Preventing Ischemic Heart Disease With mHealth (Mobile Health), Electronic Decision Support and Community Health Workers (PRIMECare)

NCT05511701

Patient Consent Form

Version 2: November 19, 2021

Protocol Title: **PRIMECare Trial: Preventing Ischemic Heart Disease with mHealth, Electronic Decision Support, And Community Health Workers (IRB20-1166)**
Principal Investigator: **Thomas A. Gaziano**
Description of Study Population: Argentinians aged 40-74 who receive health care in government primary care clinics (PCCs), insured exclusively by public health insurance, have access to a cell phone for personal use, reside within 10 km of the PCC, and who have a 10-year cardiovascular disease risk ≥ 10%.
Version Date: Version 2_11192021 (Phase 2)

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Overview

You are invited to participate in a research study being carried out by Instituto de Efectividad Clinica y Sanitaria (IECS) and the Harvard T.H. Chan School of Public Health relating to the health care services provided to people at risk of heart disease. The purpose of this study is to improve the identification and management of persons with high cardiovascular risk. The study will take place over 12 months and will include 954 people from 18 primary care clinics (PCCs) in three provinces in Argentina. The information provided on this document is to help you decide whether you would like to participate in our research study. If there something that you do not understand, or if you would like to obtain more information, please let us know, and we will gladly clarify it. Please take your time to decide whether you wish to take part in our study.

Why is this study being done?

The main reason we are doing this study is to find out if the risk of developing heart disease amongst people who live in Argentina can be reduced through early detection of high-risk individuals. Cardiovascular disease is leading cause of death in Argentina and people with cardiovascular risk factors like (high cholesterol, high blood pressure, etc.) are at higher risk for suffering a cardiovascular event such as a heart attack or stroke. Despite care and chronic medications being available for free, many people are not aware of their cardiovascular risk or cholesterol level and a low percentage of patients (11%) receives appropriate medications like cholesterol lowering medication to prevent cardiovascular events.

This study is evaluating how useful it is to identify individuals at high risk for heart disease using a mobile app, an electronic decision support tool, and sending text messages (SMS) to these persons to promote medical appointment referral, lifestyle changes through tips on healthy living, and to assist health care providers in implementing evidence-based clinical guidelines at the point of care.

Why am I being invited to take part in a research study?
We are inviting you to take part in a research study because you are a person aged 40 to 74 years old, you are insured exclusively by public coverage insurance, have cardiovascular risk factors (e.g., diabetes, hypertension, etc.) and live in the catchment area of a primary care clinic that was selected to participate in the study.

What should I know about this research study?
It is up to you to decide if you want to participate in this study. If you choose not to participate, you will still be able to continue to receive health care services at the clinic. We will explain the details of the study and answer any questions you might have about the study. If you agree to participate, we will ask you to confirm your willingness to participate by signing two copies of this form. You will keep one copy for your records, and we will keep the second copy for the study records. However, even after agreeing, you are free to withdraw from the study at any time without the need to provide reasons for your decision. If you agree to take part now and later change your mind, you will still be able to continue to receive health care services at the clinic.
Please note that we will follow the national Ministry of Health COVID-19 guidance on authorized in-person activities, including sanitation of venues prior to the discussions taking place, hand washing, the use of masks, and maintaining at least 2 meters (6 feet) between persons.

How long will I take part in this research?
It will take 12 months to complete the study and during this time, a CHW and a nurse will visit you at your home to complete two study visits. The visits by the CHWs will take approximately 30-45 minutes and the visits by the nurse should take approximately 15-30 minutes. If your clinic is assigned to the intervention group, your doctor will ask you to come to the clinic for follow-up visits to have your cholesterol and/or blood pressure checked, and the nurse will fill out some questionnaires asking about your health. These visits will last approximately 30-40 minutes. A CHW may also visit you at home once or twice, or call you on the phone during this time to help you to improve control of your cardiovascular disease. The telephone calls will take approximately 10 minutes and the CHW visits will take approximately 20-30 minutes. If your clinic is assigned to the control group, the CHW will recommend that you schedule an appointment with a physician at the primary care clinic where you will receive usual care.
You will also be asked for your contact information so that we may invite you to participate in a focus group at the end of the study to ask about your experiences related to your medical appointments at the clinics and the treatments provided. More detailed information about the study procedures can be found under the *"What can I expect if I take part in this research*?" section.

Is there any way being in this study could be bad for me?
If you are found to be at high risk for cardiovascular disease, it may be distressing but you will be able to seek care and advice from a doctor at the primary care clinic. We will provide the results from the risk assessment and the cholesterol test that we perform to you and your doctor. Your doctor will be able to use this information to explain your risk, to provide you with the recommended course of

treatment, and provide you with all the free health care services, including any prescription medications that are available to you at no cost through the clinic. These free prescription medications are provided to you through the Remediar Program. There is a small risk of fainting when we collect 2 droplets of blood from your finger during the home visit, but we will do everything we can to help you to relax before obtaining the blood.
More detailed information about the risks of this study can be found under the *"What are the risks and possible discomforts?"* section.

Will being in this study help me in any way?
You may have no direct benefit for taking part in this study. However, you will have your cholesterol checked and your cardiovascular risk monitored by healthcare professionals, all of which could improve with appropriate therapy. We expect the knowledge gained from this study will improve cardiovascular disease management on a large scale and benefit society as a whole as well.

What happens if I do not want to be in this research?
Participation in this research is completely voluntary. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no consequences of any kind if you drop out and you will continue to receive health care services in the clinic.

Detailed Information

Below we provide more detailed information about this study for your review.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research, you will be asked to sign two copies of this informed consent. One copy of this consent form will be given to you at the start of your first visit at home so that you can take as much time as you need to review it in detail.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, please feel free to talk to a member of the research team at the Institute for Clinical Effectiveness and Health Policy in Buenos Aires led by Dra. Andrea Beratarrechea ([redacted]) or Dr. Thomas Gaziano at the Harvard TH Chan School of Public Health in Boston, MA ([redacted]).
If you have any questions about your rights as a participant of this study, you can contact the Harvard Longwood Campus Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Regulatory Affairs and Research Compliance (ORARC) at 617-432-2157 (or toll-free at 1-866-606-0573) or at irb@hsph.harvard.edu. The Institutional Review Board is made up of independent people who are not researchers and their goal is to ensure the dignity and rights of the participants in this study.

Participation is voluntary

You have been invited to participate because you are a person aged 40 to 74 years old, you are insured exclusively by public health insurance, have cardiovascular risk factors (e.g. diabetes, hypertension, etc.), and live in the catchment area of a primary clinic that was selected to participate in the study.
Your participation is completely voluntary. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation in this study will not lead to any loss of benefits to which you are otherwise entitled, and you will still be able to continue to receive health care services at the clinic.

How many people will take part in this research?
Approximately 954 people will take part in this research.

What can I expect if I take part in this research?
As a participant, you will be expected to participate in the study for 12 months during which time you will be visited by a CHW and study nurse at the start of the study (baseline visit) and again after you have been enrolled in the study for one year (12 month follow up visit). A CHW may also visit you at home 1-2 times for approximately 20-30 minutes, or call you on the telephone for approximately 10 minutes, to help you to improve control of your cardiovascular disease. You may also be selected to participate in a focus group discussion with participants at the end of the trial to get their opinions about their experiences obtaining health care from the primary care clinic. The focus group discussion is expected to last 60-90 minutes.

<u>Baseline visit</u>
A Community Health Worker will visit you at your home. She/He will ask you some questions about your cardiovascular risk factors and measure your blood pressure, height, and weight to calculate your cardiovascular risk. If your cardiovascular risk is 10% or more and you meet all the other eligibility criteria, the CHW will invite you to participate in the study. If you agree, the CHW will ask you to sign two copies of an informed consent form and will give you one signed copy to you for your records. A nurse will visit you in your home within a week to complete your enrolment in the study and to collect a blood sample consisting of 2 droplets for point-of-care testing (POCT) of cholesterol. You will decide from which finger she should take the drops of blood.
A small area of that finger will be wiped down with an alcohol swab and then a lancet will be used to pierce the skin to draw 2 droplets of blood from the finger. The droplets will be collected in capillary tubes, which then be placed into the POCT machine for analysis. Then your finger will be wiped with another alcohol swab and a band-aid will be applied with slight pressure to stop any blood flow that remains. Within a few minutes, the results will be made available to you and the physician to make decisions about your treatment.

If your clinic is assigned to the intervention group, you will be asked to schedule visits at the clinic every 1-3 months to have your cholesterol checked and for an appointment to see your physician. You will also receive SMS educational messages regarding the control of CVD, reminders of your clinical appointments at the clinic, and your prescription refills. CHWs will make up to four home visits or telephone calls over the 12 months of the study to help you to control your cardiovascular disease.

If your clinic is assigned to the control group, the CHW will recommend that you schedule an appointment with a physician at the primary care clinic where you will receive usual care.

12 months Follow-up
A nurse will visit you at the end of the study to re-test your cholesterol 12 months after your first visit. The nurse will repeat the same steps taken at the baseline visit to re-test your cholesterol and will ask questions to get information about your health.

Patient focus group discussion
At the end of the study, we will randomly select some participants who were in the intervention arm of the study to take part in a focus group discussion of their experiences. If you are selected, a CHW will contact you to ask if you are still willing to participate in the focus group. Details about the meeting time and location for the focus group will be provided to you if you decide to participate.

What are my responsibilities?
If you choose to participate, we will ask you to complete the study activities as described above. However, you may choose not to participate in any of the study activities at any time without any negative impact on your ability to receive free health care services at the primary care clinic. If you change your mind about participating, you may drop out at any time. There are no consequences of any kind if you drop out and you will continue to receive health care services in the clinic.

What are the risks and possible discomforts?
Being told you have a high risk of CVD may be stressful, but you can obtain free healthcare services at the primary care clinic to reduce this risk. The CHW and the nurse will ask if there is a private space in your home where you can conduct study activities to ensure confidentiality. Measurement of your cholesterol will be performed by the nurse without the need to draw a blood sample with a syringe. However, you may feel some discomfort when the nurse obtains the drops of blood with a small prick of your finger.
Some people may faint at the sight of blood or feel lightheaded due to fasting the night before. The nurse will ask if you have a history of fainting before trying to obtain the droplets of blood. To help with fainting, the nurse will ensure the part of your home where you are meeting is well ventilated space, ask you to stay seated during the time that the blood sample is being obtained, to do your best to relax, and to let him/her know when you are ready for the finger prick. If you do feel faint, tell the nurse and put your head between their knees until you no longer feel faint. If you do faint, the nurse will make sure that you are lying down safely and comfortably. We will also reschedule the visit, if needed.

If your clinic is assigned to the intervention group, receiving educational text messages or reminders about clinical appointments and prescription refills may be somewhat inconvenient for you. You can opt out from receiving these text messages at any time during the study.

Are there any benefits from being in this research study?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits of this study may include the reduction of your risk for heart disease and the development and implementation of an effective program to address cardiovascular disease that can benefit many people with cardiovascular risk factors to prevent cardiovascular events.

What happens if I say yes, but I change my mind later?
If you agree to be in the study, but later change your mind, you may drop out at any time without any consequences of any kind and your health care at the PCC will continue as usual.

Can I still get medical care at the primary care center that I now attend if I choose not to participate in this research*?*
Yes, your medical care at the primary care clinic will continue if you choose not to participate in this study. Your decision will not change the care you receive now or in the future. Taking part in this research is your choice. If you decide to take part in this study, you may leave/stop the study at any time without any consequences and your health care at the PCC will continue as usual. There will be no consequences and your medical care will not be affected. If you would like to stop participating in this research, please let us know.

Will I be compensated for participating in this research?
You will not be paid to participate in this study.

What will I have to pay for if I participate in this research?
It will not cost you anything to participate in this research

If I take part in this research, how will my privacy be protected? What happens to the information you collect?
The information that you provide us with will be confidential, anonymous and will be only used by the researchers. Your name will not be registered, and it will not be possible to identify you after the interview. Research records will be labeled with a unique code. A master key that links names and codes will be maintained in a separate and secure location. All electronic files (e.g., database, spreadsheet, audios etc.) containing identifiable information will be password protected. Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all your identifiers are removed.

Data that will be shared with others will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format, and you will not be identified in any publications or presentations. Any master key, audio recording, and other data described in this paragraph will be maintained in accordance with the security provisions until destroyed by the researchers. The participant has the right to access his/her own data that is being collected during the study period.
In case of withdrawing from the study, the informed consent will not be processed personal data in the future, except those stored until the moment of deciding to withdraw it. In accordance with Argentinean

law 25.326, you have the right to access your personal data without any cost. In addition, you have the right to request the rectification of your data and to exit the study. Their Personal data will be protected under confidentiality under Law 25.326 (through the National Directorate for the Protection of Personal Data is the control body of the Directorate: Sarmiento 1118, 5 floor C1041AAX, CABA, tel. 011-4383-8512 / 13, email: infodnpd@jus.gov.ar).

All your personal information, including research study documents and medical records, will be accessed only by authorized persons. Organizations that may inspect and copy your information include (1) the IRB and other authorized representatives of IECS and the Harvard TH Chan School of Public Health who involved in this research and (2) authorized representatives, monitors, and auditors of the funder of this research, the National Institutes of Health.

Some publishers may require sharing a limited subset of data in order to verify published results. We will not share any information that will identify you individually. No names or any other identifiable information will ever be provided to such publishers and all study results will be reported as summaries only. Five years after completion of the study, study investigators may use some of your personal information to review data in the national vital statistics registry (RENAPER) to determine the vital status of the study participants. This review will not require contacting you at that time.

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 website at any time.

What else do I need to know?

This research is being funded by the National Institutes of Health.

You may choose not to participate in this study and there are no risks or possible benefits for refusing to participate.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without consequences or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE

Your signature below indicates your permission to take part in this research

Name of participant	
Signature of participant	Date
Signature of person obtaining consent	Date
Printed name of person obtaining consent	