Key Information for:

Family Palliative and End-of-Life Care for Advanced Heart Failure

You are being asked to participate in the research described below. This page provides key information that may help you to make this decision; more detailed information can be found after this section.

Why is this research being done and what is involved?

This research study tests to see if our coaching intervention for heart failure (HF) patients and theirfamily caregivers helps them manage worsening HF symptoms and assists with advanced HF home care. Nurses lead the in-person coaching sessions and follow-up per telephone with the patients and families.

This study will last approximately 6 months. At the beginning of the study, you and your family member will berandomly placed into one of two groups. You will receive an information letter that tells you what group you are inand a short questionnaire that you will complete at the start of the study and at 6 months.

Do I have to participate and what are the risks involved?

Participation in this research study is completely voluntary and you are free to withdraw from the research at any time. If you do not wish to participate, please discuss alternatives with the researcher or refer to the "Alternatives" section in the consent form. You may or may not benefit from this study. You, your family, and health professionals will be more aware of advance directives and HF-related palliative and end-of-life care options.

Risks from participation in this study include feeling stress or anxiety when talking about your chronic illness. The discussion may trigger someworries about worsening HF or unpleasant memories that you may feel uncomfortable discussing. If you feel ill,tired, upset, or are concerned about the privacy of your answers you can stop at any time.

Who can I talk to if I have questions or concerns?

If you have any questions or concerns about this research or would want to withdrawal from the study, you can contact Dr. Ubolrat Piamjariyakul or Dr. Trisha Petitte at 304-203-1084 from the School of Nursing at West Virginia University.

Informed Consent for Research | Minimal Risk
Family Member Consent Information and HIPPA Form

Principal Investigator (PI) |	Ubolrat Piamjariyakul, PhD, RN
Department |	School of Nursing, Health Sciences Center
Co-Investigator(s) |	Trisha Petitte, PhD, MSN, APRN, FNP-BC
Sponsor or Funding Source |	National Institutes of Health
WVU IRB Protocol # |	1709754988
Study Title |	Family Palliative and End-of-Life Care for Advanced Heart Failure

Introduction

You have been asked to participate in this research study, which has been explained to you by an authorized member of the research team. This study is being conducted by Ubolrat Piamjariyakul, PhD, RN in the School of Nursing at West Virginia University, along with Trisha Petitte, PhD, MSN, APRN, FNP-BC; Elizabeth Morrissey, RN, BSN; Angel Smothers, DNP, FNP-BC, CHPN and Joeli Olson, RRT, CPFT. Funding for this research is provided by the National Institutes of Health.

Purpose

The purpose of this study is to tests to see if our coaching intervention for heart failure (HF) patients and their family caregivers helps them manage worsening HF symptoms and assists with advanced HF home care. Nurses lead the in-person coaching sessions and follow-up per telephone with the patients and family.

WVU expects to enroll approximately 72 subjects (36 patients and 36 caregivers). A total of approximately 72 subjects, at all sites, are expected to participate in this study.

Description of Procedures

This study will last approximately 6 months. At the beginning of the study, you and your family member will be randomly placed into one of two groups. You will receive an information letter that tells you what group you are in and a short questionnaire that you will complete at the start of the study and at 6 months.

Group One: You will participate in a study looking at coaching to improve HF home care with end-of-life and palliative care options. An experienced nurse will lead you in 5 weekly coaching sessions. Each session will last approximately 30-45 minutes. We will schedule this session at your convenience. During coaching sessions, the nurse will review a pamphlet with you that illustrates how chronic illness can progress, including an explanationof worsening symptoms, care management options, and other educational materials. You will receive this pamphlet and educational materials one week after joining this study. We will also discuss information about advance directives. If you are interested in completing an advance directive form, we will assist you in the process, including adding the form to your medical record, and with your permission submitting it to the statewide *e*-

Directive Registry and providing copies to family members. We will make follow-up calls at 3 and 6 months after our initial discussion session to answer any questions or concerns your family may have and emphasize selecting care options. We will ask for your feedback on the coaching discussion and complete a short questionnaire, which will take about 20-30 minutes.

Group 2: You will continue to receive routine care for your HF through your primary care provider. We will contact you by phone to complete a short questionnaire at the beginning of the study and at 3- and 6- months, ata time convenient to you. Completion of the questionnaire will take approximately 20-30 minutes.

Risks and Discomforts

You may feel stress or anxiety when talking about your chronic illness. The discussion may trigger someworries about worsening HF or unpleasant memories that you may feel uncomfortable discussing. If you feel ill,tired, upset, or are concerned about the privacy of your answers you can stop at any time. In addition, there is always the risk of uncommon or previously unknown side effect(s) or event.

Alternatives

You do not have to participate in this study.

Benefits

You may or may not directly benefit from participating in this research. However, you, your family, and health professionals will be more aware of advance directives and HF-related palliative and end-of-life care options. The knowledge gained from this study may eventually benefit others.

Financial Considerations

You will be compensated with a $25 gift card at the beginning of the study and a $25 gift card at the end of the study. You can earn a total of $50 if you complete the study. If you do not complete the study, you will only be compensated $25 at the beginning of the study. For information regarding the method of payment, contact the Principal Investigator.

Your information may be provided to the appropriate parties for billing and/or payment purposes. Please be advised that any compensation received for participation in a research study, including a gift card, is considered taxable income and must be reported to the Internal Revenue Service (IRS).

Your data, health information, research results or any and all other information related to this research study used in this research study may contribute to a new discovery or treatment. In some instances, your data, your health information, your research results, your specimens, these discoveries or treatments, or any other information related to this research study, even if identifiers are removed, may be of commercial value and may be sold, patented, or licensed by the investigators and West Virginia University for use in other research or the development of new products. You will not retain any property rights nor will you share in any money or commercial profit that the investigators, West Virginia University, or their agents may realize.

Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities without your additional consent.

In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to you or to others, such as suicide, child abuse, etc.

Audiotapes or videotapes will be kept locked up and will be destroyed as soon as possible after the research is finished.

In any publications that result from this research, neither your name nor any information from which you might be identified will be published without your consent.

ClinicalTrials.gov

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

HIPAA Authorization

We know that information about your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Persons/Organizations Providing the Information

Patients, caregivers and West Virginia University Hospitals

Persons/Organizations Receiving the Information

- The research site(s) carrying out this study. This includes UHA or UHA Affiliates, WVU, WVU Hospitals, West Virginia University Health System (WVUHS). It also includes each site's research and medical staff.
- Health care providers who provide services to you as part of this research study.
- Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol.
- The United States Department of Health and Human Services' National Institutes of Health (NIH).
- The members and staff of any institutional review board that oversees this research study.
- The West Virginia University Office of Human Research Protection and the West Virginia University Office of Sponsored Programs.
- The WVU School of Nursing.

The Following Information Will Be Used

Information from your existing medical records, and new information about you that is created or collected during this study, such as: history and physicals, clinic visit notes, nursing and staff notes, demographic data, cardiovascular tests, advance directives, medical orders (DNR and POST), state e-Directive Registry, address, and telephone number.

The Information is Being Disclosed for the Following Reasons

(1) Publication of study results (without identifying you).

(2) Other research purposes such as evaluating the effects of coaching on HF home care and palliative and end-of-life care discussions; developing a better understanding of disease; improving the design of future clinical trials.

You may Cancel this Authorization at Any Time by Writing to the Principal Investigator

Dr. Ubolrat Piamjariyakul, PhD, RN
West Virginia University School of Nursing
PO Box 9600, Health Sciences Center
Morgantown, WV 26506-9600

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may re-disclose it and then the information may no longer be protected by federal regulations.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until the sponsor has completed all work related to the study. At that time, you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is wrong.

This authorization will expire at the end of the study unless you cancel it before that time.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time. You may terminate your participation in this study by informing the Principal Investigator in writing. If you choose to withdraw your participation from the study, the data collected on you up until that time remains a part of the study database and may not be removed. No additional information will be added to the study database after your withdrawal. Refusal to participate or withdraw will not affect your future care or status at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

Contact Persons

If you have any questions, concerns, or complaints about this research, you can contact Trisha Petitte, PhD, MSN, APRN, FNP-BC or Angel Smothers, DNP, FNP-BC, CHPN between 8:15 am and 4:45 pm at (304) 293-1084.

If you are hurt from being in this research, you should contact Ubolrat Piamjariyakul, PhD, RN at (304) 293-0761.

For information regarding your rights as a participant in research or to talk about the research, contact the WVU Office of Human Research Protection (OHRP) at (304) 293-7073 or by email at IRB@mail.wvu.edu.

Signatures and Authorization

You have been given the opportunity to ask questions about the research and your authorization of HIPAA, and you have received answers concerning areas you did not understand. Upon signing this form, you will receive a copy.

Participant Signature

I willingly consent to participate in this research.

Signature of Subject or Subject's Legal Representative

Printed Name Date

Consenting Individual Signature

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Person Obtaining Informed Consent

Printed Name Date