Impact of Discharge Teach-Back Education on Heart Failure Patients' Knowledge/Self-Care Behaviors and 30-Day Readmissions

Informed Consent Form

NCT07280208

August 14, 2025

INSTITUTIONAL REVIEW BOARD
3301 College Avenue
Fort Lauderdale, Florida 33314-7796
PHONE: (954) 262-5369

NSU Social Behavioral Template for General Informed Consent Form (v2023-08-31)
NSU Consent to be in a Research Study Entitled
Impact of Discharge Teach-Back Education on Heart Failure Patients' Knowledge/Self-Care Behaviors and 30-Day Readmissions

Who is doing this research study?

College: Nova Southeastern University, Ron and Kathy Assaf College of Nursing

Principal Investigator: Sara Bierschenk, MSN, APRN, FNP-C, AACC, HF-Cert, CCRN

Faculty Advisor/Dissertation Chair: Dr. Virginia Lynn Waters, Ph.D., MSN, MBA, RN, CNE-BC

Co-Investigator(s): None

Site Information: HCA Florida JFK Hospital, 5301 South Congress Avenue, Atlantis, Florida 33462

Funding: This study is unfunded.

Introduction:

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to decide about participating. You can discuss your decision with your family, friends and other trusted people.

What is this study about?

This is a research study, designed to test and create new ideas that other people can use. The purpose of this research study is to see if a short teaching session can help adults with heart failure take better care of themselves and avoid going back to the hospital. The session uses a method called "teach-back," where you repeat the information in your own words to make sure you understand it. You will also fill out a short survey before and after the session.

Why are you asking me to be in this research study?

You are being asked to be in this research study because you have been diagnosed with heart failure and are staying in the hospital. You may want to join this study to see if the teach-back method helps you better understand how to care for yourself after you leave the hospital. Your participation will help us learn if this teaching method works well for people with heart failure.

This study will include about 50 people. It is expected that 50 people will be from this location.

What will I be doing if I agree to be in this research study?

If you agree to be in this study, you will scan a QR code with your phone or tablet. This will take you to a secure website called REDCap. You will read the consent form on your own and decide if you want to join. If you agree, you will make up a nickname to keep your answers private.

Next, you will answer 9 questions about how you take care of your heart. Then, you will have a 30-minute teaching session in your hospital room. The nurse will explain how to care for yourself at home, and you will repeat the information in your own words to show you understand.

After the session, you will scan another QR code and answer the same 9 questions again. About 30 days after you leave the hospital, we will check your hospital records to see if you came back to the hospital.

You will be in this study for approximately 30 days.

Research Study Procedures – If you choose to be in this study:

- You will be asked to join during your hospital stay if you meet the study requirements.
- The study leader will meet with you in your hospital room to explain the study and answer your questions.
- You will scan a QR code with your phone or tablet to go to a secure website called REDCap.
- You will read the consent form on your own and decide if you want to join the study.
- If you agree, you will make up a nickname to keep your answers private.
- You will answer 9 questions about how you take care of your heart.
- You will have a 30-minute teaching session in your hospital room. The nurse will explain how to care for yourself at home, and you will repeat the information in your own words to show you understand.
- After the session, you will scan another QR code and answer the same 9 questions again.
- About 30 days after you leave the hospital, we will check your hospital records to see if you came back to the hospital.

Time commitment:

- The survey and teaching session will take about 60 minutes during your hospital stay.
- You will not need to return for any extra visits.

Could I be removed from the study early by the research team?

There are several reasons why the researchers may need to remove you from the study early. Some reasons are:

- You no longer meet the requirements to stay in the study.
- You do not follow the study instructions.
- The research team believes that staying in the study may not be safe for you.

If this happens, the researchers will explain why and tell you how to safely stop being in the study. They will also help you get medical care if needed.

Are there possible risks and discomforts to me?

This research study involves little risk to you. To the best of our knowledge, the things you will be doing have no more risk of harm than you would have in everyday life.

Some of the most likely risks of being in this study include:

- You may feel tired or overwhelmed during the teaching session.
- You may feel uncomfortable answering questions about your health or self-care habits.
- You may feel stressed or upset when thinking about your heart condition or how to manage it.

If you feel this way, we can provide you with materials to help you, or refer you to someone who may be able to help.

What other options are there to being in this research study?

If you do not want to be in the study, there are no other choices except not to take part in the study.

What happens if I am injured because I took part in this study?

The researchers have taken steps to minimize the known or expected risks. You may still have problems or get side effects even though the researchers were careful to avoid them. Contact Principal Investigator right away if you think you have suffered a research-related injury or a bad reaction. Their contact information can be found in the contact section at the end of this form.

Nova Southeastern University does not have a program to pay you if you are hurt or have other bad results from being in this study. Medical care at Nova Southeastern University is open to you as it is to all sick or injured people. The cost for such care will be billed to you or your insurance company.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed because of participation in this study.

What happens if I do not want to be in this research study?

You can leave this research study at any time or refuse to be in it. There will be no penalty or loss of services. Any information about you that was collected **before** the date you leave the study will be kept in the research records for 36 months from the end of the study. This data may be used as a part of the research.

Are there risks if I leave the study early?

Tell the study leader if you are thinking about stopping or have decided to stop. They will tell you how to stop your participation safely.

There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

What if there is new information learned during the study that may affect my decision to remain in the study?

Any information that may impact your decision to remain in this study will be given to you by the investigators. You may be asked to sign a new Informed Consent Form if the information is given to you after you have joined the study.

Are there any benefits for taking part in this research study?

There are no direct benefits from being in this research study. We hope the information learned from this study will help improve how patients with heart failure are taught to care for themselves. This may help others in the future avoid hospital readmissions and manage their condition better.

Will I be paid or otherwise compensated for being in the study?

You will not be given any payments for being in this research study.

Will it cost me anything?

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

Will clinically relevant research results be shared with me?

The study investigators do not plan to share research results with people in the study.

How will you keep my information private?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. You will give your consent using a secure website called REDCap. After you agree to join, you will make up a nickname (alias) to keep your answers private.

We will check your hospital records about 30 days after you leave to see if you came back to the hospital for heart problems. We will only look at the information we need, like:

- If you were readmitted (yes or no)
- The date you came back (if you did)
- The reason you came back (only if it was for heart failure)

To do this, we will keep a separate list with your hospital medical record number. This list will not be connected to your nickname or survey answers. It will be the only paper we use and will be locked in a cabinet in the project leader's private office. Only the project leader can open it.

All other study information will be stored on a secure, password-protected computer.

Only people who need to review your information will have access to study files. Organizations or people that may review and copy your information include:

- Members of the research team
- Nova Southeastern University Institutional Review Board and other representatives of this institution responsible for overseeing the research

Your personal information may also be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. All confidential data will be kept in a locked cabinet (for paper forms) and on a password-protected, encrypted computer (for electronic files) in the researcher's private office. All data will be kept for 36 months from the end of the study. They will be destroyed after that time by shredding paper records with a certified company and permanently deleting electronic files from all storage devices.

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. The Web site will include a summary of the results. You can search this Web site at any time.

Whom can I contact if I have questions, concerns, comments, or complaints?

If you have questions now, feel free to ask us. If you have more questions about the research, your research rights, or have a research-related injury, please contact:

Primary contact:
Sara Bierschenk, MSN, APRN, FNP-C, AACC, HF-Cert, CCRN
Cell: 561-335-7157
Email: sb2522@mynsu.nova.edu

If primary is not available, contact:
Dr. Virginia Lynn Waters, Ph.D., MSN, MBA, RN, CNE-BC
Ron and Kathy Assaf College of Nursing
Palm Beach Campus
Health Professions Division
Can be reached at: (561) 805-2100
Email: vwaters@nova.edu

Research Participants Rights
For questions/concerns regarding your research rights, please contact:

Institutional Review Board
Nova Southeastern University
(954) 262-5369 / Toll Free: 1-866-499-0790
IRB@nova.edu

You may also visit the NSU IRB website at www.nova.edu/irb/information-for-research-participants for further information regarding your rights as a research participant.

INSTITUTIONAL REVIEW BOARD
3301 College Avenue
Fort Lauderdale, Florida 33314-7796
PHONE: (954) 262-5369

Research Consent & Authorization Signature Section

Voluntary Participation - You are not required to participate in this study. In the event you do participate, you may leave this research study at any time. If you leave this research study before it is completed, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

If you agree to participate in this research study, sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

AGREE TO THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction about the research

Adult Signature Section

I have voluntarily decided to take part in this research study.

Printed Name of Participant	Signature of Participant	Date
Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent & Authorization	Date