RESEARCH CONSENT FORM

Basic Information

Title of Project: Pilot trial of a Community Health Worker Intervention to Improve Heart Failure Care in Rural Haiti
IRB Number: H-41758
Sponsor: National Institutes of Health

NCT05091710

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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 asking you to be in this study because you are a patient with heart failure. We are doing the research to understand how Community Health Workers can help educate patients with heart failure and promote follow-up in clinic. If you agree, you will be contacted by a Community Health Worker at home and by phone before you first scheduled clinic appointment. You will be in the study for 3 months if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are feeling uncomfortable with a community health worker home visit. You will find more information about risks later in this form.

You might benefit from being in the study because a community health worker will visit you at home and contact you by phone to teach you about your condition and remind you of upcoming appointments. You will find more information about benefits later in this form.

Your doctor may also be an investigator in this research study. Being an investigator means your doctor is interested in both you and the study. Your doctor's goal as an investigator is to collect information to answer the scientific questions asked in this research study, in order to help future patients. This is different from their role as your doctor, where their goal is to treat you as a patient. You may want to get another opinion about being in the study from a doctor who is not an investigator in this study. You can do so now or at any time during the study. You do not have to agree to be in this study even though it is offered by your doctor.

Purpose

Our study is designed to assess how acceptable and effective the Community Health Worker (CHW) program is for patients with heart failure.

What Will Happen in This Research Study

In this research study, we will ask you to participate in the Community Health Worker support program as a patient. If you are to participate in this study, the following things would happen:

- A CHW would come to your home. During this visit, the CHW will make sure you have enough medications, remind you of your upcoming appointments, give you information and reminders about taking your medications, and help you monitor your symptoms.
- The day before your 1 week follow up visit at HUM, the CHW will call you to remind you of your appointment. This is the last CHW visit related to this study.
- You will attend your regularly scheduled follow up visits at HUM 1 week, 2 weeks, and 1 month after you are discharged. These visits are not considered research.
- About 1 week after your 1 month follow up visit, a research assistant from our study will contact you – by phone of by home visit. They will ask you what you like and dislike about the program, and how helpful or unhelpful you think it is. We will administer a survey and your responses may be audio recorded.
- You will attend your regularly scheduled 2 month and 3 month follow up visits at HUM.
- About 1 week after your 3 month follow up visit, a research assistant from our study will call you. They will ask the same questions and survey as before about your perceptions of the CHW program. After this, your participation in the study is ended. You will continue to receive regular medical care at HUM.

We will also review medical records from HUM to review your symptoms and test results. No blood tests or other tests will be done specifically for the study. There are no experimental medications or procedures as part of this study.

You will be one of approximately 30 total patients who will to be asked to be in the study.

Risks and Discomforts

Risks to you are minimal, meaning they are not thought to be greater than other risks you experience every day. Risks might include feeling uncomfortable being audio recorded, or being uncomfortable with a CHW or Research Assistant visiting you at your home. There is a risk of breach of confidentiality but we have protections in place to prevent this and this is described below.

Potential Benefits

Patient study participants may directly benefit from the more intensive follow-up care provided by the CHWs. However, you may not get any benefit from participating in the study. The study results will also inform ongoing clinical activities and lead to future improvements in linkage to care and will benefit patients with similar conditions.

Alternatives

The following alternative procedures or treatments are available if you choose not to be in this study: continued care with the non-communicable disease clinic at HUM, or other hospital.

Costs

There are no costs to you for being in this research study.

Payment
You will not receive any financial compensation to be in this research study.

Confidentiality
We will do our best to keep your information safe. However, we cannot guarantee confidentiality. Federal and state agencies, if they are required by law or are involved in research oversight, may access information about you from this study. Such agencies may include the U.S. Department of Health and Human Services, and the National Institutes of Health.

We will protect your information by keeping the recordings and transcript confidential. All records will be locked in a cabinet at the hospital. The person who transcribes the recordings will wear headphones so that other people will not hear your voice. Information from your hospital record will be stored in a secured, electronic database. We will destroy the recordings and all other records after seven years. Only members of the study team will have access to the records.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC**.** The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people who you give us separate permission to share your information.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

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.

Use and Sharing of Your Health Information

The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or shared during this research includes:

- Information that is in your hospital or office health records. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The reasons that your health information might be used or shared with others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information.

The people and groups that may use or share your health information are:

- Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study

We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your health information:

- The time period is not known, because research is an ongoing process. We cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and share your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.
- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you

ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the Zanmi Lasante Institutional Review Board at cer@zanmilasante.org.

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 Dr. Dawson Calixte at 3850 1784. Also call if you need to report an injury while being in this research.

You may also call 617-638-7207 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 the Zanmi Lasante Institutional Review Board at cer@zanmilasante.org.

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and sharing of information that may identify you as described, including your health information.

_____ _____
Signature of subject Date

Researcher: _____
Printed name of person conducting consent discussion

BMC and BU Medical Campus IRB
IRB NUMBER: H-41758
IRB APPROVAL DATE: 09/15/2023

I have personally explained the research to the above-named subject and answered all questions. I believe that s/he understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date

This consent form was read to and apparently understood by the subject in my presence.

_____
Printed name of witness (a person not otherwise associated with the study)

_____ _____
Signature of witness Date

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