Title of the Project: Leveraging Home Health Aides to Improve Patient Outcomes in Heart Failure: A Pilot Randomized Controlled Trial

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Study Title: Leveraging Home Health Aides to Improve Outcomes in Heart Failure: Pilot Randomized Controlled Trial
Principal Investigator: Madeline Sterling, MD, MPH, MS
Funder: National Heart, Lung, and Blood Institute (K23HL15060)

VNS HEALTH – Research Protocol

Background: Heart failure (HF) affects 6 million people in the U.S. and costs over 30 billion dollars per year. There are 1 million HF hospitalizations per year, and 25% of Medicare beneficiaries admitted for HF are readmitted within 30 days. Previous interventions to reduce HF readmissions have had mixed results, perhaps in part because they did not involve home health aides (HHAs). After a HF hospitalization, a third of Medicare beneficiaries are discharged home with home care services, which may include support from HHAs. Unlike physicians or visiting nurses, HHAs are with patients on a near-daily basis, sometimes up to 24 hours per day. However, my prior qualitative research suggests that HHAs do not receive HF-specific education and are not confident caring for HF patients. In addition, my prior work has shown that HHAs experience difficulty reaching their supervising nurses (at their home care agencies) when they have questions or need help managing patients in the home. As a result, HHAs often resort to calling 9-1-1 and subsequently bringing their patients to the emergency department (ED). While some ED visits may be clinically appropriate, many may be avoidable. Interventions that can optimize and improve the experience of HHAs caring for the HF patients have the potential to improve HHAs own self-efficacy but also patient outcomes.

To that end, we have developed a HF intervention for HHAs comprised of a) remote classroom education on HF and b) an mHealth app containing HF educational content and a messaging application that connects HHAs and their nurse supervisors. <u>This intervention requires feasibility testing, as well as preliminary testing of its acceptability and effectiveness among HHAs.</u>

<u>Study Purpose and Specific Aims</u>: To conduct a pilot randomized controlled trial (RCT) of the intervention among HHAs caring for adults admitted to home care with a primary diagnosis of HF, to determine its feasibility and its effect on HHAs (HF knowledge and caregiving self-efficacy), and to explore its effect on HF patient outcomes (ED visits and 30-day readmissions). If successful, the result of this project will be a novel and scalable intervention that has the potential to improve HHAs' ability to care for HF patients and reduce ED visits and 30-day readmissions.

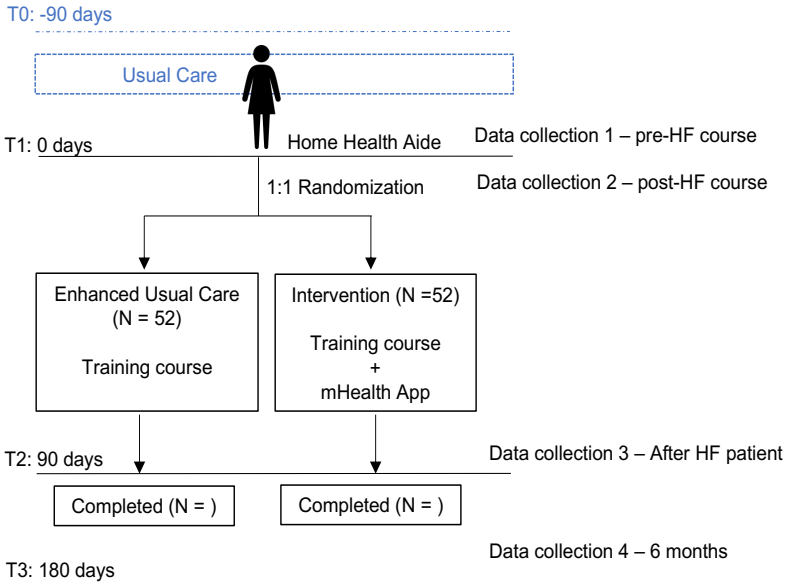
<u>Study Design</u>: PI Sterling will design and conduct a 2-arm pilot RCT in partnership with the VNS Health's licensed home care agency (Partner's in Care) under the guidance of Dr. Feldman (VNS Health-Site PI) and Margaret McDonald, MSW(VNS Health-Co-I) and leaders at Partners in Care. Dr. Safford (Dr. Sterling's Primary mentor at Weill Cornell Medicine, expert in pragmatic clinical trials), Dr. Kern (Dr. Sterling's Co-mentor at Weill Cornell, expert in care coordination, including measuring the effectiveness of interventions designed to improve care coordination) will guide her throughout the study. In addition, Dr. Dell (adviser in health technology) will advise her. Over a two-year period, 104 HHAs will be enrolled in the pilot and 52 will be randomly assigned to the enhanced usual care arm (HF training course alone) and 52 to the intervention arm (HF training course *plus* mHealth app [Partner's in Care's Care Connect

app with new features]). Four nurses will also be recruited to participate in the pilot. Because withholding education from the control arm is not favorable to HHAs and since educational interventions alone are unlikely to affect outcomes, we will not have a usual care arm. Each HHA will be followed for 90 days, since this post-discharge period is clinically challenging, and it aligns with policies that reward or penalize hospitals and agencies based on readmissions. A VNS Health staff member will help coordinate the trial and attend team meetings, assuring that the agency's priorities are integrated. The study will occur in a 24-month period.

An overview of the pilot RCT and the randomization scheme is shown in the Figure below. After being consented, all HHAs will attend a virtual orientation session and virtual HF training course. Prior to the course, all HHAs will complete a baseline questionnaire (see attached survey document) and be randomized in a 1:1 ratio (T1). The training course will be conducted via Zoom and led by WCM investigators and VNS Health staff members. After taking the course, HHAs in both arms will take a short post-course questionnaire (to assess the two primary outcomes; knowledge and HF caregiving self-efficacy). HHAs randomized to the enhanced usual care arm will receive a just-in-time course refresher via their Care Connect app (self-driven educational content) prior to caring for their HF patient. HHAs randomized to the intervention will receive a just-in-time course refresher as well as an app training session from a Weill Cornell Medicine research assistant (overseen by Nicola Dell, PhD in computer science). HHAs in this arm will be encouraged to use the app when they have questions about their patient, want to access HF-related content, or need to communicate with the nurse. To reinforce their use of the use of the application chat features, they will receive "do not reply" text based notifications reminding them that the feature is there and can be used. Following the care of their first patient, HHAs in both arms will take a follow-up questionnaire. Each HHA will be involved in the study for 90 days. During that time, if the HHA is assigned to a new HF patient, they can continue participation although they will remain randomized to their original treatment arm to avoid contamination. De-identified data on HF patients cared for by the HHAs (demographics, clinical conditions, ED visits; 30-day/90-day readmissions; hospitalization; functional status; and quality of life) will be retrospectively collected by the VNS Health from intake/referral data and OASIS. HHAs will receive $100 for participating; they will receive $25 at trial start, $25 following the completion of the heart failure training course and survey 2, $25 following the 45-day (mid-study) interview, and $25 following the final survey.

At the start of the trial, during the kickoff session, nurses will be introduced to the study and thoroughly informed of the study details. After this time, nurses will provide verbal informed consent to the study team. The study team feels that this is the most efficient use of their time; it is also more feasible since we do not plan to collect additional data from nurses (demographics, outcomes, etc.,). As such, it was felt there would not be a need to build a separate e-consent project in REDCap for the electronic consent of nurses, nor will this be feasible within our allocated staff time. Nurses in the trial will respond to alerts and messages from HHAs using the app. Nurses will also receive an orientation to the Care Connect messaging features prior to the start of the trial from the WCM/Cornell Tech team. At the end of the trial, nurses will receive $100 for participating.

Figure . Randomization and Data Collection for RCT



Evaluation and Outcome Measures: There are three main outcomes for this study:

1) *Feasibility*
2) *Acceptability*
3) *Effectiveness*

To assess feasibility we will assess: the reach of the intervention by tracking the number of HHAs approached and enrolled; the effectiveness through baseline and follow-up assessments; the adoption by the number of HHAs who completed the training course (both arms), participated in app orientation session (intervention arm), and completed the trial (both arms); the implementation through intervention fidelity (mHealth app usage, educational content accessed [both arms], Care Connect messaging with nurses [intervention arm], underlying reasons for Care Connect messaging between HHAs and nurses [intervention arm]). This feasibility data will be extracted from the mHealth app by the Care Connect team (lead, Mike Gelman) and Dr. Dell. *Acceptability* will be assessed with exit interviews with HHAs, nurses, and agency staff from both trial arms. Additional exit interviews will be conducted with a subset of patients from both trial arms. *Effectiveness* will be assessed for *two primary outcomes:* 1) HF knowledge; 2) HF caregiving self-efficacy and *two secondary outcomes*: 1) job satisfaction and 2) intention to leave (See Table). Patient outcomes (ED visits; 30-day/90-day readmissions; hospitalization; functional status; and quality of life) will be assessed in exploratory analyses (See Table 1).

Table 1. Effectiveness Outcome Measures for Pilot RCT

Outcomes	Validated Scale	Description	Data source
Primary Outcomes (HCWs)			
HF knowledge	Dutch HF Knowledge Scale	15 item scale measures HF knowledge in general, knowledge of HF treatments, and HF symptom recognition. Scores range from 0-15, with higher scores indicating higher HF knowledge.	Baseline and follow-up questionnaires
HF caregiving self-efficacy	Caregiver Contribution to Self-Care in HF Index (CC-SCHFI)	22-item scale measures caregivers' 1) contributions to HF maintenance; 2) contributions to HF management; and 3) HF caregiving self-efficacy (confidence). Each of these 3 sub-scales are scored independently. The third sub-scale (self-efficacy) will be the main outcome. Self-efficacy scores range from 0-100, with higher scores indicating greater self-efficacy.	Baseline and follow-up questionnaires
Secondary Outcomes (HCWs)			
Intention to Leave	Turnover intention scale	2-item scale measures workers' intentions of 1) leaving their current job (at their agency) and 2) searching for a new job (in another field) in the next year	Baseline and follow-up questionnaires
Job satisfaction	Work Domain Satisfaction Scale	This 5-item scale measures 1) job satisfaction among care workers; and 2) examines the associations with work environment factors, work stressors, and health issues. Scores range from 5-20, with higher scores indicating stronger satisfaction.	Baseline and follow-up questionnaires
Other Specified Outcomes			
Communication practices	Preventable 911 Calls	2 novel questions "I have called 911 when that could have been prevented if I had been able to reach my supervisor/the nurse." And "I have called 911 when that could have been prevented if my supervisor and I had been able to reach the client's doctor."	Baseline and follow-up questionnaires

		Responses for both included a 7-point likert scale of: very strongly disagree, strongly disagree, disagree neutral, agree, strongly agree, very strongly agree. Both questions dichotomized into "agree", "strongly agree", and "very strongly" vs. all other responses.	
Patient Outcomes (exploratory)			
30-day readmission; 90-day (all-cause)	N/A	A readmission to any hospital (for any reason) at 30-days after start of home care episode.	Follow-Up VNS Health administrative data
Emergency department visit (all-cause)	N/A	A visit to the emergency department of any hospital (for any reason) after start of home care episode	Follow-Up VNS Health administrative data
Functional status	N/A	Activities of daily living, physical function	Follow-Up VNS Health administrative data
Hospitalization	N/A	A hospitalization to any hospital (for any reason) during the study period	Follow-Up VNS Health administrative data
Quality of Life	Cardiomyopathy Questionnaire (Kansas City) [KCCQ-12]	The Kansas City Cardiomyopathy Questionnaire (KCCQ-12) is a 12-item self-administered questionnaire adapted from the KCCQ, a 23-item self-administered questionnaire which independently evaluates patient's perceptions of their health status with particular focus on heart failure symptoms, impact on physical and social function, the disease's impacts on their quality of life (QOL) within a 2-week recall period.	Interview

Sample Selection/Data Sources: English and Spanish speaking HHAs assigned to care for adults admitted to home care with a primary diagnosis of HF during the study period will be eligible. According to our preliminary estimates, VNS Health HHAs care for 2,280 new HF cases per year, for an estimated 4,560 cases during the 2-year trial. HHAs with less than 1 year of job experience will be excluded. We expect 400 HHAs will need to be screened to reach the goal of 104. Additionally, 12 nurses will be recruited (convenience sampling) to participate in pilot RCT.

HHAs will be studied for 90-days. HHAs will be asked to complete an electronic survey 3 times during the study; first before the virtual orientation session at the time of recruitment (beginning

of the trial; prior to randomization); second after receiving the HF training course; and lastly at 90 days after the completion of the training course.

The questionnaire will be completed online using a link provided by text or email from the Weill Cornell Research Assistant with Research Electronic Data Capture (REDCap), a web-based, secure, data storage program at Weill Cornell Medicine (see document attached). Nurses will not complete a survey. A sub-set of participants (HHAs, nurses, patients) in the pilot RCT will be asked to complete an exit interview at the end of 90 days. Patients of HHAs in the study will be screened for diagnoses with cognitive impairment symptom presentation by a VNS Health researcher at 90 days following HHA participation in the study. Those that do not have such a diagnosis will be contacted by the VNS Health researcher according to the script provided below. Those that provide verbal consent to be interviewed will have their names and phone numbers stored on a secure VNS server and shared with WCM researchers to conduct the exit interviews through REDCap over the phone. This data will not be stored on any WCM servers, and it will be removed from the VNS servers once each respective interview is complete. The WCM researcher will forward a $25 digital gift card for the patient to the VNS Health researcher for distribution to patients for their participation in the interview.

Procedures for Recruiting Study Subjects: The VNS Health staff member will screen HHAs for eligibility and contact them about this voluntary study with a pre-written script (see recruitment template). This will be done over the phone, where participants will provide an initial verbal consent. Additionally, the VNS Health staff member may reach out via email or text according to the aide's preferences, to potential aides to invite them to in person informational sessions about the study. In a post-Covid era, this may be an important mechanism to engage and educate potential participants. The goals of these information sharing dinners are two-fold; 1. To introduce the study team and the rationale behind the study, as well as to provide information about study logistics 2. To enhance comradery among the workforce, which has been hit particularly hard during Covid (social isolation, increased risk to personal health, etc.) An email invite will be used to communicate with potential study aides about the event. Attending this event will in no way constitute consent or intent to participate in the study, it will strictly function as a means of sharing information with potential study participants. If following verbal consent by phone or at an in-person information providing event the aides are found to be eligible and agreeable, the HHA will provide electronic informed consent via REDCap when they attend the trial orientation session.

Telephone recruitment template:

> *Hello [insert name of home health aide]:*
>
> *My name is _____ from _____. I am working with Dr. Madeline Sterling on an NIH-funded study aimed at improving the experience of home health aides (like you) who care for adults with heart failure. I am contacting you to invite you to participate in this study. The goal of the study is to see how well an intervention designed for home health aides (like you) will work in real-time. The intervention we are studying is comprised of a heart failure training course and a smartphone app (care connect) with information*

about heart failure, as well as a messaging tool that would enable you to contact your supervisor to ask questions about your patient.

If you agree to take part in this study, you will be asked to participate in a heart failure training course. Some participants will also be asked to use the app while caring for a client with heart failure. If chosen, we will provide you with instructions on how to use the app.

You will be compensated with $100 upon your completion of the study.

Is this a study you would be interested in?

PAUSE

Your participation in this research is strictly confidential and voluntary. Your decision to participate will not affect your employment at VNS HEALTH.

What questions do you have?

PAUSE

If you have further questions or comments about this study, please e-mail Dr. Madeline Sterling at mrs9012@med.cornell.edu.

Thank you for your time and consideration of our research.

CLOSING

Email/Text Script for Informational Event:

Good morning/afternoon, I am writing to you to invite you to an upcoming event for home health aides that take care of clients with heart failure. Below are some details about the event.

- *This is an invite-only event for aides that care for clients with heart failure, just like you*
- *1/24/23 from 4PM-7PM*
- *We will be talking about our study and looking for volunteers to join!*
- *There is no pressure to take part!*
- *Food and beverages will be provided*
- *Your time at the event will be paid*

If you have any additional questions about the study or the event please feel free to call or text me at 646-907-2485.

To RSVP for the event, use the link below or give me call/text.

Consent Forms and Additional PHI Authorizations:

Informed Consent Form for Home Health Aides**:**

Consent to be Part of a Research Study

Title of the Project: Leveraging Home Health Aides to Improve Patient Outcomes in Heart Failure: A Pilot Randomized Controlled Trial

Principal Investigator: Madeline Sterling, MD, MPH, MS (Weill Cornell Medical College)

VNSHealth Investigators: Penny H. Feldman, PhD (VNSHealth-Site PI), Margaret McDonald, MSW (VNSHealth-Associate Director),

Co-investigators: Monika M. Safford, MD (Weill Cornell Medicine-Mentor), Lisa M. Kern, MD, MPH (Weill Cornell Medicine-Co-Mentor), Nicola Dell, PhD (Cornell Tech-Adviser), Jacklyn Cho, BS (Weill Cornell Research Assistant)

Study Sponsor: Visiting Nurse Service of New York and Weill Cornell Medical College

Study Funder: National Heart, Lung, and Blood Institute of the National Institute of Health

Invitation to be Part of a Research Study

You are invited to participate in a research study. In order to participate, you must: be a home health aide at Partners in Care with more than 1 year of experience on the job, ages 18 or older, speak English or Spanish, and be assigned to care for adults admitted to home care with a primary diagnosis of heart failure. Taking part in this research project is voluntary.

Important Information about the Research Study

Things you should know:

- The purpose of the study is to improve the experience of home health aides (like you) who care for adults with heart failure.
- This study will test how well a program designed for home health aides will work. The program has three parts. The first part is a heart failure training course, the second part is a mHealth app with information about heart failure that you learned from the course, and the third part is a messaging tool within the mHealth app.
- If you choose to be in this study, you will be asked to do an orientation session and a heart failure training course. The orientation session and the heart failure training course will take place on video via Zoom. You *may* also be asked to use a mHealth app (your Care Connect app) in addition to the heart failure training course. Our goal is to find out if these things help you understand heart failure and make it easier for you to communicate with your supervising nurse, while caring for your client with heart failure.
- We do not expect any risks from this research.
- We cannot be sure that you will receive any direct benefits from this study.
- You will be given $100 after finishing the study.
- Taking part in this research project is voluntary. You don't have to participate and you can stop at any time.

Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

What is the study about and why are we doing it?

The purpose of the study is to determine the effectiveness of an intervention among home health aides caring for adults admitted to home care with a primary diagnosis of heart failure at VNSHealth's Partners in Care. We hope to explore the interventions' effect on your own heart failure knowledge and confidence caring for clients, as well as on the client's overall health (visits to the emergency department and hospital readmissions).

Our goal for this project is to determine if the intervention improves your ability to care for heart failure clients and in doing so, improves clients' overall health.

What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to participate in a heart failure training course. Some participants will also be asked to use an mHealth app while caring for a client with heart failure. If chosen, we will provide you with instructions on how to use the mHealth app. The mHealth app will provide heart failure-specific education and allow you to report clinical observations and ask supervising nurse(s) questions in real-time. You will be asked to complete baseline and follow-up questionnaire (electronically) 4 times during the study: beginning of the study; after the training course; after your first heart failure client; after 6 months. We expect your participation to take 90 days in total. Information about your client (whether or not they went to the hospital or the emergency department during the 90-day period) will be assessed.

How could you benefit from this study?

There is no immediate benefit for participating in this study. However, you may learn more about heart failure from the heart failure training course and/or the mHealth app. This knowledge may improve your understanding of the disease course, its symptoms and how to better care for your clients. If you are chosen to use the mHealth app, you may further benefit from having on-demand access to heart failure materials and the ability to contact your supervising nurse immediately.

What risks might result from being in this study?

The risks from participating in this research are minimal.

Potential risks of participating include: a) distress from learning how to use a mHealth app, b) distress of integrating the mHealth app into your caregiving routine and c) feeling worried that you may not be able to answer all of the questions that we ask you about heart failure in questionnaires correctly. These risks are minimal, however, and will be lessened with support from the study team. Please know that there are no repercussions for information about quality of care. We encourage you to answer all questionnaires (that are part of this study) honestly. Your answers will be completely confidential from your employer and they will not affect your job standing.

How will we protect your information?

While we do plan to publish the results of this study, to protect your privacy, we will not include any information that could directly identify you.

We will protect the confidentiality of your research records by keeping them without your identity (name) and in a secure, locked office, as well as password protected computers. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**.**

Because this project meets the definition of an **NIH clinical trial**, a description of this study will be posted on a public website,

https://clinicaltrials.gov/ct2/show/NCT04239911, and summary results of this study will be posted on this website at the conclusion of the research, as required by the National Institutes of Health (NIH), the study sponsor. However, no information that can identify you will be posted.

What will happen to the information we collect about you after the study is over?

We will keep your research data to inform future studies. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you. We will not share your research data with other investigators.

How will we compensate you for being part of the study?

You will receive a total of $100 for your participation in this study upon completion. You will receive $25 upon consent and completion of survey 1 at the time of orientation, $25 following the completion of the HF training course and completion of the second survey, $25 following the completion of your 45-day interview, and $25 following the completion of your final survey at 90 days.

If you decide to withdraw from the research before the end of the study, your compensation will be prorated. This means that you will only receive compensation for the procedures that you completed up until the point of your withdrawal.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

Contact Information for the Study Team and Questions about the Research

If you have questions about this research, you may contact the study leader, **Dr. Madeline Sterling at mrs9012@med.cornell.edu or at 646-962-5029.**

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.

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

VNSHealth

Institutional Review Board

Phone: (212) 609-5766

Your Consent

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. We will email you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____

Printed Participant Subject Name

_____

Participant Signature Date

_____

Person Obtaining Consent Printed Name

_____

Person Obtaining Consent Signature Date

Script for Obtaining Oral Informed Consent from Nurses:

WAIVER OF DOCUMENTATION OF CONSENT -- SCRIPT

Title of the Project: Leveraging Home Health Aides to Improve Patient Outcomes in Heart Failure: A Pilot Randomized Controlled Trial
Principal Investigator: Madeline Sterling, MD, MPH, MS (Weill Cornell Medical College)
VNS Health Investigators: Penny H. Feldman, PhD (VNS Health-Site PI), Margaret McDonald, MSW (VNS Health-Associate Director),
Co-investigators: Monika M. Safford, MD (Weill Cornell Medicine-Mentor), Lisa M. Kern, MD, MPH (Weill Cornell Medicine-Co-Mentor), Nicola Dell, PhD (Cornell Tech-Adviser), Jacklyn Cho, BS (Weill Cornell Research Assistant)
Study Sponsor: Visiting Nurse Service of New York and Weill Cornell Medical College
Study Funder: National Heart, Lung, and Blood Institute of the National Institute of Health

KEY INFORMATION
I am going to start off with a few summary bullet points and then go into more specific details. You can ask questions about the study at any point during this time and at any time in the future. The goal of this research study is to improve the experience of home health aides who care for adults with heart failure.

- We are inviting you to participate in this research study. In order to participate, you must: be a nurse supervisor at Partners in Care with more than 1 year of experience on the job, ages 18 or older, speak English, and be assigned to supervise home health aides caring for adults admitted to home care with a primary diagnosis of heart failure. Please take this time to review the eligibility criteria and let me know if you have any questions.
- Once you consent to this study, you will be asked to respond to alerts and messages from home health aides using the mHealth app (Care Connect) that is being tested for acceptability and effectiveness among home health aides. At the beginning of this study, you will be asked to join an orientation session to learn about the Care Connect messaging features. The orientation session will take place virtually via Zoom.
- Participating in this study poses minimal risk to you. There are no costs to you to participate.
- We cannot be sure that you will receive any direct benefits from this study.
- After finishing the study, you will be given $100 for your participation.
- Taking part in this research project is voluntary. You don't have to participate and you can stop at any time.

PURPOSE
The purpose of the study is to determine the effectiveness of an intervention among home health aides caring for adults admitted to home care with a primary diagnosis of heart failure at Visiting Nurse Service of New York (VNS Health's) Partners in Care. We hope to explore the intervention's effect on home health aides' own heart failure knowledge and confidence caring for clients, as well as on the client's overall health (visits to the emergency department and hospital readmissions).

Our goal for this project is to determine if the intervention improves home health aides' ability to care for heart failure clients and in doing so, improves clients' overall health.

PROCEDURES
If you agree to take part in this study, you will be asked to: (1) participate in a virtual orientation session, and (2) respond to alerts and messages from home health aides using the mHealth app (Care Connect). At the end of the study, you may be asked to complete an exit interview with the study team.

RISKS/DISCOMFORTS
The risks from participating in this research are minimal. Potential risks of participating include: a) distress from learning how to use the mHealth app, b) distress of integrating the mHealth app into your routine and c) feeling worried that you may not be able to respond to the alerts and messages from home health aides from the mHealth app. These risks are minimal, however, and will be lessened with support from the study team. Please know that there are no repercussions for information about quality of care. Your participation will be completely confidential from your employer, and it will not affect your job standing.

BENEFITS
There is no direct benefit to you from being in this study.

However, you may learn more about heart failure from the mHealth app. This knowledge may improve your understanding of the disease course, its symptoms and how to better supervise your home health aides caring for clients with heart failure.

VOLUNTARY PARTICIPATION
You do not have to agree to be in this study. If you do not want to join the study, it will not affect your employment at the Visiting Nurse Service of New York. You can agree to be in this study now and change your mind later. If you wish to stop, please tell us right away. Leaving this study will not affect your employment.

PAYMENT
After completing the study, you will receive a $100 electronic gift-card for your participation. At the end of the study, we will ask you for an email address to send you the gift-card.

IDENTIFIABLE INFORMATION IN FUTURE RESEARCH
We will keep your research data to inform future studies. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.

We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you.

HOW WILL WE PROTECT YOUR INFORMATION?

While we do plan to publish the results of this study, to protect your privacy, we will not include any information that could directly identify you.

We will protect the confidentiality of your research records by keeping them without your identity (name) and in a secure, locked office, as well as password protected computers. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project.

Because this project meets the definition of an NIH clinical trial, a description of this study will be posted on a public website, https://clinicaltrials.gov/ct2/show/NCT04239911, and summary results of this study will be posted on this website at the conclusion of the research, as required by the National Institutes of Health (NIH), the study sponsor. However, no information that can identify you will be posted.

YOUR PARTICIPATION IN THIS STUDY IS VOLUNTARY
It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

ABILITY TO CONSENT:
I will now ask you a few questions to determine whether this study is a good fit for you:
- Do you feel that you understand the study procedures and are able to provide consent?
- What is the purpose of this study?
- Which activities are included in this study: physical exam or mHealth app?
- Are you required to participate in this study?
- Will participating in this study affect your health care?

CONTACT INFORMATION:
If you have questions about this research, you may contact the study leader, Dr. Madeline Sterling at mrs9012@med.cornell.edu or at 646-962-5029.

A description of this clinical trial will be available on https://clinicaltrials.gov/ct2/show/NCT04239911, 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.

The IRB can help if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB coordinator, Lori King at 212-609-5766.

YOUR CONSENT
- Do you understand what this study is about?
- Do you have additional questions that have not been answered so far?
- Do you agree to participate in this study?

Data to be Collected and Analyzed: The questionnaire (see attached document) will be administered using Research Electronic Data Capture (REDCap), a web-based, secure, data storage program at Weill Cornell Medicine at several time points during the study. A research assistant at Weill Cornell Medicine will export the de-identified data that is collected in REDCap to STATA, a statistical software package, for analysis. A data analyst at Weill Cornell Medicine will analyze this data under PI Sterling's supervision (IRB at WCM to safeguard this aspect of the project). App usage data from the mHealth app (intervention arm) will be monitored by Dr. Dell (Scientific adviser/collaborator from Cornell; health technology). After 90 days, data from the mHealth app will be extracted by Dr. Dell and the Care Connect team (that works with Partner's in Care) and transferred and stored on a secure server on a password-protected computer at Weill Cornell Medicine which is monitored by WCM ITS. This data will be analyzed by a data analyst at Weill Cornell under PI Sterling's supervision. Finally, data on the HF patients cared for by the HHAs in the trial (demographics, clinical co-morbidities, and outcomes [ED visits and 30-day readmissions, functional status]) will be extracted by the VNS Health programmer from the agency's clinical records and administrative data. This type of data collection is part of the agency's ongoing quality improvement activities and falls under the agency's routine admissions procedures with patients. Like many studies at VNS Health, the clinical outcomes will be extracted from the Home Health Outcome and Assessment Information Set (OASIS). Data will be de-identified and analyzed at VNS Health, under Site-PI Dr. Feldman's supervision. All OASIS data will be analyzed at VNS Health. At the end of the study, under Dr. Sterling's supervision, trial participants (HHAs, nurses) will be interviewed to assess their experience with the training course and mHealth app. Additionally, short, telephone-based interviews will be conducted with a sub-set of patients by Dr. Sterling. These interviews will focus on their perspectives towards their HHAs, not about their medical care or their health, and will not last more than 30 minutes. They will be audio-recorded and professionally transcribed. Transcripts will be stored on a secure password-protected computer at WCM, which is monitored by WCM ITS. Dr. Sterling will oversee the qualitative data analysis.

Brief Overview of Analytic Methods:

Baseline analyses: For each baseline characteristic in the questionnaire (see attached document), we will examine the distribution and outliers. We will test whether baseline characteristics are balanced between intervention arms using parametric or non-parametric bivariate tests as appropriate. All tests will be conducted at $\alpha=0.05$.

Outcome analyses: Feasibility measures (described above) will be characterized with descriptive statistics (frequencies and proportions) using STATA statistical software. To assess the acceptability of the intervention and trial among study participants, Dr. Sterling will conduct a series of exit interviews with HHAs and nurses in the trial, as well as with VNS Health staff. The effect of the intervention among HHAs will be assessed for two primary outcomes: 1) HF knowledge; 2) HF caregiving self-efficacy and two secondary outcomes: 1) intention to leave and 2) job satisfaction (See above Table); alongside other specified outcomes of interest including communication practices (and preventable 911 calls). Finally, the effect of the intervention on two patient outcomes (emergency department [ED] visits; 30-day readmissions; functional status) will be assessed in exploratory analyses. To determine the effect of the intervention on the primary outcomes, we will compare HF knowledge and HF caregiving self-

efficacy scores by trial arm using paired t-tests for normally distributed data or Wilcoxon signed rank test for non-parametric data. We will examine the effect of randomization on the change in scores, using mixed linear regression models. Mixed-effects included a fixed effects categorical variable for time point (baseline/post-course/90 day), an indicator for study arm (control/intervention), a study arm by timepoint interaction and subject-specific random intercept. Primary analyses will be conducted using intention-to-treat, when appropriate. We will examine HHA characteristics across trial arms and adjust for covariates that are imbalanced ($p<0.10$). We will conduct the same analyses for the secondary outcomes (burnout and job satisfaction). For patient outcomes, we will perform exploratory analyses to determine the effect of the intervention on ED visit rates and hospitalization rates; and functional status, using Poisson mixed effects regression models to account for clustering of patients within HHAs. To measure what would have occurred with usual care (e.g. without enhanced usual care or the intervention), we will assess ED visit rates and 30-day readmission rates among HHAs 90 days before vs. 90 days after randomization, adjusting for clustering of patients within HHAs, and stratified by trial arm Analyses will be done using STATA statistical software.

Power and Sample Size: To detect minimal clinically important differences (MCID) for both outcomes (a 1-point change in mean score on the Dutch HF Knowledge Scale; an 8-point change in mean score on the HF caregiving self-efficacy), with 80% power, α at 0.05, and conservatively allowing for 15% attrition, we will need 104 HHAs (52 per arm). The overall α at 0.05 enables testing of two hypotheses using Bonferroni's method. Consistent with the goals of this study (to assess feasibility and acceptability of the intervention and obtain preliminary effectiveness estimates on primary outcomes), we have not powered our study on secondary outcomes or on patient outcomes. These calculations were done in Stata v13, College Station, TX.

Statement of the Risks/Benefits for the Study Subjects:

There are minimal to no risks involved with participating in this study (attending a HF training course and/or using a mHealth app with HF educational content and a messaging application to contact the supervising nurse). The questionnaires that HHAs will be asked to complete are de-identified, minimizing confidentiality risks. The mHealth app is Care Connect, which is HIPAA compliant and the standard of care app used at Partner's in Care for regular HHA work and patient care, thereby minimizing the risks. Potential risks of participating include: a) distress from learning how to use the mHealth app, b) distress of integrating the mHealth app into their caregiving routine and c) HHAs feeling worried that they may not be able to answer all of the questions that we ask them about HF in questionnaires correctly. These risks are minimal, however, and will be lessened with support from the study team and an orientation video. There will be no disruption to standard clinical care at VNS Health during this study. HHAs will not face any repercussions for information about quality of care. If any risks are reported by participants or study team members, PI Sterling will report these cases directly to VNS Health, the IRB, and the patient's primary care physician.

There is no immediate benefit for participating in this study. However, HHAs in the trial may learn about HF (from the HF training course and/or the mHealth app). This knowledge may be reinforced by the mHealth app and may improve their understanding of the disease course, its

symptoms and how to better care for patients. Those in the intervention arm may also benefit from having on-demand access to HF materials and an ability to contact their supervising nurse quickly (without using a telephone and waiting on hold, which is the current standard of care).

How Privacy, Confidentiality, and the Rights of Human Subjects will be Protected:

The HHAs will receive a HF training course and will perform routine caregiving tasks while caring for HF patients in this study. Those in the intervention arm, will also have the opportunity to engage (electronically) with their supervisors to ask clinical questions, rather than usual care (trying to reach them by phone). The questions will be asked via a secure, HIPAA protected function on the mHealth app (Care Connected) (monitored by Dr. Dell, adviser in health technology, and the Care Connect team) and no identifying information will be used. All participants will be asked to complete questionnaires at 4 time points during the trial, which contain no identifying information. Although every reasonable effort has been taken, confidentiality during Internet communication procedures cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study. The VNS Health and Weill Cornell Medicine take the privacy and security of study data seriously. To preserve confidentiality, data will be collected and stored at Weill Cornell Medicine on secure servers monitored by Weill Cornell Medicine ITS. Data will only be available to authorized individuals on the study team. When necessary, data will be sent over private connections secured by the WCM ITS. Furthermore, data sets will be encrypted and reported in aggregate form only. VNS Health study staff will have initial access to patient-level data in order to merge data sources and identify the patient cohort of interest; and to link a home health aide to a specific patient for intervention workflow processes. The outcome file that will be shared with Weill Cornell study staff will include a Study ID, the age of the patient, and information on hospitalizations and ED visits within 90 days of the start of the intervention. Both VNS Health and Weill Cornell study staff will have access to the communication (via the Chat feature in Care Connect) between the home health aide and the supervisory nurses. It is possible that patient name and other identifiers will be included within this communication. At both sites all data will be secured in password protected, HIPAA secured data systems. Sharing of data across sites will be done through the VNS Health approved email encryption process and/or through the approved MSTeams application. For the entire study, data will be reported in aggregate form only. PI Sterling will ensure that all study team members will be trained thoroughly in the need to maintain confidentiality and no information collected will be used for any purpose other than those stated in the informed consent form. Rules for handling confidential data and security of patient information will be strictly abided by all study team members in charge of handling data.

Participation by HHAs and nurses is voluntary.

- At the start of the trial, during the kickoff session, nurses will provide informed consent verbally. During the kickoff session, the study team will thoroughly explain the study details to the nurses. Upon agreeing to participate, nurses will provide verbal informed consent. We are submitting a waiver of written informed consent documentation for nurses because we are not collecting additional data from them. As such, the study team

has deemed that it will not be necessary nor feasible to build a separate REDCap project for electronic consent for nurses.

- At the start of the trial, HHAs will provide informed consent twice. First, HHAs will provide informed consent verbally over the phone at the time of screening and eligibility assessment, by VNS Health staff. At the time of recruitment into the study (orientation session, before HF training course), HHAs that are eligible and agree to participate will provide electronic signed informed consent. For all participants who meet eligibility criteria, the VNS Health staff member and WCM research assistant will explain the study protocol and discuss the risks and benefits of participating. The staff member will explain that the decision to participate will not affect the care that they provide to patients or their job at the agency. There will be many opportunities for questions about the study to be answered. As per the Institutional Review Board, the informed consent form will provide a section explaining what comprises protected health information (PHI) and how this study will not collect this type of information; it will also explain how participants' data will remain confidential and protected. The informed consent form will also provide the contact information for PI Sterling as well as the Weill Cornell Institutional Review Board and the Privacy Office and the Site-PI contact information (Feldman). Note, because this study (and the intervention) is focused on HHA and nurse behavior, patients will not be initially consented. The intervention is non-intrusive and includes information-based strategies that do not require HHAs or nurses to do anything other than provide care that they view as appropriate in light of information provided by the agency. In fact, participation in the implementation of interventions with a research component is part of the VNS Health's contractual agreement with employees. With respect to patients (who are not the primary focus of this study), only a Waiver of Patient Authorization will be required by the VNS Health IRBs with review and approval before beginning the study. To understand their perspectives towards the HHAs in the trial, we will ask a sub-set of patients to participate in a one-time, virtual (telephone or zoom)-based interview at the end of the study. This will take 30 minutes and will be conducted by the research assistant using a topic guide. In order to recruit patients to participate, only their socio-demographic data will be needed. From this, a VNS Health research assistant will screen the participants using a pre-written script and obtain verbal consent.

<u>Telephone Recruitment Script for Recruiting Patients:</u>

Hello [insert name of patient]:

My name is _____ from _____. I am working with Dr. Madeline Sterling, a primary care doctor from Weill Cornell. I am contacting you because your home health aide was part of an NIH-funded research study. We would like to interview you about your experience receiving care from the HHA, who was trained about heart disease (heart failure) and given resources (like a smartphone app) to help care for you.

We are inviting you to participate in a brief interview, so our research team can learn more about your experiences working with home health aides. Our ultimate goal is to improve the health of adults with heart failure (like you), so we are interested in learning about what worked and what didn't with respect to the care you received at home.

Our one-time interview will be conducted remotely (via telephone or Zoom) and will last up to 30 minutes. Following completion of the interview you will receive a $25 electronic gift card to compensate you for your participation.

Is this a study you would be interested in?

PAUSE

Your participation in this research is strictly confidential and voluntary. Your decision to participate will not affect your relationship with VNS HEALTH.

Do you have any questions for me?

PAUSE

If you have further questions or comments about this study, please e-mail Dr. Madeline Sterling at mrs9012@med.cornell.edu.

Thank you for your time and consideration of our research.

CLOSING

Data Safety Monitoring Board: This study does not require a formal Data and Safety Monitoring Board (DSMB) as it is not a Phase III clinical trial, does not involve multiple field sites, and is minimal risk. However, should the IRB feel this is necessary, a DSMB of external investigators will be appointed by Dr. Sterling (PI) and Dr. Feldman (Site-PI).

Data Use Agreement (DUA): This study does not require a DUA.

Study Closure Report: Dr. Madeline Sterling agrees to adhere to the reporting requirements of the VNS Health IRB, including agreement to submit a study closure report within 60 days of the end of primary data collection or within 60 days of completing primary objective analysis if using secondary data. She also agrees to submit a summary of main project findings when available.

Enrollment end date: March 31st, 2024

Primary data collection end date: August 17th, 2024