Consent to Participate in a Research Project: Patient Participant

Study Title: An accessible, scalable, patient-facing mHealth application for heart failure in LMIC

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Research Center: Uganda Initiative for Integrated Management of Non-Communicable Diseases, Kampala, Uganda; Yale School of Medicine, New Haven, CT, USA; University Health Network, Toronto, Canada

Funding: National Institutes of Health, USA

Research Study Summary:

We are asking you to join a research study.

The purpose of this research study is to help you improve your ability to care for your medical condition (heart failure) through the use of a mobile phone application called Medly Uganda.

Study activities will include completing surveys and an interview, completing a brief walking test, and having ultrasound scans of your heart.

Your involvement will require approximately 2 hours today and again in 3 months and 6 months.

There may be some risks from participating in this study but these are minimal and limited to your time spent completing the study activities and any personal discomfort you may experience while doing so.

The study will benefit you by giving you encouragement and more tools to help you care for yourself and by connecting you more frequently with clinicians at Uganda Heart Institute.

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with the health centre where this research is being conducted.

If you are interested in learning more about the study, please continue reading or the Research Nurse will read it to you. Ask the Research Nurse questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will verbally agree to do so.

Invitation to participate

You are invited to participate in a research study designed to to help you improve your ability to care for your medical condition (heart failure) through the use of a mobile phone application called Medly Uganda. The researchers for this study are located at Makerere Univeresity, Kampala, Uganda; University of Toronto, Canada; and Yale University, USA. When you have heart failure, it is important to learn more about the condition, learn to recognize the symptoms, and learn how to help yourself feel better. Mobile phone applications can be used to help people learn to care for their chronic conditions. We have designed Medly Uganda to serve this purpose. Medly Uganda is endorsed by the Uganda Ministry of Health, is integrated into another successful mobile phone application called FamilyConnect, and has been designed to work on any type of mobile phone. The goal of this study is to find out how patients like you use Medly Uganda and whether it helps to improve your health and the way you feel.

To decide whether or not you wish to participate in this study, you should know enough about its risks and benefits to make an informed decision. Please ask me to explain any words that you do not understand as we review the

study. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to verbally agree to do so.

Who is eligible to participate in this study?

You are eligible to participate in this study if you are a patient at least 18 years of age; are receiving care for heart failure at Uganda Heart Institute; are here today for a routine or urgent care visit; have (or have had) symptoms related to heart failure; have access to a mobile phone; and have basic reading skills in English, Luganda, and/or Runyankole.

Description of study activities

If you decide to participate in this study, you will be asked to complete the following procedures:
Today: You will be oriented to Medly Uganda and registered in the system. At this visit, we will measure your height, weight, heart rate, and blood pressure. You will have a urine pregnancy test. We will record a list of your medicines. You will complete a survey. We will measure how far you can walk in 6 minutes. We will perform an ultrasound scan of your heart.
3 Months: You will come back here so that we can measure your weight, heart rate, and blood pressure. You will complete a survey. We will measure how far you can walk in 6 minutes. We will perform an ultrasound scan of your heart.
6 Months: You will again come back here so that we can measure your weight, heart rate, and blood pressure. You will complete a survey and participate in an interview about your experience with Medly Uganda. We will measure how far you can walk in 6 minutes. We will perform an ultrasound scan of your heart.
Completion of these procedures should take approximately 2 hours each time. After each session, a transport refund/ time compensation of UGX 10,000-25,000 will be given to you.

Using Medly Uganda: Every Monday, Wednesday, and Friday morning you be expected to start a Medly Uganda session by dialing a code on your phone just like you would do if you were using Mobile Money. If you have not done so by 11:00am, you will receive an SMS message reminder on your phone. The application will then present a five or six Yes/No questions asking you how you feel and whether you are experiencing symptoms of heart failure. You will then be sent a message that teaches you about heart failure. If your answers indicate that you are experiencing symptoms, the message will instruct you to take an action such as taking more medicine. If your symptoms are more severe, you will receive a phone call from the Uganda Heart Institute staff within one hour.

Risks and Inconveniences

The risks of participating in this study are minimal. They include your time spent completing the survey and study procedures and any personal discomfort you may experience while doing so.

Benefits:

The study will benefit you by giving you encouragement and more tools to help you care for yourself and by connecting you more frequently with clinicians at Uganda Heart Institute. By helping us learn how healthcare providers can support patients with chronic conditions more effectively, society stands to benefit from your participation in this study as well.

Privacy and Confidentiality (HIPAA)

If you choose to participate, the Research Nurse will obtain certain personal information from you, including your name, address, date of birth, telephone number, weight, height, resting heart rate, resting blood pressure (sitting and

standing), list of prescribed medications and doses, responses to the survey tools (Self-Care of Heart Failure Index and EQ-5D, 6-Minute Walk Time and an echocardiogram (ECG).

The survey questions will be read to you from a digital form on a tablet and your answers will be directly recorded in that form. All of your responses will remain confidential and only the researchers involved in this study will have access to the information you provide. Research records will be kept in a locked file. All electronic materials will be stored in password-protected databases. Information about you, collected as part of this research, will not be used or distributed for future research studies.

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance.
- Yale and Ugandan Principal Investigators
- Yale and Ugandan Co-Investigators and other investigators
- Yale and Ugandan Study Coordinators and Members of the Research Teams
- Representatives from Makerere University School of Medicine Research and Ethics Committee
- Representatives from University Health Network Research Ethics Board in Toronto, Canada

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Voluntary Participation

Participation in this study is entirely voluntary. You are free to not participate, to withdraw from the study at any time, or not participate in any aspect of the study as you decide. Your decision to participate in this research project or not will not affect the care and support you receive from Uganda Heart Institute.

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Dr. Jeremy Schwartz at Yale School of Medicine, Department of Internal Medicine, New Haven, CT 06520, USA

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

Who to Contact

If you have any questions about the research you can ask now or later. If you wish to ask questions later, you may contact Principal Investigator Dr. Isaac Ssinabulya at 0782 083968 or Dr. Jeremy Schwartz at +1 2036801598.

At any time, if you have any questions related to your rights as a study participant, please call Prof. Ponsiano Ocama, Chairman of the Makerere University School of Medicine Research and Ethics Committee, at 0772 421190, the

Uganda National Council for Science and Technology at 0414 705500, or the Yale University Human Subjects Committee, +1 203 785-4688 / human.subjects@yale.edu.

Questions

At this time, please feel free to ask questions about anything you do not understand. You may take as long as you feel is necessary before you make a decision.

Authorization

I have been invited to participate in this research study. I have read/ been read the foregoing information. I have had the opportunity to ask questions about this study and all my questions have been answered to my satisfaction. I consent voluntarily to participate in this study, effective immediately. I also understand that I can withdraw from this study for any reason and at any time.

Participant Name _____

Participant Signature _____ or thumb print

Date _____

Witness (if thumb print):

Name of witness _____

Signature of witness _____Date _____

Research staff name _____

Research staff signature_____ Date _____