

Primary Palliative Care in Heart Failure: A Pilot Trial

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University of Pittsburgh

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: Integrating Supportive Care in Heart Failure: A Pilot Study

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SOURCE OF SUPPORT: National Institutes of Health

We are conducting a research study to understand whether providing supportive care consultation to patients with advanced Heart Failure (HF) is beneficial. Supportive care (also known as palliative care) is specialized medical care for people living with serious illness. It focuses on providing relief from the symptoms and stress of a serious illness. The goal of supportive care is to improve quality of life for both patients and their families. Supportive care is provided in addition to patients' existing healthcare, as an extra layer of care. It is considered to be experimental because it has not yet been proven in large clinical studies to be effective in improving outcomes for patients with HF. However, studies have shown its benefits in other illnesses, like cancer and cystic fibrosis.

Who will be invited to participate?

We are inviting you, along with approximately 29 other people who have HF, to help us learn more about the potential benefits of supportive care involvement with patients who have HF.

What happens if I agree to participate in this study?

If you are eligible for the study, we will randomly assign you to one of two groups: 1) Supportive Care, or 2) Usual Care.

You will have a 2:1 chance of being assigned to the supportive care intervention or to receive usual care. No clinician or research staff member can determine whether you will receive supportive care or care as usual before assignment; it is made randomly by a computer program.

If you are assigned to the **Usual Care** group, you will continue to receive your usual Heart Failure care, as well as any additional services that you or your doctors feel that you need. Nothing will change about the care that you receive. The only study activities you will participate in are assessments completed on a tablet computer, over phone, or via email every 8 weeks for 56 weeks, for a total of 7 assessments.

- Even though you are assigned to the Usual Care group, you are not prohibited from receiving a supportive care consult at any time. If you or your physician feels a supportive care consult would be beneficial, you will remain in the study as a participant in the control group; we will ask that you continue to participate in the study as before, completing the same questionnaires.

If you are assigned to the **Supportive Care** group, you will continue to receive your usual HF care. In addition, you will receive the supportive care intervention which consists of the following:

- Completing baseline assessments, so that we have a good idea about your current health.
- Agenda-setting questions, which will give the intervention nurse a rough outline of what needs to be discussed with you.
- An initial visit with a member of the nursing staff who will deliver the intervention. This visit will take between 30-60 minutes on average and will be at UPMC McKeesport. During this visit, the nurse will ask you about your illness, any symptoms you might be having, your overall physical and emotional well-being, and any difficult decisions you might be considering about your healthcare. You and the nurse will make plans together as to how to manage any issues that might be identified.
- Follow-up visits with the supportive care clinician will occur at least every three months. These visits will occur when you come to UPMC McKeesport for your normal clinic visits. Supportive care visits may occur more frequently if you and the intervention nurse feel that this is beneficial and/or necessary for your care. If you are hospitalized, the supportive care nurse may be consulted by the cardiology team to assist in your care.

- A follow-up via in person, phone, or email, during which a new round of assessments will be completed. This will take place every 8 weeks for 56 weeks, for 7 assessments total. They will be similar to the baseline assessments.
- Phone calls from the intervention nurse in order to monitor your status and receive any updates regarding your health.

All intervention visits as well as any assessments conducted over phone will be audio recorded for quality assurance. We are also requesting your permission to review your medical records. We will use this information to determine if you meet the condition for participation in this study, and to monitor your medical records to track healthcare utilization and expenditures for the duration of the study. No blood samples, x-rays, or other diagnostic tests will be taken or performed as part of this study. You may receive these tests as part of your routine medical care at the judgment of you and your clinician. This authorization is valid for an indefinite period of time. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing.

What information will be reviewed in my medical records?

- Healthcare utilization
- Test results related to your heart failure
- Demographic information

Participants in the supportive care intervention arm should also be aware that as part of this research study, information that we obtain from you may be placed into your medical records held at UPMC Hospitals, such as your responses to questionnaires about your symptoms and the results of relevant medical tests. Any information that is entered into your medical records will be available to you, in accordance with the UPMC Notice of Privacy Practices.

How long will participation last?

We anticipate that you will be actively participating in the study for one year. It will take 9 months to complete the 4 intervention visits, and we will monitor your medical records and conduct the assessments for 3 additional months. You may be removed from the study if any of the following occur:

- You or your clinicians decide the study is no longer in your best interest
- You are not able to follow all the study-related instructions
- The study is stopped

What are the risks involved with this study?

- The completion of interviews, questionnaires and discussion of personal problems can occasionally be stressful, uncomfortable or embarrassing to some people. Our staff is highly trained in the administration of these measures; you are not obligated to answer any questions or perform any tasks that make you uncomfortable.
- You may feel uncomfortable discussing symptoms of anxiety, depression, and/or pain with your doctor. All discussions with a doctor or staff completing the study are kept confidential and will not be shared with anyone outside of the study without your permission.
- The privacy of your information is very important to all of the researchers. However, there is always a risk that it could be accidentally disclosed. We will take every precaution possible to protect your confidentiality.

Will I ever be contacted by the research team for reasons unrelated to study visits?

Yes, if we learn of any new information about study risks that could cause you to change your mind about continuing to participate, we will notify you promptly.

Are there any direct benefits to participating in this study?

You may not receive any direct benefit from participation in this research study. The results of your screening tests will be shared with you and your doctor unless you state otherwise. It is possible that participating in the study may help to reduce your symptoms, but there is no guarantee of that benefit.

Will I ever receive a bill for study procedures?

None of the procedures you receive during this research study will be billed to you or your health insurance. If you get a bill or believe your health insurance has been billed for something that is part of the study, notify a member of the research team. Any evaluations or drug treatments that are not part of this study will be your responsibility. This can be described better by Dr. Kavalieratos, Dr. Arnold or other members of the research team.

Will I be compensated for participating in this study?

Yes, you will be compensated with \$10 for completing the surveys at study entry and at each 8-week assessment. Over the course of one year, you will be asked to complete 7 sets of surveys. If you complete all 7 sets of surveys, you will receive a \$30 bonus, for a total possible compensation of \$100. Compensation will be disbursed via the University of Pittsburgh's WePay system.

Who should I call if I believe I am injured as a result of the study?

If you believe that the research procedures have resulted in an injury to you, immediately contact Dr. Kavalieratos or Dr. Arnold at the numbers listed on the first page. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

How will the study team protect my privacy and maintain my confidentiality?

To protect your privacy and maintain the confidentiality of information we obtain from you and from your medical records, we will keep all information about you in a secure location. All paper records that could identify you will be stored in locked file cabinets, and all electronic records (including audio recordings) will be stored in password-protected files. Your identity on these records will be indicated by a case number rather than by your name, and the code linking your name to this number will be maintained separately with very limited access to research team members. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-

funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Will other people have access to my study information?

It is possible that we may use the information obtained from this study in other research studies examining the treatment of Heart Failure or the impact of supportive care. This information may also be shared with other researchers here and at other research centers. In those instances, your identity will be concealed by using the case number previously mentioned.

Although we will do everything in our power to protect your privacy and the confidentiality of your records, just as with the use of your medical information for health care purposes, we cannot guarantee the confidentiality of your research records, including information that we obtained from your medical records.

Individuals may have access to your identifiable information in three instances:

- First, staff at UMPC Shadyside Hospital and UPMC Presbyterian Hospital will have access to your identifiable information related to the laboratory or diagnostic procedures.
- Second, authorized representatives UPMC Shadyside Hospital and UPMC Presbyterian Hospital may have access to identifiable information only for handling internal hospital operations.
- Third, authorized representatives of the National Institutes of Health, and the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable information for monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release your identifiable research information (which may include your identifiable medical record information) in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.

Am I under any obligation to participate in this research study?

No – your participation in this study is entirely voluntary. If you choose to not participate in this study, you will continue to receive your usual healthcare as you do now.

If you choose to participate in the study and then change your mind, you can withdraw at any time, and you can skip any questions or procedures that you do not want to complete.

Your doctor may be an investigator in this research study, and as both your doctor and a research investigator, s/he is interested both in your medical care and in the conduct of this research. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is in no way associated with this research project. You are not under any obligation to participate in any research study offered by your doctor.

If you decide you no longer wish to continue to participate after you have signed the consent form, you should contact Dr. Kavalieratos (412-246-6929) or the Study Coordinator (412-692-

2747). You may also withdraw, at any time, your authorization to allow the research team to review your medical records, but if you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will, however, continue to be used by the research team. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh or with UPMC or its affiliate health care and insurance operations.

VOLUNTARY CONSENT:

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified member of the research team or by Dr. Kavalieratos (412-246-6929) or Dr. Arnold (412-692-4810). I understand that I may always request that my questions, concerns or complaints be addressed to Dr. Kavalieratos or Dr. Arnold. At any time I may also contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. **By signing this form I agree to participate in this research study, and allow the use and disclosure of my medical record information for the purposes described above.** A copy of this consent form will be given to me.

Printed Name of Participant

Participant's Signature

Date

CERTIFICATION OF INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Study

Signature of Person Obtaining Consent

Date