spent at each log in, topics discussed during each session and your responses to specific health behaviors during your two-month participation. The information that we track in Nthabi mobile application will not collect any information that will reveal your identity.

What happens once I complete the research study? During the two week period, we will ask you to provide feedback about your experience using the Nthabi conversational agent and any technical issues that occur as they arise. The feedback form will be accessible directly in the Nthabi application so you can provide feedback after each interaction if you choose to do so. After the two-week testing period, you will no longer be able to log on to the application. A pop-up window will prompt you to complete the two-week post-assessment on your health behavior and app satisfaction and then ask you to uninstall the application stating that the project trial period is over. Information you entered in the Nthabi mobile application will be not be analyzed and will only be used for testing purposes to ensure the data is being collected and populated in the server. Feedback from the survey will be used to address any technical issues that may arise. Research staff will download this information directly from the application. If you have any technical issues you can call the Project Manager, M'e Elizabeth Nkabane-Nkholongo at +266 2232 4262.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

Risks and Discomforts

There is the possibility of some embarrassment in talking with study staff or the Nthabi mobile application about your health. You do not need to answer any questions or participate in any discussions that make you feel uncomfortable.

If you decide that you want to stop being in the study, we ask that you let us know. If you stop early, you will not have continued access to the Nthabi mobile application and may not receive health information that may be useful to you. Your decision to withdraw will not impact the care you receive at the district hospital in any way.

Potential Benefits

The benefits of being in this study may be increased knowledge on the health topics addressed in the Nthabi application. You may also choose to make changes in your behavior to become healthier. However, you may not receive any benefit. Your being in the study may help the investigators learn best practices to deliver preconception health education to Lesotho women.

Costs

If you are in this study, you may have to pay for data usage of your smartphone to use the Nthabi application. If you are connected to WiFi while using the Nthabi application, no data usage costs should occur.

Payment

You will receive 75 Maloti (the equivalent of $5 USD) upon enrollment. You will also be able to receive 75 Maloti (the equivalent of $5 USD) if you choose to complete the feedback survey accessible in the Nthabi at least once during the two-week testing period. In total, you will be able to receive up to 150 Maloti (the equivalent $10 USD) for your participation in this study.

Confidentiality

We will only collect your name and contact information so that we may remind you to complete the feedback survey. Your name will not be linked with any study data.

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

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes_____No You may contact me again to ask for additional information related to this study

____Yes_____No You may contact me again to let me know about a different research study

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact M'e Elizabeth Nkabane- Nkholongo at +266 2232 4262. Also call if you need to report an injury while being in this research.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

You may also contact information for the local Ethics Board at +266 2222 6317.