Continuous Wearable Monitoring Analytics to Improve Outcomes in Heart Failure - LINK-HF2 multicenter implementation study

NCT04502563

February 6, 2024

Participant Name: _____ IRBNet ID:_____

Title of Study: Continuous Wearable Monitoring Analytics to Improve Outcomes in Heart Failure - LINK-HF2 multicenter implementation study

Principal Investigator: VA Facility: George E. Wahlen Department of Veterans Affairs Medical Center

Principal Investigator for Multisite Study: Josef Stehlik MD, MPH

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by HSR&D and PhysIQ. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

Read the information below closely and discuss it with family and friends if you wish. Ask a member of the research team if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this form will show that you have received all the information below, and that you were able to discuss any questions and concerns you had with a member of the research team. Contact information for the local Study Doctor can be found near the end of this form.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

- Participants in this study will wear an adhesive Band-Aid-like multi-sensor patch that will be used to collect continuous vital signs. Participants will be randomly (by chance) put to one of two groups: 1. A group where if abnormal results detected by the software analyzing the data from the patch, an alert will be sent to your Cardiology team, or 2. A group where all the data will be collected but alerts will not be sent to your Cardiology team. You or your Cardiology team will not know which group you are assigned to (unless or until the first alert is sent). This is done to show whether the active monitoring can help care for patients like you. For the purposes of the study, data from neither group will be monitored in real-time.

By doing this study, we hope to learn if this type of remote monitoring can improve care for patients like you. This research study is expected to take approximately 4 years.

There will also be a group of 20 individuals from the 5 participating centers that will be invited to participate in a recorded interview regarding study experiences. There will be no photographs or videos of the interview. We will be recording and then transcribing audio of the interviews. All identifying information will be removed during the transcription process by the VA CTSP Transcription Services. Anyone invited to participate in the interview process may decline at any time if not interested.

Your participation in the optional research interview process may take 1 hr.

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WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There are potentially direct benefits to you from closer monitoring by providers that can avoid a hospital admission due to heart failure worsening. The information we get from this study may help us treat future heart failure patients.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Participation in the study may involve risks that are currently unforeseeable. In addition to the risks listed below, you may experience a previously unknown risk of using the monitoring.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. _____at the_____.
If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is Dr._____at 801-582-1565.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

You are being asked to take part in a research study. The purpose of this study is to see whether hospital admission due to heart failure for patients such as you can be avoided. We believe we could predict your next hospital admission by looking at vital signs captured on a device you wear and intervene early to avoid the need for a hospital admission due to worsening heart failure. This device is a wearable sensor that records heart rate, breathing rate and your activity level. If we can use this information to predict admissions to the hospital before they happen, doctors could improve patients' condition and avoid the need for some admissions to the hospital.

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A prior smaller study has already shown that this device is safe and reliable and could predict when you are about to have heart failure worsening. This study will focus on how we can intervene. This study will be conducted at 6 VA Medical Centers (Salt Lake City, Utah; Houston, Texas; Gainesville, Florida, Palo Alto, California, Richmond, VA and Portland, Oregon). The wearable patch sensor being used is an FDA-approved device called VitalConnect. The software used to collect

the data gathered has been developed by a private company called PhysIQ in Naperville, Illinois. PhysIQ has received funding from the Veteran's Affairs in Washington, D.C., to develop innovative technologies that improve health care.

The patch will be worn by you during normal daily activities. The device is a wearable adhesive Band-Aid-like sensor that will collect your vital signs. The device communicates wirelessly and transmits information to a smart phone given for you to use while in the study. The smart phone securely transmits the information to remote computers which will analyze the data and make results available to your doctors.

However, neither the study investigators nor your clinical Cardiology team are continuously monitoring the uploaded data. The data is being monitoring and analyzed by a computer software. If abnormal results based on analysis of the data are seen by the computer software, an alert will be sent to your Cardiology team. Your Cardiology team will review the results and reach out to you by telephone. Depending on how you are feeling, your Cardiology team will follow a protocol to ask you to either adjust your medication (water pills, blood pressure pills, etc.) at home, or come to clinic or emergency room for a visit. The goal is to make these changes early and stop your heart failure from worsening before you need a possible admission to a hospital.

Apart from what was described, participation in this study will NOT change the care you would normally receive for your condition. Your Cardiology team will NOT be observing your data every day, they will only respond to alerts if these happen. You should continue to rely on the regular ways you normally get medical care.

Identifiable data collected from you will only be used for the present study and will not be shared for future research.

HOW LONG WILL I BE IN THE STUDY?

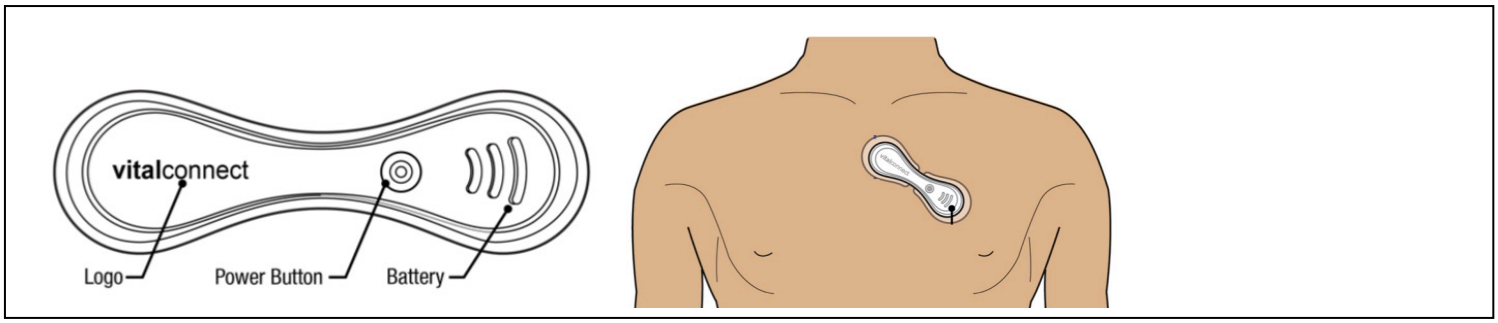
A total of 240 patients will participate in this study, with approximately 60-125 at the Salt Lake City VA hospital and 30-80 patients at each of the other five sites.

Your participation in the project will take 90 days.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Participants in this study will be randomly (by chance) assigned to one of two groups: 1. A group where if abnormal results are detected by the software, an alert will be sent to your Cardiology team, or 2. A group where all the data will be collected but alerts will not be sent to your Cardiology team. You or your Cardiology team will not know which group you are assigned to (unless or until the first alert is sent). This is done to show whether the active monitoring can help care for patients like you.

If you choose to participate in this study, we will provide you with the VitalConnect wearable patch and a smart phone to take home. You will be trained on how to use the device. We will ask you to wear the device for as long each day as possible for 90 days. Specifically, we ask that you wear the device every day while in the study.



Before you leave the hospital, the device will be placed on you to start the data collection. Additional adhesive patches, adhesive remover wipes and replacement devices will be sent to you by mail as needed. You will also be provided with a technical support phone number to call for assistance if needed.

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You will be given a smartphone to use that is paired with the wearable patch to receive data from the patch and send it to a computer server through a cellular network.

Study staff will see you during your scheduled clinic visits. Study staff may also call you if there is a medical event question and or to make sure everything is going well with you and with using the device. Staff from the company PhysIQ may also call you if it seems that the data from the device are not being sent to help you troubleshoot. Once you have completed wearing the study device, arrangements will be made for the return of any study devices or device materials by a prepaid US postal package sent to your home.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

While participating in this study it is important to:

- Wear the patch daily as instructed.
- Let study team know if any problems arise with a patch.
- Let study team know if any problems arise with device
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Keep the study patches and device in a safe place for your use only and away from children or pets.
- Tell the investigator or research staff if you believe you might be pregnant.
- While participating in this research study, do not take part in any other research project without approval from the investigators.

Also, while you are participating is this study, we may ask to request copies of medical records from non-VA facilities if you receive care outside the VA during the study.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

The adhesive patch is similar in adhesive strength to a Band-Aid and may pull at your skin when you remove it. You may have to shave hairs from your chest where you attach the patches for easier removal. Also, though the patches are manufactured for long- term use on the skin, they can feel slightly itchy over the course of a day. Your skin may appear red and irritated for about

half an hour after removal. There is a risk that you may be allergic to skin contact with the material of the adhesive patches, which could result in a rash.

Since we are collecting signal information from you as well as events you report when we call you, there is a very small risk that the confidentiality of the signals we collect from you could be compromised. All medical information will be saved on password-protected computer systems. The monitoring data will be encrypted and transferred wirelessly and also stored on secured computers. The data we will collect from your electronic medical record will also be stored in a secure computer system. These data will be at the same risk level as medical data not used for research stored by the hospital.

UNFORESEEABLE RISKS

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

REPRODUCTIVE RISK

There are no known risks.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include those from potentially closer monitoring and early interventions by providers that can avoid a hospital admission due to heart failure worsening. In addition, the information we get from this study may help us treat future patients.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If you do not want to take part in the study, you may discuss other options with your doctor.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

There are three kinds of data we will be collecting about you if you participate:

1. The signal data and vital signs the device records while you wear it.
2. Details from your medical record such as your medical conditions, medications, procedures.
3. The information you provide us about your health events and changes at regular intervals when we call or see you in follow up, as well as your feedback on the use of the devices.

All of these data will be stored on secured, password-protected computer systems. The only people who will have authorized access to any of the data are the research staff conducting this study at the Salt Lake City VA hospital, and authorized personnel of the company PhysIQ who have been certified under VA-required patient confidentiality training. Additional 5 VA hospitals will also be participating in this study and the investigators may see some of the data.

The signal data and vital signs will be encrypted and saved on secure computer servers.

The details from your medical record will be kept on paper in our locked offices, and electronically in a secure, password-protected computer system overseen by PhysIQ in Naperville, Illinois.

The information you provide during our regular telephone conversations with you will also be stored in the same secured computer system.

We intend to report medical results of this study in published medical literature and other reports. However, your identity will never appear in any such publication. The data from you will always be de-identified so that anyone who sees it cannot possibly know it is from you. Because this study is subject to Food & Drug Administration (FDA) regulations, there is a possibility that the FDA may inspect or copy study records that identify you.

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

After completion of the study, all identifiers (information that could link the data to you) will be removed from your vital sign data and medical information data. After removal of the identifying information, the research data may be used in future research studies or distributed to another investigator for future research studies without additional informed consent.

We will include information about your study participation in your medical record.

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 ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

Your participation in this study comes at no cost to you. We do not believe that you will receive or require any additional medical services from participating in this study. However, if you do require medical care due to your participation in this study (for example, you suffer an injury from one of the devices), you will not be required to pay for that care. However, as usual, you may be charged a co-pay for any standard of care treatment that is NOT related to this study.

Should you choose to participate in the study, we will NOT compensate you monetarily. However, if you complete the 90-day study, you will be given an option to keep the study phone after the data has been collected and removed. The device will NOT come with any prepaid or WI-FI services at study end. Any additional services for using the device will need to be paid out of pocket by you.

Should you damage, lose or have a malfunctioning study phone or device, a replacement will be provided to you at no expense. Such circumstances will not affect your study participation nor incur any financial responsibly. However, if you repeatedly lose the equipment (phone/band aid) generally it prevents acquisition of data, and the study team may withdraw you from the study.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

The VA has the authority to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment according to federal law. If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S. Government. If you sign this document, you are not giving up your right to make a legal claim against the United States.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

Dr./Mr./Ms. _____at _____
AFTER HOURS:

Dr. /Mr./Ms._____at _____.

DO I HAVE TO TAKE PART IN THE STUDY?

It is up to you to decide whether or not to participate in this study. If you decide to participate you are still free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will not involve a penalty or loss of benefits to which you are otherwise entitled. If you do not take part, you will still receive all standard care that is available to you. This will not negatively affect the relationship you have with your doctor or other staff, nor decrease the standard of care you receive as a patient.

Sometimes during the course of a research project, new information becomes available about the device that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study.

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RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION (Include if applicable)

During the study, the investigator can withdraw you without your approval. Possible reasons for withdrawal include:

- You are unable to wear the devices regularly, perhaps because of a change in your health.
- You don't wear the device often enough.
- You frequently forget to carry the smart phone with you, so data cannot be collected.
- Where you live has such poor cellular network coverage that the smart phone rarely uploads your data.
- We can rarely reach you by phone to get answers to our regular questions about medical events, medication, symptoms, etc.
- You don't come for clinical appointments we make with you for purposes of this study. It's okay to miss or reschedule once or twice for good reason.

If you are withdrawn from the study, we will need to make arrangements to get the devices and smart phone back from you.

No additional follow-up that will be requested after the participant is withdrawn from the active portion of the study.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions, complaints, or concerns about this research, you can call your Study Doctor _____ , at 801-582-1565 or the Patient Advocate at 801-582-1565 ext.1900.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

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Participant Name: _____ IRBNet ID:_____

Title of Study: Continuous Wearable Monitoring Analytics to Improve Outcomes in Heart Failure - LINK-HF2 multicenter implementation study

Principal Investigator: VA Facility: George E. Wahlen Department of Veterans Affairs Medical Center

Principal Investigator for Multisite Study: Josef Stehlik MD, MPH

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ _____has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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