

**Partners in Health: Pilot test of a Pre-Visit Question Prompt List to
Enhance Engagement of Heart Failure Patients and Family Members
During Medical Visits**

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Complete Title: Partners in Health: Pilot test of a Pre-Visit Question Prompt List to Enhance Engagement of Heart Failure Patients and Family Members During Medical Visits

Short Title: Partners in Health

Drug or Device Name(s): N/A

FDA IND/IDE (if applicable): N/A

Sponsor: NC Translational and Clinical Sciences Institute; RTI, International

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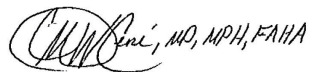
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I confirm that I have read this protocol and understand it.

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ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
HF	Heart Failure
HCP	Health care provider
NC TraCS	North Carolina Translational and Clinical Sciences
RA	Research Assistant
SC	Study coordinator
EHR	Electronic Health Record
PIH	Partners in Health (short title of the study)
PHI	Personal health information

PROTOCOL SYNOPSIS

Study Title	Partners in Health: Pilot test of a Pre-Visit Question Prompt List to Enhance Engagement of Heart Failure Patients and Family Members During Medical Visits
Funder	North Carolina Translational and Clinical Sciences Institute RTI International
Clinical Phase	N/A
Study Rationale	<p>Heart failure (HF) is prevalent in more than 6 million Americans and is a leading cause of hospitalizations. Active HF self-management reduces hospitalizations but patient adherence to HF self-care behaviors is poor. Data suggests that family involvement in the patient's care enhances patients' self-management.</p> <p>Patient and family engagement is critical to obtaining the knowledge, skills, and confidence for effective self-management. Engagement is often manifested through asking questions, expressing concerns, and clarifying information from health care providers (HCPs). Engagement is generally low among individuals with HF.</p> <p>Strategies such as pre-visit prompt lists can enhance patient and family engagement by encouraging patients and family members to ask relevant questions and discuss sensitive topics with HCPs. However, several important gaps in the literature exist. First, the effect of prompt lists on self-management has not been tested. Second, few studies have used them with family members. Lastly, prompt lists have not been tested in HF patients.</p>
Study Objective(s)	The specific aims of this pilot study are to: 1) Develop a pre-visit question prompt list for use with HF patients and family members; and 2) Conduct a pre-post pilot study in up to 30 HF patients and family members to evaluate feasibility, acceptability, and effects of the prompt list on HF self-care behaviors (of patients and family members/caregivers), communication behaviors, and self-efficacy with communication.
Test Article(s) <i>(If Applicable)</i>	The question/topic prompt list is the main intervention in this study. A prompt list is a written document containing suggested questions that the family member and/or patient may want to ask the health care provider during the visit. A section is included for the patient to check which behaviors they would like for their family member to engage in during the visit and space is provided for the family member to check which behaviors they are willing to perform during the visit.
Study Design	Single group pre-post design
Subject Population	We will enroll adult patients with HF, family members, and HCPs. Patient Eligibility Ambulatory adult patients ≥ 30 years old

key criteria for Inclusion and Exclusion:	<p>Receive care in the UNC Cardiology or General Internal Medicine practice</p> <p>Have a clinical diagnosis of HF</p> <p>Currently prescribe a loop diuretic</p> <p>Have a New York Heart Association class II-IV</p> <p>Must speak English</p> <p>Must have a working telephone or live with the patient</p>
	<p><u>Family Member Eligibility</u></p> <p>Must be at least 18 years old and able to give informed consent</p> <p>Must be willing to participate in the intervention activities and provide informed consent</p> <p>Must speak English</p> <p>Must have a working telephone or live with the patient</p>
	<p><u>Health Care Provider Eligibility</u></p> <p>Must be an MD or advance practice provider (NP or PA) in the UNC cardiology or General Internal Medicine practice</p> <p>Must be willing to have an enrolled patient visit audio-taped</p>
Number Of Subjects	Up to 80 participants, including up to 30 HF patients and family members, and HCPs
Study Duration	<p>Each subject’s participation will last up to 6 months</p> <p>The entire study is expected to last 1 year</p>
Study Phases Screening Study Treatment Follow-Up	<p>(1) <u>Screening</u>: screening for eligibility and obtaining consent and (2) <u>Intervention</u>: study intervention; and (3) 2-day post clinic visit and 1 month follow-up</p>
Efficacy Evaluations	<p>Primary outcome: Percent of eligible patients and companions who enrolled in the study.</p> <p>Secondary outcomes: 1) mean acceptability checklist score, 2) mean score on self-care of heart failure index scores (maintenance, management, and confidence subscales); 3) mean score on caregiver contribution to self-care of heart failure index scores (maintenance, management, and confidence subscales); 4) mean score on perceived efficacy in patient-physician interactions score; 5) mean score on communication with physicians measure</p>
Pharmacokinetic Evaluations	N/A
Safety Evaluations	N/A
Statistical And Analytic Plan	This is a pilot study and as such, our sample size was selected based largely on feasibility. Specifically, we examined the expected margin of error for varying recruitment and recruitment yields.
DATA AND SAFETY MONITORING PLAN	We will not have a DSMC, DsMC, or DMC for this study given that the safety risk to participants is extremely low.

1 BACKGROUND AND RATIONALE

Heart failure (HF) is prevalent in more than 6 million Americans and is a leading cause of hospitalizations. Active HF self-management reduces hospitalizations but patient adherence to HF self-care behaviors is poor. Data suggests that family involvement in the patient's care enhances patients' self-management.

Patient and family engagement is critical to obtaining the knowledge, skills, and confidence for effective self-management. Engagement is often manifested through asking questions, expressing concerns, and clarifying information from health care providers (HCPs). Engagement is generally low among individuals with HF.

Strategies such as pre-visit prompt lists can enhance patient and family engagement by encouraging patients and family members to ask relevant questions and discuss sensitive topics with HCPs. A prompt list is a structured list of questions or topics related to illness, treatment, and support that is developed from interviews with patients, family members, and HCPs. Prompt lists are completed by patients and family members before a visit. Prompt lists have been shown to increase the number and relevance of questions asked by patients and family members. However, several important gaps in the literature exist. First, the effect of prompt lists on self-management has not been tested. Second, few studies have used them with family members. This gap is important given that about 1 in 3 adults are accompanied to medical visits by a family member. Moreover, family members' concerns are often ignored by HCPs, thus adversely affecting families' ability to support patients' self-management. Lastly, prompt lists have not been tested in HF patients. Most of the research on their use has been conducted in cancer patients facing oncology-specific clinical decisions. To address these gaps, we will:

1) Develop a pre-visit question prompt list for use with HF patients and family members; and 2) Conduct a pre-post pilot study in up to 30 HF patients and family members to evaluate feasibility, acceptability, and effects of the prompt list on HF self-care behaviors (of patients and family members/caregivers), communication behaviors, and self-efficacy with communication.

This study will take place in the UNC Cardiology clinic or the General Internal Medicine clinic at the Ambulatory Care Center.

1.1 Name and Description of Investigational Product or Intervention

A question/topic prompt list is the main intervention in this study. A prompt list is a structured list of questions or topics related to illness, treatment, and support that the family member and/or patient may want to ask the HCP during the visit. The prompt list includes a section for the patient to check which behaviors they would like for their family member to engage in during the visit and space is provided for the family member to check which behaviors they are willing to perform during the visit.

1.2 Non-Clinical and Clinical Study Findings N/A

1.3 Relevant Literature and Data. See section

2 STUDY OBJECTIVE

The objective of the study is to evaluate feasibility, acceptability, and effects of the prompt list on HF self-care behaviors (of patients and family members/caregivers), communication behaviors, and self-efficacy with communication in up to 30 HF patients and family members.

3 INVESTIGATIONAL PLAN (Brief Overview)

3.1 Study Design

This is a single-group pre-post prospective study design.

3.2 Allocation to Treatment Groups and Blinding (if applicable) N/A

3.3 Study Duration, Enrollment and Number of Subjects. After IRB approval, the study will be active until 1-month follow-up data has been collected on all study participants (i.e., up to 30 dyads.) We anticipate that be no longer than 1 year.

3.4 Study Population. We will enroll HF patients, family members, and HCPs

Patient Eligibility

Ambulatory adult patients \geq 30 years old
Receive care in the UNC Cardiology or General Internal Medicine practice
Have a clinical diagnosis of HF
Currently prescribe a loop diuretic
Have a New York Heart Association class II-IV
Must speak English
Must have a working telephone or live with the patient

Family Member/Companion Eligibility

Must be at least 18 years old and able to give informed consent
Must be willing to participate in the intervention activities and provide informed consent
Must speak English
Must have a working telephone or live with the patient

Health Care Provider Eligibility

Must be an MD or advance practice provider (NP or PA) in the UNC cardiology or General Internal Medicine practice
Must be willing to have an enrolled patient visit audio-taped

4 STUDY PROCEDURES

4. 1 Screening/Baseline Visit procedures: Thirty HF dyads will receive the prompt list. Each dyad member will receive a prompt list to complete in the clinic waiting room immediately before their appointment. HF dyads will complete the prompt list without staff help. Completing the prompt list involves two steps. In step 1, participants will independently select from a list of questions or write in their own questions they would like to ask their health care provider during the visit. Patients will also be asked to select among a pre-determined list of behaviors they would like their family member to engage in during the visit (e.g., write down the providers instructions). In step 2, dyad members will collaboratively decide which questions to discuss during the visit. Participants will be encouraged to take the prompt list into the exam room and use it to facilitate communication with the HCP. The RA may take a picture of the prompt lists (which will not contain any identifying information, only a study id) to assess areas of agreement and disagreement between the dyad on what to discuss with the HCP. This information will inform future studies.

Potential participants will be identified using several sources: the Carolina Data Warehouse (CDW-H); the HF social support and family studies registry (SSR; IRB #11-0562); medical record audits by the study PI; and suggestions from HCPs.

After initial identification, we will query HCPs of potentially eligible patients to confirm the diagnosis of HF. (based on their clinical assessment), determine if the patients are appropriate to approach for possible study participation (procedures we have successfully used in our prior studies). When we provide participating providers with a list of their potentially eligible patients, we will all ask them to check how often the patient has a companion enter the exam room with them (none of the time, rarely, some visits, most visits, every visit). Patients will be considered "likely to be accompanied" if the provider indicates that a companion enters the exam room "most visits or every visit." We anticipate that the providers will be very accurate in predicting patients who usually bring a family member into the exam room, since these will be their regular patients. This method will be used to facilitate more efficient recruitment of patients most likely to be eligible for the study. For patients deemed ineligible by providers, we will ask providers to provide reasons why the patients should not be contacted, Provider approved patients will be approached by a research assistant (RA) to assess eligibility and possible interest in the study either during a scheduled clinic visit, via a provider-approved letter, or via telephone using an IRB approved telephone script. For those presenting for a clinic visit, the RA/SC will approach them about participation in the study. If they are interested, the study staff will consent the patient at that time and administer the baseline survey. If there isn't time to complete the entire baseline survey before the visit, we will finish the remainder of the survey either after the visit or via phone within the week of the visit.

We will use several approaches to identify and enroll family members: 1) If a family member has accompanied the patient to the clinic visit, the family member will be approached by a study coordinator at that time about participation in the study and they can provide written consent at that time, if they are interested and eligible. They will also be administered the baseline survey either before (or after the visit depending on the time) or via phone in the week of the visit. 2) If a family member is not present with the patient at a clinic visit, an IRB-approved study recruitment letter and a copy of the consent form will be sent home with the patient to give to a family member who may be interested in participating, and the family member can contact a study coordinator to discuss the study and/or mail in the signed consent form. The study team will provide a pre-paid self-addressed envelope to return the signed consent form. After receiving signed consent form, the study team will call the potential participants to schedule the baseline study interview for both members of the dyad. For potential participants identified through the CDW or from the HF social support and family studies registry, the study team will mail an IRB approved recruitment letter to potential patient participants. The letter will notify the patient that a family member (preferably who one attends medical visits with them) is required to also participate in the intervention, so they should discuss the study with family members and get their permission to share their contact (phone number or address) with the study team. The letter will include an opt-out form that potential participants may return using pre-paid, self-addressed envelope that will accompany the recruitment letter. We will follow-up with potential patient participants via telephone 1 week after the letters have been mailed. If they are interested in participating and have identified a family member who is interested, the study team will obtain verbal consent from each person and a written consent form will also be mailed to them to sign and return to the study team. The RA/Project Coordinator will also schedule the baseline study interview. If the patient and family member provide verbal consent, but do not return the written consent form via mail, we will have them sign a written consent form at the time of baseline study interview. We will make it clear to the patient and family member that both individuals must be eligible and provide informed consent for either to be eligible to participate in the study. An RA/Study coordinator will obtain informed written consent for all eligible and interested dyads.

Partners in Health Eligibility SCREENING FORM

The following form will be used to determine eligibility for Patients:

Partners in Health: Pilot test of a Pre-Visit Question Prompt List to Enhance Engagement of heart failure (HF) patients and Family Members During Medical Visits

Patient Eligibility Form

Research Assistant: _____

Study ID#: _____

QUESTIONS TO ASK PATIENT TO VERIFY ELIGIBILITY

DATE: _____

1. Is English your preferred language?"
YES NO
2. "Do you see a health care provider at the UNC Cardiology Clinic?"
YES NO
3. "Do you have a diagnosis of Heart Failure (or Diastolic Dysfunction)?"
YES NO
4. "Do you take a loop diuretic medication?" (e.g. Furosemide, Lasix, Bumetanide, Bumex, Demadex, Torsemide)
YES NO
5. "Do you take a thiazide diuretic medication?" (e.g. Hydrochlorothiazide, HydroDIURIL, Chlorothiazide, Diuril, Chlorthalidone, Metolazone, Zaroxolyn, Indapamide, Lozol)
YES NO
6. "What is your current age?"
7. "Do you require assistance with basic activities of daily living?"
YES NO
8. "Do you live in a nursing home or care facility?"
YES NO

(Patients who receive nursing home services (including help with basic activities of daily living are NOT eligible to participate; patients living independently in senior centers or independent living facilities ARE eligible)

9. Do you have a working telephone?
YES NO
10. Do you agree to have one of your visits with your provider audiotaped
YES NO
11. Symptom Assessment (Patient must answer "YES" to at least one question)

"Think about the last six months and the days you felt the worst.

So, on your worst days..."

1) "How many city blocks could you walk before getting short of breath?"

If states a specific number, has symptoms (Number _____ = symptoms)

YES

If says can walk as far as s/he wants—go to #2

NO

If unable to walk enough to answer question, go to 1a below

Unable to answer

2) "Did you have to walk at a slower pace than normal to keep from getting short of breath?"

If says Yes, has symptoms

YES

If says No—go to #3

NO

3) "If you had to rush or hurry, did you get short of breath?"		
If says Yes, has symptoms		YES
If says No—go to #4		NO
4) "How many flights of stairs could you climb without getting short of breath or needing to stop to catch your breath?"		
If less than 2 flights or needs to stop at 2 flights catch breath, has symptoms		YES
If can walk up 2 or more flights then is truly class I and does not have symptoms		NO
(If unable to answer question 1 above, ask the following questions)		
1a) "Have you experienced swelling of the legs or ankles due to excess fluid?"	YES	NO
1b) "Do you sleep on more than one pillow at night to help you breathe easier?"	YES	NO

TO BE COMPLETED BY RESEARCH ASSISTANT ELIGIBILITY CRITERIA—for Heart Failure Patients

Patients must have ALL of the following eligibility criteria.

1. Relationship – Patient must be seen by a health care provider at the UNC Cardiology clinic at least one time before? YES
2. Diagnosis – Carry a clinical diagnosis of Heart Failure or Diastolic Dysfunction YES
3. Medications– Currently prescribed a loop or Thiazide diuretic. YES

Loop Diuretics: Bumetanide (Bumex®), Torsemide (Demadex®), Furosemide (Lasix®)

Thiazide Diuretics: Hydrochlorothiazide (HydroDIURIL®), Chlorothiazide (Diuril®), Chlorthalidone, Metolazone (Zaroxolyn®), Indapamide (Lozol®)

4. Symptoms – Have New Class II, III or IV symptoms now or in the past 6 months YES
5. Age – Over the age of 21 YES
6. Communication – Speak English and have adequate hearing to communicate and talk in person or on the phone. YES
7. Audiotaping – Must agree to have a visit audiotaped YES

INELIGIBILITY CRITERIA

Patients will be ineligible if they meet ONE of the following criteria:

1. Do not speak English
2. Have significant cognitive impairment (e.g. a diagnosis of dementia/severe cognitive impairment)
3. Have significant psychiatric impairment (e.g. schizophrenia)

4. Require assistance with Activities of Daily Living (ADL)
5. Live in a nursing home

IS THE PATIENT ELIGIBLE? (Circle one) ELIGIBLE INELIGIBLE

Partners In Health Eligibility SCREENING FORM

The following form will be used to determine eligibility for Family Members:

Research Assistant: _____

Study ID#: _____

QUESTIONS TO ASK INDIVIDUAL TO VERIFY ELIGIBILITY

1. "What is your current age?" _____
Family member must be at least 18 years old.

2. "What is the highest grade you completed?" _____
(If 6th grade or below, or if have knowledge that family member is illiterate, have witness present when signing consent)

3. Do you have a working telephone or live with the patient?
YES NO

4. "Is English your preferred language?"
YES NO

If family member does not speak English, then they are ineligible to participate.

The family member and the patient MUST answer YES to the following question for the visit companion to be eligible to participate.

Read the following definition to the participant:

"Family is broadly defined as two or more persons who are related in any – biologically, legally, or emotionally. Therefore, "family" is defined by the patient.

5. Do you think the patient considers you family?

YES NO

If "yes", confirm with the patient. If the patient does not agree then the individual is not eligible to participate.

IS THE INDIVIDUAL ELIGIBLE AS A FAMILY MEMBER? (Circle one)

ELIGIBLE INELIGIBLE

BASELINE ADMINISTRATION PROTOCOL

The following is protocol for the administration of the **BASELINE QUESTIONNAIRES** to study participants.

The baseline questionnaires can be collected in 3 different ways: 1) on the phone with the participant after the participant has provided verbal consent; 2) in person, after the participant has completed their informed consent; or 3) by phone after the participant has met with the RA/SC in person at a medical appointment at enrollment and completed their informed consent but did not have time to complete the baseline questionnaires.

After participants have consented (verbally or by in-person informed consent), the **BASELINE QUESTIONNAIRES** will be administered.

The RA/SC will need the following:

- iPad and power source for data collection into REDCap
- Paper copies of the questionnaire
- Answer key for the patient
- Pen/pencil for both the RA/SC and the subjects

Note: For iPad administration of the surveys, refer to the REDCap section in this protocol.

After the participant has provided consent, the RA/SC will administer the baseline questionnaires. It is important to speak clearly and slowly so that the participant can understand what is being asked, especially if the baseline data collection occurs over the phone.

Baseline data collection is preceded by the following prompt:

Hello, _____. This is [NAME] calling from UNC Health Care. I'm calling about the Heart Failure Study that you joined last week.

As a first step in the study, I'd like to ask you a few questions about your health and your healthcare experiences. Our conversation should take about 15 minutes. Is this a good time to talk?

[IF YES, PROCEED]

[IF NO, RESCHEDULE FOR A LATER DATE/TIME]

You are in this study because you have heart failure. Doctors sometimes call this congestive heart failure, an enlarged heart, or fluid in the lungs.

During our conversation, I'll ask you questions about yourself, your visit companion, and your interactions with your doctor. Your "visit companion" is the family member or friend who comes with you to your health appointments. Your "doctor" is the doctor, nurse practitioner, or other health care provider who you usually see during your visit.

After completing the prompt and if the participant is able to conduct their data collection at that time, the RA/SC will collect their data either by using one of the following: 1) paper data collection materials; 2) the iPad REDCap application; or 3) by computer using the REDCap online data capture system. Regardless of the way in which the data is collected, each data collection will be administered uniformly to all participants.

Below are the **BASELINE QUESTIONNAIRES** with their respective variables for analysis for patients

List of measures included in this questionnaire:

1. Relationship with companion
2. Companion involvement
3. Closeness with companion
4. Health literacy
5. Knowledge of heart failure+
6. Self-care behaviors
7. Self-efficacy related to self-care
8. Perceived health status
9. Heart failure symptom severity
10. Communication with provider
11. Perceived efficacy in interactions with doctor
12. Perceived social support
13. Demographic/background questions

*Note that the Baseline Questionnaires **for companions** includes the following measures, which parallel the patient questionnaires:

List of measures included in this questionnaire:

1. Relationship with patient
2. Companion involvement
3. Closeness with patient
4. Knowledge of heart failure
5. Caregiver care behaviors
6. Self-efficacy related to patient care
7. Perceived efficacy in interactions with doctor
8. Demographics
9. Health literacy

Companion for visit with doctor

1. **Will you have a companion, such as a family member or friend, come with you to visit your doctor during this study? Variable name: accompanied**

- a. Yes
- b. No

IF NO:

- 2. Does someone usually go with you to your medical appointments? **Variable name: usual_accomp**
 - a. Yes
 - b. No

Relationship with Companion

[IF PARTICIPANT WILL NOT HAVE A COMPANION COME WITH THEM TO THEIR APPT, ASK ABOUT THE PERSON WHO USUALLY GOES WITH THEM. IF PARTICIPANT DOES NOT USUALLY HAVE A COMPANION COME WITH THEM TO THEIR APPT, SKIP AHEAD TO HEALTH LITERACY.]

For these first few questions, please think about the person who will come with you to your medical appointment during this study [or who usually comes with you to your medical appointments]. This might be your spouse, your brother/sister, one of your children, or someone else.

- 1. **What is your relationship to this person? You are that person's ____.** **Variable name: relationship**
 - a. Spouse
 - b. Partner
 - c. Mother
 - d. Father
 - e. Brother
 - f. Sister
 - g. Daughter
 - h. Son
 - i. Friend
 - j. Other relationship. Please specify _____

Closeness with Companion

For the next two questions, please continue to think about the person who will come with you to your medical appointment during this study [or who usually comes with you to your medical appointments].

- 1. **Relative to all your other relationships (both same and opposite sex) how would you characterize your relationship with this person?** **Variable name: closeness_1**

Not close at all						Very close
0	1	2	3	4	5	6

2. Relative to what you know about other people's close relationships, how would you characterize your relationship with this person? **Variable name: closeness_2**

Not close at all 0	1	2	3	4	5	Very close 6
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Health Literacy

Now I have a couple of questions about how you handle hospital materials and forms.

1. How often do you have someone (like a family member, friend, hospital/clinic worker or caregiver) help you read hospital materials? **Variable name: reading_lit**

None of the time 0	A little of the time 1	Some of the time 2	Most of the time 3	All of the time 4
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2. How confident are you filling out forms by yourself? **Variable name: fill_forms**

Not at all confident 0	1	2	3	Extremely confident 4
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Knowledge of Heart Failure

Next, I would like to find out how much you know about heart failure and its treatment. I'm going to read a question and some possible answers. Tell me which answer you think is correct. If you don't know the answer, you can just say "I don't know."

1. Heart failure means that: **Variable name: meaning**

- a. your heart is beating out of rhythm
- b. your heart might stop beating sometime soon
- c. your heart is not pumping blood as well as it should,
- d. you are having a heart attack
- e. DON'T KNOW

2. Heart failure can cause which of the following problems? **Variable name: signs_sxs**

- a. headache
- b. skin that turns yellow

- c. shortness of breath when you lie down
- d. vomiting blood
- e. DON'T KNOW

3. Which of the following are signs that you are dehydrated (lost too much water)? Variable name: dehydrated

- a. dizziness
- b. shortness of breath
- c. chest pain
- d. peeing a lot
- e. DON'T KNOW

I'm going to read a list of problems, and I want you to tell me whether each one is a sign that heart failure is getting worse. If you don't know the answer, you can just say "I don't know."

4. Is shortness of breath a sign your heart failure is getting worse? Variable name: sob

- a. YES
- b. NO
- c. DON'T KNOW

5. Is swelling of the legs or ankles a sign your heart failure is getting worse? Variable name: swelling

- a. YES
- b. NO
- c. DON'T KNOW

6. What about yellowing of the skin? PROBE: Is yellowing of the skin a sign your heart failure is getting worse? Variable name: yellowskin

- a. YES
- b. NO
- c. DON'T KNOW

Waking up at night short of breath? PROBE: Is waking up at night short of breath a sign your heart failure is getting worse? Variable name: pnd

- a. YES
- b. NO
- c. DON'T KNOW

8. Vomiting blood? PROBE: Is vomiting blood a sign your heart failure is getting worse? Variable name: vomiting

- a. YES
- b. NO
- c. DON'T KNOW

9. Headaches? PROBE: Are headaches a sign your heart failure is getting worse? Variable name: headaches

- a. YES
- b. NO
- c. DON'T KNOW

10. Weight gain? PROBE: Is a gaining weight a sign your heart failure is getting worse? Variable name: wtgain

- a. YES
- b. NO
- c. DON'T KNOW

11. If you eat a lot of salt, it will: Variable name: highsalt

- a. make your heart failure worse
- b. make your heart failure better
- c. have no effect on your heart failure
- d. DON'T KNOW

12. What should you do when you feel more short of breath and your weight has increased by 6 lbs from your good weight? Variable name: knowsxs

- a. stop taking your fluid pill

- b. call your doctor
- c. go on a diet
- d. weigh yourself tomorrow to see if you have gained more
- e. DON'T KNOW

13. What should you do when your legs swell up more than normal? Variable name: legswell

- a. take an extra dose of your fluid pill
- b. walk more
- c. eat more salt
- d. eat more protein
- e. DON'T KNOW

14. Compared to someone without heart failure, a person with heart failure should drink: Variable name: knowdrink

- a. more fluids than usual
- b. about the same amount of fluids
- c. less fluids than usual
- d. DON'T KNOW

15. Someone with heart failure should weigh himself or herself: Variable name: wtfreq

- a. every day
- b. once a week
- c. once a month
- d. only if he or she feels badly
- e. DON'T KNOW

Self-Care Behaviors (Self-Care of Heart Failure Index or SCHFI)

Now, think about how you have been feeling in the **last month** as you respond to these questions.

SECTION A: Listed below are common instructions given to persons with heart failure.

How routinely do you do the following?	Never or rarely	Sometimes	Frequently	Always or daily
1. Weigh yourself? <i>weigh_self</i>	1	2	3	4
2. Check your ankles for swelling? <i>check_ankles</i>	1	2	3	4
3. Try to avoid getting sick (e.g., get a flu shot, avoid ill people)? <i>avoid_sick</i>	1	2	3	4
4. Do some physical activity? <i>phys_activity</i>	1	2	3	4
5. Keep doctor or nurse appointments? <i>keep_appts</i>	1	2	3	4
6. Eat a low salt diet? <i>eat_low_salt</i>	1	2	3	4
7. Exercise for 30 minutes? <i>exercise</i>	1	2	3	4
8. Forget to take one of your medicines? <i>forget_meds</i>	1	2	3	4
9. Ask for low salt items when eating out or visiting others? <i>ask_lowsalt</i>	1	2	3	4
10. Use a system (pill box, reminders) to help you remember your medicines? <i>med_system</i>	1	2	3	4

SECTION B: *sectionb_score*

Many patients have symptoms due to their heart failure. Trouble breathing and ankle swelling are common symptoms of heart failure. *Variable name: schfib_adequate*

In the past month, have you had trouble breathing or ankle swelling? (circle one) *Variable name: trouble*

- 0) No
- 1) Yes

11. If you had trouble breathing or ankle swelling in the past month... (circle one number) *Variable name: freq_trouble*

12.

	Have not had these	I did not recognize it	Not Quickly	Somewhat Quickly	Quickly	Very Quickly
--	--------------------	------------------------	-------------	------------------	---------	--------------

How quickly did you recognize it as a symptom of heart failure? Variable name: quick_recognize	N/A	0	1	2	3	4
--	-----	---	---	---	---	---

Listed below are remedies that people with heart failure use.

If you have trouble breathing or ankle swelling, how likely are you to try one of these remedies? (circle one number for each remedy)	Not Likely	Somewhat Likely	Likely	Very Likely
13. Reduce the salt in your diet reduce_salt	1	2	3	4
14. Reduce your fluid intake reduce_fluid	1	2	3	4
15. Take an extra water pill extra_pill	1	2	3	4
16. Call your doctor or nurse for guidance call_dr	1	2	3	4

17. Think of a remedy you tried the last time you had trouble breathing or ankle swelling

	I did not try anything	Not Sure	Somewhat Sure	Sure	Very Sure
How sure were you that the remedy helped or did not help? sure_remedy	0	1	2	3	4

Self-Efficacy Related to Self-Care

SECTION C:

In general, how confident are you that you can do the following:

	Not Confident	Somewhat Confident	Very Confident	Extremely Confident
18. Keep yourself free of heart failure symptoms? free_sxs	1	2	3	4

19. Follow the treatment advice you have been given? follow_advice	1	2	3	4
20. Evaluate the importance of your symptoms? evaluate_sx	1	2	3	4
21. Recognize changes in your health if they occur? recognize_changes	1	2	3	4
22. Do something that will relieve your symptoms? relieve_sxs	1	2	3	4
23. Evaluate how well a remedy works? evaluate_success	1	2	3	4

Perceived Health Status

1. **How would you rate your overall health? **srh****
 - a. Excellent
 - b. Very good
 - c. Good
 - d. Fair
 - e. Poor

Health Status: Symptom Severity

Which one of the following statements best describes how your heart condition affects you today?
nyha_class

1. Usual physical activity does not cause fatigue, shortness of breath or chest pain. You have no difficulties with usual physical activity
2. Usual physical activity results in fatigue, shortness of breath or chest pain. You have some difficulty with usual physical activity.
3. Less than usual activity causes fatigue, shortness of breath or chest pain. You have great difficulty with usual physical activity.
4. You are unable to do any physical activity without discomfort. Fatigue, shortness of breath or chest pain may be present even at rest.

Communication with Provider

When you visit your doctor, how often do you do the following?

1. Prepare a list of questions for your doctor **make_list**

Never 0	Almost never 1	Sometimes 2	Fairly often 3	Very often 4	Always 5
------------	-------------------	----------------	-------------------	-----------------	-------------

2. Ask questions about your treatment [ask_questions](#)

Never 0	Almost never 1	Sometimes 2	Fairly often 3	Very often 4	Always 5
------------	-------------------	----------------	-------------------	-----------------	-------------

3. Discuss any personal problems that may be related to your illness [discuss_probs](#)

Never 0	Almost never 1	Sometimes 2	Fairly often 3	Very often 4	Always 5
------------	-------------------	----------------	-------------------	-----------------	-------------

Perceived Efficacy in Interacting with Doctor

Next, I'd like to ask you some questions about your interactions with doctors.

1. How confident are you in your ability to know what questions to ask a doctor? [know_to_ask](#)

Not at all confident 0	1	2	3	Very confident 4
------------------------------	---	---	---	---------------------

2. How confident are you in your ability to get a doctor to answer all of your questions?
[get_answers](#)

Not at all confident 0	1	2	3	Very confident 4
------------------------------	---	---	---	---------------------

3. How confident are you in your ability to make the most of your visit with a doctor?
[maximize_visit](#)

Not at all confident 0	1	2	3	Very confident 4
------------------------------	---	---	---	---------------------

4. How confident are you in your ability to get a doctor to take your health concerns seriously?
[take_serious](#)

Not at all confident 0	1	2	3	Very confident 4
------------------------------	---	---	---	---------------------

5. How confident are you in your ability to get a doctor to do something about your health concerns?
[make_dr_act](#)

Not at all confident 0	1	2	3	Very confident 4
---------------------------	---	---	---	---------------------

6. How confident are you in your ability to ask a doctor questions? [able_to_ask](#)

Not at all confident 0	1	2	3	Very confident 4
---------------------------	---	---	---	---------------------

Emotional Support (Enriched Social Support Instrument)

1. Is there someone available to you whom you can count on to listen to you when you need to talk.
[count_on](#)

None of the time 0	A little of the time 1	Some of the time 2	Most of the time 3	All of the time 4
-----------------------	---------------------------	-----------------------	-----------------------	----------------------

2. Is there someone available to give you good advice about a problem. [good_advice](#)
3. Is there someone available to you who shows you love and affection? [shows_love](#)
4. Is there someone available to help you with daily chores? [help_chores](#)
5. Can you count on anyone to provide you with emotional support (taking over problems or helping you make a difficult decision)? [provide_support](#)
6. Do you have as much contact as you would like with someone who feel close to, someone in whom you can trust and confide? [desired_contact](#)
7. Are you currently married or living with a partner? [marital_status](#)

Tangible Support

In the last 3 months, have you needed any kind of extra help at home because your health kept you from taking care of yourself or doing what you usually do? [need_support](#)

- a. Yes
- b. No

IF YES:

Of the help you got at home, would you say you got: [amt_received_support](#)

- (1) All the help you needed
- (2) Most of the help you needed
- (3) Some of the help you needed
- (4) Only a little of the help you needed
- (5) None of the help that you needed

Demographic/Background Information

Next, I'd like to ask you a few questions about yourself.

1. **What year were you born ? _____**

2. **Which of these groups best represents your race? You can choose more than one answer.**
 - a. American Indian or Alaskan Native
 - b. Asian
 - c. Black or African American
 - d. Native Hawaiian or Other Pacific Islander
 - e. White or Caucasian

3. **Which of these groups best represents your ethnicity? You can choose more than one answer.**
 - a. Hispanic
 - b. Non-hispanic

4. **What is the highest level of education you have completed? *education***
 - a. Less than high school
 - b. Grade 12 or GED (High school graduate)
 - c. Technical school or associate's degree, 2 years
 - d. College 4 years or more (College graduate)
 - e. Advanced degree (Master's degree or Doctorate)

5. **What is your current employment status? *employed***
 - a. Currently employed
 - b. Retired
 - c. Unemployed
 - d. On disability

6. **When did you first learn you had heart failure? *hf_duration***
 - a. Less than 1 year ago
 - b. 1- 5 years ago
 - c. More than 5 years ago

Social Support Registry

1. Can we include your name and contact information on a list to call for future studies about social support or social relationships and chronic illness? *registry*

Yes

No

The following script will be used after the participant has completed their baseline data collection.

The next part of the study is to meet you at your next doctor's appointment at the heart clinic in Meadowmont. At this appointment you will receive a list of topics and questions that you and your family member will review and complete before your appointment. We will also audio record your appointment with your provider.

So that you have time to complete your list, we ask that you and your family member arrive 30 minutes before your scheduled appointment.

Do you know when your next appointment at the heart clinic at Meadowmont is?

[If yes] **Great, when is your appointment?**

Date _____

Time _____

Don't forget that your family member will need to join us for that appointment.

Will your family member be able to attend that appointment with you?

[if not or if the patient is unsure, ask the patient to follow up with the family member, the RA/SC should plan to follow up with the family member to remind them of the appointment as well]

I would like to call you 1 – 2 days before your appointment to remind you that I will be there.

Do you have a telephone number that I can reach you?

Great, thank you!

When would you prefer I call you to remind you of your appointment?

__ Morning __ Afternoon __ Evening __ Specific time _____

Again, we really appreciate you taking the time to participate in the study. For your time and participation on the study, you will receive a gift card.

[provide them with their gift card if in person]

[if baseline is completed over the phone, use the following script...]

When we meet at your appointment, I will provide you with your gift card for completing today's questions.

[hand them the PiH Study informational and contact sheet if in person or provide the information if over the phone]

Here is our information. Please contact us if you have any questions or if your appointment has been rescheduled.

Thank you for taking time to answer my questions today. I'll call you again a few days after your appointment with your heart doctor to ask some additional questions. I look forward to talking with you then. Have a great day!

4.1 Intervention/Treatment procedures (by visits)

PATIENT'S MEDICAL APPOINTMENT

The following protocol is for the administration of the study visit at the time of the patient's medical appointment.

Each dyad member will receive a prompt list to complete in the clinic waiting room immediately before their appointment. HF dyads will complete the prompt list without staff help. Completing the prompt list involves two steps. In step 1, participants will independently select from a list of questions or write in their own questions they would like to ask their health care provider during the visit. Patients will also be asked to select among a pre-determined list of behaviors they would like their family member to engage in during the visit (e.g., write down the providers instructions). In step 2, dyad members will collaboratively decide which questions to discuss during the visit. Participants will be encouraged to take the prompt list into the exam room and use it to facilitate communication with the HCP. The RA may take a picture of the prompt lists (which will not contain any identifying information, only a study id) to assess areas of agreement and disagreement between the dyad on what to discuss with the HCP.

The RA/SC will meet participants in the waiting room and introduce their self and review the directions of completing the prompt list with the participant(s) as well as the process of the data collection.

Note: If a participant has not completed an informed consent, one must be obtained prior to proceeding with the audio recorded medical appointment.

The RA/SC will obtain consent from the patient's HCP and remind the HCP that the appointment will be audio recorded. After the HCP has consented and the RA/SC has confirmed which exam room the patient will be in, the RA/SC can set up the audio recording equipment. When the HCP enters the room, the RA/SC will start the recording and exit the room. Once the appointment is over, the RA/SC will knock on the door and enter the exam room to stop the recording.

After the recording has been stopped, the RA/SC will need to collect a copy of the completed prompt list from the participant. The copy can be provided as a carbon copy, a picture taken by a camera, a scanned copy, or a copy from the copy machine in the clinic. Scanned copies and pictures must be saved on a study approved computer in order to prevent loss of data. It is preferable to obtain a picture using the study iPad; pictures will be taken on the iPad and entered into the REDCap application.

Once the RA/SC has obtained a copy of the completed prompt list, the RA/SC will provide the participant(s) with their gift card(s) for completing their baseline questionnaire for the study. The RA/SC will also have each participant sign a gift card receipt which the RA/SC will keep track of all gift cards. The RA/SC will also schedule a time to call the participant(s) for their 2 day follow up call and confirm telephone contact information. After their appointment and scheduling their next visit, the RA/SC will thank the participant(s) for their time and exit the room.

The following script will be used after the patient's in person medical appointment and data collection has completed.

Thank you for allowing us to audio record your appointment. The next part of the study is for you to complete a telephone survey 2 days from today. This call should last approximately 20. I will call you at a time that works best for you.

What is the best telephone number where I can reach you?

Great, thank you!

When would you prefer I call you?

__ Morning __ Afternoon __ Evening __ Specific time _____

Again, we really appreciate you taking the time to participate in the study.

[if the participant did not receive their gift card for completing their baseline questionnaires, provide them with their gift card and obtain a signed gift card receipt from the participant]

[hand them the PiH Study informational and contact sheet & the answer prompt for the 2 day follow up call]

Here is our information and a sheet with answer responses for our call in 2 days. You can use the answer response sheet to help you answer the questions when we talk on the phone.

Please contact us if you have any questions or if your appointment has been rescheduled.

Thank you and I will be in touch soon.

Copy of the Patient Prompt List [Note- the family member prompt list exactly parallel's the patient prompt list]

Part 1: Questions for Your Heart Doctor

Below is a list of questions that people with heart failure might want to ask their doctor. You can select questions on this list that you may want to ask or you can write in your own questions.

Three easy steps for using the question list below:

Step 1. **Review** the questions under each topic.

Step 2. **Select** the questions that you'd like to ask your doctor during today's visit.

Step 3. If you'd like to ask your doctor questions that aren't on the list, **write** those questions in the blank spaces on page 3.

The person who came with you today also might have questions. He or she will complete a separate list.

Remember that doctors answer all kinds of questions, even ones that might seem embarrassing. Talking honestly with your doctor will help you to make the most of your visit.

Topic: Heart Failure	Step 2: Select Your Questions
What is heart failure?	
How is heart failure different from other heart problems (such as heart disease and heart attack)?	
What type of heart failure do I have?	
What caused my heart failure?	
How can someone prevent heart failure?	
What increases a person's risk of heart failure (such as family history)?	

Topic: Managing and Treating Heart Failure	Step 2: Select Your Questions
Can heart failure be cured?	
What are my treatment options?	
How can I prevent my heart failure from getting worse?	
What tools can I use to track my health (such as a pulse ox or food journal)?	
How can I manage my heart failure while also managing other conditions (such as diabetes or arthritis)?	
Medicine	
What medicines am I taking? What is the purpose of each one?	
How long will I need to take each medicine?	
What medicine interactions or conflicts should I know about?	
Are there any medicines that I can stop taking?	
What are the possible side effects of my medicines?	
Food and Diet	
What diet should I follow?	
What are healthy foods that I can eat?	
What are some high salt foods that I should avoid?	
How much water should I drink each day?	
Is it okay for me to eat meals at a restaurant?	
What programs can help me to eat healthy (such as Meals on Wheels)?	
Exercise and Movement	
Am I healthy enough to exercise?	

What kind of exercise should I do? How much should I do?	
Should I participate in a special exercise program (such as physical therapy or cardiac rehab)?	
Will walking (instead of using a wheelchair) make my heart failure worse?	
Weight Management	
What is a healthy body weight for me?	
Would losing weight reduce the number of medicines that I need to take?	
What is the best way for me to lose weight?	
Surgery and Other Treatments	
What are the surgical options for treating my heart failure (such as a heart transplant)?	
Am I healthy enough to have surgery for other problems (such as a knee replacement)?	
Will I need to use oxygen at home (daytime or nighttime)?	
What should I do if I'm using oxygen and the power goes out?	

Topic: Signs and Symptoms of Heart Failure	Step 2: Select Your Questions
What are the <u>common</u> signs and symptoms of heart failure?	
What are some <u>uncommon</u> signs and symptoms of heart failure?	
What are the signs that my heart failure is getting better or worse?	
What signs and symptoms should I tell my doctor about right away?	
What is the best way to deal with...	
...memory problems?	
...mood swings?	
...sleep problems?	
...chest pain?	
...feeling tired?	
...feeling dizzy?	
...trouble breathing?	
...swelling or bloating?	
...gaining weight?	
...fast heartbeat?	

Topic: Signs and Symptoms of Heart Failure	Step 2: Select Your Questions
...colds or infections that won't go away?	

Topic: Day-to-Day Life with Heart Failure	Step 2: Select Your Questions
Work and Career	
Am I healthy enough to work?	
What kind of work should I not do?	
Sleep	
How much sleep should I be getting?	
Why might I have trouble sleeping?	
How can I improve my sleep quality?	
Fun Activities	
Am I healthy enough to have sex?	
What outdoor activities are safe for me to do?	
What are some healthy recreational activities for me to participate in?	
Am I healthy enough to _____ [fill in your favorite activity]?	
Around My House	
Am I healthy enough to cook my own meals?	
Am I healthy enough to do chores in and around the house (such as cleaning or gardening)?	
Travel	
Am I healthy enough to drive on my own?	
Am I healthy enough to fly on an airplane?	

Topic: What To Expect with Heart Failure	Step 2: Select Your Questions
How bad is my heart failure?	
Can my heart failure get better?	
How long do most people with heart failure live?	
What can we do to help me live longer?	
What can we do to help me live more comfortably?	

What are my options when my heart failure gets really bad?	
How can I prevent other problems caused by heart failure (such as stroke)?	

Topic: Support for You and Your Family/Friends	Step 2: Select Your Questions
What support services are available through this health system?	
What support services are available in my community?	
Emotional Support	
How can I find a support group for people with heart failure?	
How can I find a support group for my caregiver, family members, or friends?	
What is the best way to tell my family and friends about my heart failure?	
Financial Support	
Who can help me with disability and unemployment benefits?	
How can I get help with insurance and medical bills?	
How can I get help affording my medications?	
Is there a way to reduce the cost of my current medications?	
Logistical Support	
Who can help me with transportation to and from medical appointments?	
Who can help me with transportation for other needs (such as running errands)?	
How can I find help with daily activities (such as cooking, running errands, etc.)?	
What types of adult daycare are available for me?	
Life Planning	
How can I help my family prepare if my heart failure gets really bad?	

Topic: Healthcare Team Roles and Responsibilities	Step 2: Select Your Questions
Who are the members of my healthcare team?	
What does each member of my healthcare team do? Who is responsible for what?	

Topic: Healthcare Team Roles and Responsibilities	Step 2: Select Your Questions
How can I find the right healthcare team if I'm moving to a new area?	
When should I...	
...call my heart doctor?	
...call my primary care doctor?	
...go to the hospital?	
...call 911?	

Step 3: Write Your Own Questions (Optional)	

Part 2: Help from Your Companion

Having a family member or friend accompany you to your medical appointment can be useful, especially if that person knows how to help. Below are some ways a companion might support you during your visit. Read through this list and put a checkmark next to the ways you'd like your companion to help.

✓	I would like my companion to...(check all that apply)
<input type="checkbox"/>	Take notes on what the doctor says during my appointment.
<input type="checkbox"/>	Remind me to ask my questions.
<input type="checkbox"/>	Ask my doctor questions for me.
<input type="checkbox"/>	Remind me to tell my doctor about my symptoms.
<input type="checkbox"/>	Tell my doctor about my health.
<input type="checkbox"/>	Make sure I understand what my doctor says.
<input type="checkbox"/>	Stay in the waiting room for part of the visit.
<input type="checkbox"/>	Other ways you would like your companion to help you: _____ _____ _____
<input type="checkbox"/>	I don't need my companion to help me during my visit.

Once you and your companion have each completed your own forms, please compare the forms and decide together which concerns are most important to discuss with your doctor today.

4.2 Follow-up procedures (by visits)

2 DAY & 1 MONTH FOLLOW UP CALL ADMINISTRATION PROTOCOL

Hello, _____. This is [NAME] calling from UNC Health Care. I'm calling about the Partners in Heart Health Research Study that you are participating in. Thanks again for participating in our study.

I'd like to ask you a few questions about your most recent appointment [interviewer to specify when the appointment was- e.g. 2 days ago]. Our conversation should take about 15 minutes. Is this a good time to talk?

Yes → [Continue]

No → [Reschedule interview for next available time- preferably within the same week]

During our conversation, I'll ask you questions about yourself, your visit companion, and your interactions with your provider. Your "visit companion" is the family member or friend that came with you to your appointment. Your provider is the doctor or nurse practitioner you saw during your visit.

2-Day Follow-Up Measures

1. Prompt List Acceptability
2. Satisfaction with visit
3. Perceptions of provider communication
4. Patient communication
5. Perceived efficacy in interactions with doctor
6. Self-efficacy related to self-care

The following protocol is for the administration of the 2 Day Follow Up and the 1 Month Follow Up Calls for each study participant.

Hello, _____. This is [NAME] calling from UNC Health Care. I'm calling about the Heart Failure Study that you joined earlier this year. My records show that your family member or friend had an appointment with their healthcare team 2-3 days ago. Is that right?

Yes → [Continue]

No → [Clarify appointment date and reschedule interview accordingly]

As part of the study, I'd like to ask you a few questions about your family member or friend's appointment. Our conversation should take about 15 minutes. Is this a good time to talk?

Yes → [Continue]

No → [Reschedule interview for next available time]

During our conversation, I'll ask you questions about yourself, your family member or friend who has heart failure, and your interactions with the doctor who treats your family member or friend's heart failure. We will use "doctor" to refer to the doctor, nurse practitioner, or physician assistant who your family member or friend usually sees during medical appointments.

[*Note that the 2-day follow-up questionnaires **for companions** includes the same measures, which parallel the patient questionnaires].

Prompt List Acceptability

1. **Do you remember receiving the "Preparing for Your Visit with Your Heart Doctor" checklist before your appointment?** **remember_list**
 Yes → **CONTINUE TO Q2**

- No → **READ BRIEF DESCRIPTION OF CHECKLIST (below), THEN ASK Q1 AGAIN. IF STILL “NO,” SKIP TO NEXT SECTION (SATISFACTION WITH VISIT).**

The “Preparing for Your Visit with Your Heart Doctor” checklist looks like a list of questions you can ask your doctor. Then, at the end, there is a section in which you can indicate what kind of help you would like from the person accompanying you to your appointment.

Relative Advantage					
2. Did the checklist make it easier or more difficult to talk to your doctor? Variable name: help_talk					
Much More Difficult					Much Easier
1	2	3	4	5	6
Compatibility					
3. The questions in the checklist matched the types of questions that you wanted to ask your doctor. good_questions					
Strongly Disagree					Strongly Agree
1	2	3	4	5	6
4. You had enough time to fill out the checklist in the waiting room before your appointment with your doctor. enough_time					
Strongly Disagree					Strongly Agree
1	2	3	4	5	6

--

Complexity

5. How much of the checklist did you fill out while waiting for your appointment with your doctor? *amount_done*

- All of it
- Most of it
- Some of it
- None of it → **SKIP TO Q8**

6. How easy or difficult was it to fill out the checklist? *ease_completion*

Very Difficult					Very Easy
1	2	3	4	5	6

7. The instructions on the checklist were clear and understandable. *clarity*

Strongly Disagree					Strongly Agree
1	2	3	4	5	6

8. How did you use the checklist during your visit with your doctor? *use_list*

- I handed the checklist to my doctor
- I asked my doctor questions by reading from the checklist
- I asked my doctor questions using my memory of the checklist
- I did not use the checklist when talking to my doctor → **SKIP TO Q13**

9. How easy or difficult was it to use the checklist when talking with your doctor? *ease_of_use*

Very Difficult					Very Easy
1	2	3	4	5	6

--

Trialability

10. You would use the checklist again at your next appointment with your doctor. *use_again*

Strongly Disagree					Strongly Agree
1	2	3	4	5	6

Observability

11. The checklist helped you to get more of your questions answered by your doctor. *get_answers*

Strongly Disagree					Strongly Agree
1	2	3	4	5	6

12. You were able to learn more during your appointment with your doctor because of the checklist. *learn_more*

Strongly Disagree					Strongly Agree
1	2	3	4	5	6

For these next questions, please think about the person who came with you to your appointment with your doctor.

13. How did you and your companion complete the checklist? *completion*

- We each filled it out separately
- We filled it out together
- We didn't fill it out at all → **Skip remainder of section**

<p>14. Did you and your companion compare and discuss the checklist after filling it out? <i>discuss_list</i></p>					
<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>					
<p>15. After using the checklist, you have a better understanding of your companion's questions and concerns about your heart failure. <i>understand_more</i></p>					
Strongly Disagree					Strongly Agree
1	2	3	4	5	6
<p>16. You felt supported by your companion as a result of using the checklist. <i>feel_support</i></p>					
Strongly Disagree					Strongly Agree
1	2	3	4	5	6

For participants who report in #13 that they did not complete the checklist:

1. What are some topics that you want to talk with your heart doctor about?

2. What topics are hardest to talk about? What topics are you most hesitant to talk about?

3. What some questions that you you like to ask your heart doctor?

Satisfaction with Visit

We are interested in your feelings, good and bad, about the medical care you have received. Think about the visit you had with your doctor a few days ago. How strongly do you agree or disagree with each of the following statements?

1. I was very satisfied with the medical care I received at my recent visit. *overall_satis*

Strongly disagree 1	Disagree 2	Uncertain 3	Agree 4	Strongly agree 5
------------------------	---------------	----------------	------------	---------------------

2. There were some things about the medical care I received at my recent visit that could have been better. *could_be_better*

Strongly disagree 1	Disagree 2	Uncertain 3	Agree 4	Strongly agree 5
------------------------	---------------	----------------	------------	---------------------

3. All things considered, the medical care I received at my recent visit was excellent *excellent_care*

Strongly disagree 1	Disagree 2	Uncertain 3	Agree 4	Strongly agree 5
------------------------	---------------	----------------	------------	---------------------

4. There were things about the medical system I received my care from that need to be improved *med_syst_improv*

Strongly disagree 1	Disagree 2	Uncertain 3	Agree 4	Strongly agree 5
------------------------	---------------	----------------	------------	---------------------

5. The medical care I received at my recent visit was just about perfect *perfect_care*

Strongly disagree 1	Disagree 2	Uncertain 3	Agree 4	Strongly agree 5
------------------------	---------------	----------------	------------	---------------------

6. I was dissatisfied with some things about the medical care I received at my recent visit
some_dissatis

Strongly disagree 1	Disagree 2	Uncertain 3	Agree 4	Strongly agree 5
------------------------	---------------	----------------	------------	---------------------

7. My doctor spent plenty of time with me during my recent visit. **satis_timespent**

Strongly disagree 1	Disagree 2	Uncertain 3	Agree 4	Strongly agree 5
------------------------	---------------	----------------	------------	---------------------

8. My doctor hurried too much during my recent visit **dr_hurried**

Strongly disagree 1	Disagree 2	Uncertain 3	Agree 4	Strongly agree 5
------------------------	---------------	----------------	------------	---------------------

Perceptions of Provider Communication

For these next questions, please think about the appointment you recently had with your heart doctor.

1. How much effort did your doctor make to help you understand your health issues?**dr_understand2**

No effort at all 0	1	2	3	4	5	6	7	8	Every effort was made 9
-----------------------	---	---	---	---	---	---	---	---	----------------------------

2. How much effort did your doctor make to answer your questions?**dr_answer2**

No effort at all									Every effort was made
0	1	2	3	4	5	6	7	8	9

3. How much did your doctor focus on the things that matter most to you about your health issues? **dr_focus2**

Not at all									Very much
0	1	2	3	4	5	6	7	8	9

4. How much did your doctor consider what matters most to you when choosing what to do next? **dr_consider2**

Not at all									Very much
0	1	2	3	4	5	6	7	8	9

Patient Communication

When answering the next set of questions, please continue to think about the visit you had with your doctor a few days ago. How strongly do you agree or disagree with each of the following statements?

1. I asked for recommendations about my medical condition **asked_recs2**

Strongly disagree									Strongly agree
0	1	2	3	4	5	6	7	8	9

2. I asked a lot of questions about my medical condition **asked_questions2**

Strongly disagree									Strongly agree
0	1	2	3	4	5	6	7	8	9

3. I went into great detail about my medical symptoms [detailed_sxs2](#)

Strongly disagree									Strongly agree
0	1	2	3	4	5	6	7	8	9

4. I asked the doctor to explain the treatment or procedure in greater detail [explain_tx2](#)

Strongly disagree									Strongly agree
0	1	2	3	4	5	6	7	8	9

5. I offered opinions to the doctor [offer_opinions2](#)

Strongly disagree									Strongly agree
0	1	2	3	4	5	6	7	8	9

6. I expressed concerns to the doctor [express_concern2](#)

Strongly disagree									Strongly agree
0	1	2	3	4	5	6	7	8	9

Perceived Efficacy in Interacting with Doctor

Next, I'd like to ask you some questions about your interactions with your doctor.

1. **How confident are you in your ability to know what questions to ask a doctor?** *know_to_ask2*

Not at all confident 0	1	2	3	Very confident 4
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2. **How confident are you in your ability to get a doctor to answer all of your questions?** *get_answers2*

Not at all confident 0	1	2	3	Very confident 4
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3. **How confident are you in your ability to make the most of your visit with a doctor?** *maximize_visit2*

Not at all confident 0	1	2	3	Very confident 4
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4. **How confident are you in your ability to get a doctor to take your health concerns seriously?** *take_serious2*

Not at all confident 0	1	2	3	Very confident 4
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5. **How confident are you in your ability to get a doctor to do something about your health concerns?** *make_dr_act2*

Not at all confident 0	1	2	3	Very confident 4
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6. **How confident are you in your ability to ask a doctor questions?** *able_to_ask2*

Not at all confident 0	1	2	3	Very confident 4
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1-MONTH FOLLOW-UP PATIENT QUESTIONNAIRE

1-Month Follow-up Measures

1. Self-care behaviors (Same measure as at baseline)
2. Self-efficacy related to self-care (Same measure as at baseline)
3. Communication with provider (Same measure as at baseline)
4. Emotional support
5. Tangible support
6. Perceived efficacy in interacting with doctor

Hello, _____. This is [NAME] calling from UNC Health Care. I'm calling about the Heart Failure Study that you joined earlier this year. This is the final part of the study, and I'd like to ask you a few questions about your health and your healthcare experiences. Our conversation should take about 15 minutes. Is this a good time to talk?

Yes → [Continue]

No → [Reschedule interview for next available time]

During our conversation, I'll ask you questions about yourself, your visit companion, and your interactions with your doctor. Your "visit companion" is the family member or friend who comes with you to your health appointments. Your "doctor" is the doctor, nurse practitioner, or other health care provider who you usually see during your visit.

4.3 **Unscheduled visits** N/A

4.4 **Concomitant Medication documentation** N/A

4.5 **Rescue medication administration (if applicable)** N/A

4.6 **Subject Completion/ Withdrawal procedures.** The total duration of study participation will be up to 6 months. Participants are eligible to withdraw at any time.

4.7 **Screen failure procedures.** For individuals who refuse or who are not eligible to participate, eligibility screening forms will be destroyed within 1 week of refusal or ineligibility is determined. We will keep a list of participant names who were approached and who are not eligible or not interested in participating so that they are not approached a second time.

5 **STUDY EVALUATIONS AND MEASUREMENTS (how measurements will be made)**

Data sources for this study include survey data and audio-taped data. Research staff will administer the surveys to study participants. We will use validated survey measures, where-ever possible. We will submit copies of all data collection instruments for IRB approval. We will not collect biometric or laboratory data as part of this study.

- 5.1 **Efficacy Evaluation (if applicable)** N/A
- 5.2 **Pharmacokinetic Evaluation (if applicable)** N/A
- 5.3 **Safety Evaluations** N/A

6 STATISTICAL CONSIDERATION

6.1 Primary Endpoint

Primary outcome= Percent of eligible patient participants who enrolled in the study. The investigators will assess enrollment rate into the study. The investigators aim to have at least 50% of screened patients consent and enrollment. This is a pilot study and as such, our sample size was selected based largely on feasibility. Specifically, we examined the expected margin of error for varying recruitment and recruitment yields.

6.2 Secondary Endpoint

Secondary outcomes include: 1) mean score on acceptability checklist; 2) mean score on self-care of heart failure index scores (maintenance, management, and confidence subscales); 3) mean score on caregiver contribution to self-care of heart failure index scores (maintenance, management, and confidence subscales); 4) mean score on perceived efficacy in patient-physician interactions score; 5) mean score on communication with physicians measure

6.3 Statistical Methods

Analysis for this study will be quantitative pre-post analyses. We will compute descriptive statistics (percentages, means, and standard deviations) for feasibility, acceptability, and behavioral outcomes. For each behavioral outcome (HF self-care behaviors, self-efficacy related to self-care, communication with provider, communication with providers, and perceived efficacy in interactions with doctor), we will use paired t-tests to compare changes in mean scores from baseline to 1-month separately for accompanied patients, companions, and unaccompanied patients. In this pilot study, we are not conducting hypothesis testing. To help plan for future proposals, point estimates of effect sizes for the mean change value in each behavioral outcome will be computed as the ratio of the mean difference in each change value between baseline and 1-month follow-up.

6.4 Sample Size and Power.

This is a pilot study and as such, our sample size was selected based largely on feasibility. Specifically, we examined the expected margin of error for varying recruitment and recruitment yields.

6.5 Interim Analysis. N/A

7 STUDY INTERVENTION (drug, device or other intervention details) N/A- this is not a drug or device trial. Behavioral intervention is described above in Sections 1.1 and 4.2.

8 STUDY INTERVENTION ADMINISTRATION (if applicable) N/A- this is a non-randomized trial design. Behavioral intervention administration is described above in Sections 4.1

9 SAFETY MANAGEMENT

We will not have a DSMC, DsMC, or DMC for this study given that the safety risk to participants is extremely low. However, the PI and Co-I (Chang), both physicians, will review any safety concerns raised, including involving others from the study team (or external to it, if necessary) and decide on an appropriate action. For any unanticipated problems, the PI and study coordinator will conduct an aggregate review using SOP 19.2 and 19.3 to decide if an event or events meets the criteria for unanticipated problems and whether it is an adverse event. If found to meet the requirements, all unanticipated problems will be reported using the online reporting portal within required timelines (SOP 19.5).

10 DATA COLLECTION AND MANAGEMENT

Data will be collected at baseline, the day of the participant's medical appointment, 2 days (+/- 2 days) following the medical appointment and 1 month (+/- 7 days) after the participant's medical appointment. There are several ways in which data may be collected: at baseline, data collection instruments may be administered by telephone or in person using the REDCap online data capture system, the REDCap iPad application, or pen and paper surveys; at the participant's medical appointment, the visit will be audio-recorded; and two day follow up and 1 month follow up data will be collected over the telephone using the REDCap online data capture system, the REDCap iPad application, or pen and paper surveys. All data will be entered into the study REDCap database.

We will have a follow up call with participants 2-days (+/- 2 days) after the visit to gather their perspectives on the utility of the prompt list as well as their perspectives on the communication during the visit and their satisfaction with the visit. The study team will also send participants a reminder letter at least 1 week before time for their 1-month (+/- 7 days) follow-up outcomes assessment. Finally, we will conduct the 1-month follow-up outcomes assessment via phone.

We will make every possible effort to keep the data confidential. All contact information will be kept in electronic files that are password protected and only accessible by study staff. Any hard copy of contact information (used to process the mailing of incentives) will be kept in a secure place (locked office and file cabinet). No names will appear on questionnaires; files linking name with study ID will be kept electronically under password protection. During participant identification, the RAs, PI, and Co-Investigators will know the identity of the patient and their family member. This is required to contact providers for approval, to mail letters to potential patients, and/or to conduct direct in-person recruitment. Upon enrollment, patients and family members will be given a unique study ID number and all data collected thereafter will be linked to this study ID number.

We will use the web-based application known as REDCap (Research Electronic Data Capture project-redcap.org) for data management. REDCap is used for building and managing online surveys and databases. It is a flexible informatics systems-based approach used to support research studies, including clinical trials. Critical components of REDCap include but are not limited to: 1) user authentication and role-based security; 2) intuitive electronic case report forms; 3) real-time data validation, integrity checks and other mechanisms for ensuring data quality (e.g. double-data entry options); 4) data attribution and audit capabilities; 5) protocol document storage and sharing; and 6) central data storage and backups. The graphical view and stats tool allows the user to look at numerical and categorical variables to determine the amount and frequency of missing questionnaire data. The report builder tool serves as a search engine to conduct database queries, which can be used to track attrition rates. The documents linking study identification number to

PHI will be kept on a secure, password-protected server that only the RA/study coordinator and PI can access. Data will be transmitted between the PI and the project biostatistician by copying files directly from one computer to another; email will not be used to transmit data. All computerized data will be kept on password protected computers. Audiotaped data will be stored on a secure, password protected server at UNC-CH. At the end of the award period, the electronic files will be destroyed.

11 RECRUITMENT STRATEGY

11.1 CONSENT PROCESS

Recruitment will be completed by the Study Coordinator or other approved study personnel. Screening to determine eligibility to participate will take place via telephone or in a private location within the clinic. An IRB-approved eligibility form will be used by the RA. The informed consent process will occur in a private location within the clinic.

Potential participants will be given a description of the study in a clear, concise manner and given time to ask questions and have their questions answered by study personnel. Consent will be obtained immediately after the initial consent discussion; and will be obtained directly from the participant. An unsigned hard copy of consent documents (Consent, HIPAA) will be given to each participant for their records. This document will contain contact information for the study coordinator and the PI.

Potential participants (both patient and visit companion) will be given the choice of either reading the consent on their own, or having the consent read to them. If the consent form is read to the participant, the signature page will indicate that the consent was read to the participant. The consent form will describe the study including the potential risks and benefits and will explicitly state that if participants choose not to participate; their medical care at UNC will not be impacted in any way. In addition to the consent form, the HF patient will read a HIPAA authorization form. The patient will be informed that if they choose not to sign the HIPAA authorization form then they may not participate in the study. This information will also be on the written consent form.

The HF patient and the family member will have similar, but separate consent forms. Both the HF patient and the family member will be asked to consent to be audio-taped. The consent form for the family member will state that if s/he is a patient of the health care provider at UNC Hospitals, we will not access their protected health information (PHI) and thus, will not require patient authorization. Potential participants will be allowed to ask questions and have the answers, and the consent forms will then be signed. During this entire process, the PI will be available by pager or cell phone for questions. Copies of all consent documents will be given to participants.

We will also consent select health care providers who see patients at the Cardiology clinic at Meadowmont. Most, if not all, of these providers are individuals who consented and participated in the PI's previous study. The health care providers will be approached by the PI or Co-I (Dr. Chang) either in person or via email, informed of the study, and asked to participate. The informed consent process will occur in a private location within the Cardiology clinic. An IRB-approved written consent form will be given to the health care provider to read while the RA explains the form to them. The consent form for the health care provider will state that taking part in this research is not a part of their University duties as an employee, and refusing will not affect their employment at UNC-CH. In addition, the consent form will also state that the health care provider will not be offered or receive any special job-related consideration if they choose to take part in

this research. Potential participants will be allowed to ask questions and have them answered, and the consent forms will then be signed. During this entire process, the PI will be available by pager or cell phone for questions. Copies of all consent documents will be given to participants.

All consent forms will be designed to be read at the 5th grade level. They will describe the study, its potential benefits and risks, and indicate that participation is strictly voluntary and that participants may stop at any time.

12 PLANS FOR PUBLICATION

We plan to publish 2 papers from this clinical. One paper will present the main study findings for the primary and secondary outcomes. The other study will describe findings from comparing audiotape data (actual questions asked during the visit) as compared to questions patients and companions indicated on the prompt list that they wanted to ask during the visit.

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15 APPENDIX: None