Informed Consent to Participate in Research and Authorization to Collect, Use, and Share your Health Information

Pro00038118

You are being asked to take part in a research study. Research studies include only people who choose to take part. This document is called an informed consent form. Please read this information carefully and take your time making your decision. Ask the researcher or study staff to discuss this consent form with you, please ask him/her to explain any words or information you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

We are asking you to take part in a research study called: “HeartMapp: A Closed-Loop Assessment and Treatment Mobile Application for Heart failure. A Pilot Randomized Clinical Trial.”

The person who is in charge of this research study is Ponrathi Athilingam, PhD, RN, ARNP, Associate Professor, USF College of Nursing. This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge.

The research will be conducted at USF Morsani Health Center and Florida Hospital, Tampa.

This research is being sponsored for by the National Institute of Nursing Research (NINR).

Purpose of the study

The purpose of the study is to find out if patients with heart failure can use the mobile phone apps called “HeartMapp” or CHF Info App (chronic heart failure info App). The HeartMapp will be compared to a heart failure education app called the “CHF Info App”.

These apps are designed to help patients improve their daily self-care monitoring of heart failure symptoms at home. We want to find out if these apps will improve quality of life and reduce hospital admissions.

These apps have been tested in a small number of patients and has been revised and improved based on feedback from patients.
**Why are you being asked to take part?**

We are asking you to take part in this research study because you may have been told that your heart is weak and have a diagnosis of heart failure. You may have been told by your doctors to check your weight daily, follow a low salt diet, take several medications daily, and monitor symptoms such as swelling of legs and abdomen, and trouble breathing. We want to compare these apps to find out if they can help patients improve self-care at home.

These apps are not approved by the Food and Drug Administration (FDA) for the treatment of heart failure. It is being used as part of this research study to find out how well patients can use HeartMapp or the CHF Info App and to find out if these are beneficial for patients.

**Study Procedures: What will happen during this study?**

If you take part in this study, you should be 40 years of age or older, have been told by a doctor that you have heart failure, able to speak, understand and read English. To qualify for the study, you must not have major depressive disorder, mental health problems, or a stroke within the last year. You should be living at home or in a facility where you can independently use a mobile phone. If you are willing to be part of the study, you will be asked to sign this consent form.

Once the study staff obtain your consent to participate in the research, you will complete an eligibility questionnaire to determine if you qualify to participate in the study. You will be screened and have the following tests to see if you qualify to participate in this research.

- Brief hearing and vision tests
- The Montreal Cognitive Assessment Test which screens for memory impairment
- Patient Health Questionnaire (PHQ-9) to measures your mood and screen for depressive symptoms.

**Randomization**

This is a clinical trial and therefore this study has two study groups, half of the group will be equally given access to HeartMapp and half will have access to CHF Info App. A computer will by chance assign you to use either the HeartMapp or the CHF Info App. This is called randomization. This is done by chance and you cannot choose your study group.

**Study Procedure:** The research nurse will download HeartMapp or the CHF Info App either on your own mobile phone or we will loan you an Android device after you sign a loaner agreement. The study staff will help you to register and accept the disclaimer to use the HeartMapp or CHF Info App and will train you to use them at home.

You will be instructed to:

- Use either HeartMapp or CHF Info All daily,
- respond to daily alerts,
- view daily text messages on heart failure related health topics,
- use the games included in the App for 30-minutes per day for 4 days a week,
- use zoom and audio function features of the App.

Once consented to take part in this study, participants will complete the same questions online using your mobile phone or computer and will provide an email address to access the questionnaires online. The participants will complete the following:

- Speed and accuracy of identifying shapes, colors, and directions in a computer.
• You will answer questions on the following online.
  o Questions on thinking ability, comprehension, and mental quickness,
  o How you care for heart failure symptoms at home,
  o How your quality of life is affected because of having heart failure
  o Your overall health affected by heart failure,
• Heart rate will be recorded by placing a patch on the chest for 10-minutes, similar to recording the heart rhythm using electrocardiogram or (EKG).
• Questions on personal information name, age, education, race, and mobile phone use.
• In addition, with your permission we will access your medical record for obtaining your heart function such as ejection fraction, heart failure stage, medications and number of hospital admissions and emergency room visits.
• We will give you a weighing scale and blood pressure monitor if you don’t have one.

Follow-up
Once you are enrolled in the study:
• The study staff will call you three time during the first week after enrollment to make sure you are getting familiar using HeartMapp or CHF Info App.
• After the first week, the study will call you once a week for three months and once a month throughout the remainder of the study duration, which is 6-months.
• You will be asked to visit the USF College of Nursing twice at 3-months and 6-months after enrollment. If for any reasons, you are unable to come to the College of Nursing, we will plan to visit you at your house.
• During this visit, the study staff will help you complete the same online questions, complete tests that involves connecting dots and identifying symbols and heart rate will be recorded by placing a patch on the chest for 10-minutes.
• Also, we will ask you if you had any emergency room visits or hospital admissions for heart failure.
• At the end of the study at 6-months, you will be given access to the other program that you didn’t receive during the study to use if you choose to do so.

Total Number of Participants
About 40 individuals will take part in this study at USF Morsani Health Center and Florida Hospital, Tampa. A total of 20 participants will be randomly assigned to use HeartMapp and 20 to use CHF Info App.

Alternatives / Voluntary Participation / Withdrawal
You do not have to participate in this research study. You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.
You can decide after signing this informed consent document that you no longer want to take part in this study for any reason at any time. If you decide you want to stop taking part in the study, tell the study staff as soon as you can.
  • If you decide to stop, you will need to any smartphone loaned to you.
  • You will continue getting care from your regular doctor.
Please note, even if you want to stay in the study, there may be reasons we will need to withdraw you from the study. You may be taken out of this study if we feel that it is not safe for you to stay in the study or you wish to stop or minimize use of the HeartMapp or CHF Info App. Potential reasons for this decision might include a change in residence, health or psychiatric issues, family or personal issues, or a lack of interest in research program activities. Your personal commitment to the research study is very important. In such cases, after discussion with the study coordinator, you will be permitted to cease using the program, and be scheduled for a post-assessment (completion) visit at the appropriate time relative to the pre-assessment (baseline) visit.

**Benefits**

We are unsure if you will receive any benefits by taking part in this research study. This study has the potential to benefit the participant by being monitored. However, this study will provide important scientific knowledge about the potential of the Apps being tested to enhance the lives of persons with heart failure.

**Risks or Discomfort**

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study. This study will use routine, standardized, non-invasive measures of sensory function (e.g., pure-tone audiometry), psychological tests of thinking ability, and functional assessments. Established protocols will be followed during testing to minimize risk to participants.

The following risks may occur:

- You may feel uncomfortable answering questions about your condition. You are free to skip any question you do not wish to answer.
- You will be completing the questions online, hence it is possible that unauthorized individuals could gain access to your online responses. We will make every effort to keep your data safe in a password protected server.
- Assessments may cause fatigue and discomfort. To minimize this potential discomfort, breaks are encouraged and you can complete the assessments later.
- We expect that some of you may have difficulty completing games for 30-minutes in one sitting. To accommodate this issue, you may use the games for a shorter segment, such as 15 minutes in the morning and 15 minutes later that day.
- If completing follow-up visits at the USF College of Nursing is a problem for you, you should let the study staff know. In this case, we will make plans to visit you at home or your doctor’s office during your regular visits.
- Participation in any research study, including this one, may involve a loss of privacy, and absolute confidentiality cannot be guaranteed. To lessen this risk, all information collected on paper (consent form) will be kept in locked file cabinets. Electronic data will be password protected and stored on a secure network. All data keys will be stored separately and securely. Only study personnel will have access to the study data. No participant names will be used in study reports or publications.
- Participating in this research study and providing responses through either of the apps does not negate for the subjects to see their physicians and attending regular clinical appointments. They will be required to have regular follow-ups with their providers.
Compensation
You will be compensated a total of $215.00. You must complete all the scheduled study related games and complete online assessments to receive compensation. You will receive

- $20 for initial screening, consent, and completing baseline data
- $25 for completing assessments at 3-months
- $3 per training session completed up to a maximum of $120.
- $50 for post-training assessment at 6-months.

The funds for participant payment will be administered via Payoneer; a third-party vendor by the sponsor, who will directly deposit funds into a centralized account that is accessible by study personnel, who will transfer payment to participant issued gift cards.

If you withdraw for any reason from the study before completion you will be compensated only for the training sessions or activities completed. Also, you will be compensated for each study follow-up data collection you complete.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

Costs
There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further.

Conflict of Interest Statement
Researchers conducting this medical research study might benefit financially from this study. Specifically, Dr. Ponrathi Athilingam and Dr. Miguel Labrador are authors of the mobile apps being studied. Research studies like the one you are thinking about joining are done to determine whether the treatment is safe and effective. If research shows the intervention is safe and effective, Dr. Athilingam and Dr. Labrador would receive a part of the profits from any sales of this intervention.

The Institutional Review Board that reviewed this study and a committee at the University of South Florida have reviewed the possibility of financial benefit. They believe that the possible financial benefit to Dr. Athilingam and Dr. Labrador is not likely to affect your safety and/or the scientific quality of the study. If you would like more information, please ask the researchers or the study coordinator.

Privacy and Confidentiality
We will keep your study records private and confidential. Certain people may need to see your study records. Anyone who looks at your records must keep them completely confidential. These individuals include:

- The research team, including the Principal Investigator, co-investigators, study coordinator, and all other research staff.
• It is possible that unauthorized individuals could gain access to your online responses. Confidentiality will be maintained to the degree permitted by the online technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this study involves risks similar to a person’s everyday use of the Internet. If you complete and submit an anonymous survey and later request your data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database.

• Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.

• Any agency of the federal, state, or local government that regulates this research. This includes the Department of Health and Human Services (DHHS) and the Office for Human Research Protection.

• The USF Institutional Review Board (IRB) and its related staff who has oversight responsibilities for this study, and staff in USF Research Integrity and Compliance.

• The National Institutes of Health and the National Institute of Nursing Research.

• The National Institute of Nursing Research grant was awarded to Dr. Tom Vleet at Posit Science, Inc. located in San Francisco, California. Therefore, aggregated de-identified data will be shared with Posit Science Inc. for analysis. Your name and other identifiable information will not be shared.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

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.

What if new information becomes available about the study?
During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in this study. We will notify you as soon as possible if such information becomes available.

You can get the answers to your questions, concerns, or complaints.
If you have any questions, concerns or complaints about this study, call

Dr. Ponrathi Athilingam (Dr. Pon) at 813-974-7526.

If you have questions about your rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

Authorization to Use and Disclose Protected Health Information (HIPAA Language)
The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are
permitting the University of South Florida to use your health information for research purposes. You are also allowing us to share your health information with individuals or organizations other than USF who are also involved in the research and listed below. In addition, the following groups of people may also be able to see your health information and may use that information to conduct this research.

- The medical staff that takes care of you and those who are part of this research study;
- The USF Institutional Review Board (IRB) their related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance and the USF Health Office of Clinical Research.
- Data Safety Monitoring Boards or others who monitor the data and safety of the study.
- There may be other people and/or organizations, who may be given access to your personal health information, including Florida Hospital, Tampa and Posit Science Inc. San Francisco, California

Anyone listed above may use consultants in this research study, and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, USF may collect, use, and share the following information:

- Your research record,
- All of your past, current or future medical and other health records held by USF, other health care providers or any other site affiliated with this study as they relate to this research project. This may include, but is not limited to records related to your cardiac health and mental health.

You can refuse to sign this form. If you do not sign this form you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. Your authorization to use your health information will not expire unless you revoke (withdraw) it in writing. You can revoke this form at any time by sending a letter clearly stating that you wish to withdraw your authorization to use your health information in the research. If you revoke your permission:

- You will no longer be a participant in this research study;
- We will stop collecting new information about you;
- We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and
- Staff may need to follow-up with you if there is a medical reason to do so.

To revoke this form, please write to:

Principal Investigator Dr. Ponrathi Athilingam (Dr. Pon)
For IRB Study # Pro00038118
12901 Bruce B. Downs Blvd. MDC 22, Tampa, Fl-33612
While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by USF policies.

**Consent to Take Part in Research**

**And Authorization for the Collection, Use and Disclosure of Health Information**

I freely give my consent to take part in this study and authorize the use of my health information as outlined above. I understand that by signing this form I am agreeing to take part in research. I have received a signed copy of this form to take with me.

______________________________________________
Signature of Person Taking Part in Study                                          Date

______________________________________________
Printed Name of Person Taking Part in Study

**Statement of Person Obtaining Informed Consent and Research Authorization**

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

______________________________________________
Signature of Person Obtaining Informed Consent                                          Date

______________________________________________
Printed Name of Person Obtaining Informed Consent