Randomized Trial of ENABLE CHF-PC for Heart Failure Patients & Caregivers
(Comprehensive Heartcare For Patients and Caregivers)

Informed Consent Forms - Patient & Caregiver
Site Specific: UAB-last approved version
NCT02505425

February 5, 2018

Marie Bakitas, DNSc, NP-C, FAAN,
Principal Investigator
University of Alabama at Birmingham
Birmingham, AL 35294

PATIENT CONSENT FORM

TITLE OF RESEARCH: Randomized Trial of ENABLE CHF-PC for Heart Failure Patients and Caregivers.

IRB PROTOCOL NO.: X140813007

INVESTIGATOR: Marie Bakitas, DNSc, CRNP

SPONSOR: National Institutes of Health/National Institute of Nursing Research

Purpose of the Research

You are being asked to take part in a research study. Taking part in research is voluntary.

You are being asked to take part in this study because you have been diagnosed with a condition known as heart failure. Your decision whether or not to take part will have no effect on the quality of your medical care. Please ask questions if there is anything about this study you do not understand. You may discontinue your participation in the study in general or in any portion of the intervention phone calls or questionnaires at any time.

The purpose of this study is to learn how to improve supportive care for patients and caregivers as they live with heart failure. We have developed a phone-based, educational program to help patients and their caregivers have a better quality of life and mood and lower symptom burden, in addition to the care services that you currently receive at UAB. The goal of this study is to determine if this additional education program improves patient and caregiver outcomes. Nearly 1,000 patients with cancer and their caregivers have experienced this type of care; however, this approach is relatively new for patients with heart failure.

We expect 210 patients with 210 caregivers at UAB to enroll. Half of the participants in this study will have access to these additional services and half of participants in this study will have access to supportive services that are currently available at UAB.

Explanation of Procedures

Your participation in this study may last up to 48 weeks. If you decide to enroll into this research study, you will be assigned by chance (like the flip of a coin) by a computer to one of two groups (either Group A or Group B). Neither you nor your doctor can control into which group you will be assigned.

Group A - receives the normal standard of heart failure and supportive care that you would receive if you did not enroll in this study, including access to palliative care, social work, pastoral, and financial planning services.

Also you will be asked to complete questionnaires (at the beginning and at weeks 8, 16, 24, 32, 40, and 48) about your symptoms, quality of life and mood, and quality of your medical care.

Group B - receives additional supportive services, which includes two components: One In- person comprehensive Palliative Care Team (PCT) Consultation by a palliative care team member with special training in supportive care, as soon as feasible after enrollment, performed at UAB and telephone sessions with a Nurse Coach (NC) who will cover materials found in a guidebook called *Charting Your Course* (CYC) that you will receive. These calls will be scheduled at a day/time that is convenient for you. Also you will be asked to complete questionnaires (at the beginning and at weeks 8, 16, 24, 32, 40, and 48) about your symptoms, quality of life and mood, and the quality of your medical care.

Timeline:

When	Type of meeting	Description/Topics	Group A	Group B	Approx. Duration
Today	In-person	1) Sign consent 2) Eligibility screening 3) First set of quality of life questionnaires	x	x	1 hour
Ongoing	Ongoing	Normal standard of heart failure management support	x	x	
As soon as	In-person	In-clinic palliative care team assessment		x	1 hour
Week 1	Phone	*Charting Your Course 1* (CYC) Session		x	45 min.
Week 2	Phone	*CYC 2:* Self-care management		x	45 min.
Week 3	Phone	*CYC* 3 Assessing, Prioritizing, and Managing Symptoms		x	45 min.
Week 4	Phone	*CYC 4:* Communication skills, decision-making, and advanced care planning		x	45 min.
Week 5	Phone	*CYC 5:* Discussion and supportive counseling		x	30 min.
Week 6	Phone	*CYC 6:* Discussion and supportive counseling		x	30 min.
Once per month	Phone	Your nurse coach will check-in with you monthly to follow-up		x	15 min.
Weeks 8 to 48	Phone	Quality of life questionnaires	x	x	25-45 min.

Risks and Discomforts

You may become distressed, short of breath, or fatigued when reflecting on your symptoms, mood, and quality of life during the questionnaires or the educational sessions

with the nurse coach. If you become distressed, you can discuss this with your nurse coach or we can refer you to a counselor. You are also free to stop or pause any session at any time and reschedule should you not feel well or become fatigued during a call. In our experience of providing supportive care interventions, the risks of these occurrences are quite low.

There is a chance that people not associated with the study will see your answers to questionnaires and your medical record information. Your name and other identifying information will be removed from study documents. Data will be kept in locked files in the study research offices at UAB. Participant data will be housed in a secure, password protected REDCap database at UAB.

There is a risk related to being placed into a group by chance (randomization, like the flip of a coin). Participants placed in the intervention group may receive benefits associated with the extra support activity. The normal standard of heart failure care group may not have the same benefits as the intervention group. Participants in the intervention group may be more burdened by having to participate in extra intervention activities.

Benefits

You may not personally benefit from being in this research study. We hope to gather information that may help us to provide better care to people in the future.

Alternatives

If you decide not to enroll in this study, you will receive the normal standard of supportive heart failure care that is usually provided at UAB.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the National Institutes for Health, National Institute of Nursing Research Staff, and the Office for Human Research Protections (OHRP). The results of the study may be published for scientific purposes. However, your identity will not be given out.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

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.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may skip any questions in the questionnaire sessions you do not wish to answer. You are also free to stop or pause any session at any time and reschedule should you not feel well or become fatigued during a call. Calls are scheduled with you ahead of time for times between 8:00AM and 5:00PM, Monday through Friday or when convenient for you.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There are no fees charged to you for taking part in this study.

Participants using a cell phone for calls related to this study will be responsible for their own cell phone plan charges. The table with the Timeline on page 2 lists the estimated amount of time for phone calls in this study.

The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

Payment for Participation in Research

You will be provided with $10 for each of 7 data collection interviews (at baseline, weeks 8, 16, 24, 32, 40, and week 48). Separate $10 payments will be mailed to you after completion of each data collection interview. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit). If you do not finish the entire study, you will be paid at the time you decide to stop taking part in the study. If you complete the entire study, you will receive a total of $70.

Significant New Findings

You will be told by your doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research including available treatments, you may contact Dr. Marie Bakitas. She will be glad to answer any of your questions. Dr. Bakitas' number is 205-934-5277. Dr. Bakitas may also be reached after hours by calling 603-398-7766.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at 205-934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00AM to 5:00PM CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates you that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

_____

Signature of Person Obtaining Consent Date

Reviewed by:

_____

Signature of Principal Investigator Reviewing Consent Document Date

University of Alabama at Birmingham

AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____ **UAB IRB Protocol Number:** X140813007

Research Protocol: Randomized Trial of ENABLE CHF- PC for Heart Failure Patients and Caregivers. **Principal Investigator:** Marie Bakitas. DNSc. CRNP

Sponsor: NIH/National Institute of Nursing Research

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____

or participant's legally authorized representative: _____ Date: _____

Printed Name of participant's representative: _____

Relationship to the participant: _____

CAREGIVER CONSENT FORM

TITLE OF RESEARCH: Randomized Trial of ENABLE CHF-PC for Heart Failure Patients and Caregivers.

IRB PROTOCOL NO.: X140813007

INVESTIGATOR: Marie Bakitas, DNSc, CRNP

SPONSOR: National Institutes of Health/National Institute of Nursing Research

Purpose of the Research

You are being asked to take part in a research study. Taking part in research is voluntary.

You are being asked to take part in this study because you provide care for someone who has been diagnosed with a condition known as heart failure. Please ask questions if there is anything about this study you do not understand.

The purpose of this study is to learn how to improve supportive care for patients and caregivers as they live with heart failure. We have developed a phone-based, educational program to help patients and their caregivers have a better quality of life and mood and lower symptom burden, in addition to the care services that you currently receive at UAB. The goal of this study is to determine if this additional education program improves patient and caregiver outcomes. Nearly 1,000 patients with cancer and their caregivers have experienced this type of care; however, this approach is relatively new for patients with heart failure.

We expect 210 patients with 210 caregivers at UAB to enroll. Half of the participants in this study will have access to these additional services and half of participants in this study will have access to supportive services that are currently available at UAB.

Explanation of Procedures

Your participation in this study may last up to 48 weeks. If you decide to enroll into this research study, the patient will be assigned by chance (like the flip of a coin) by a computer to one of two groups (either Group A or Group B). Neither you nor the patient's doctor can control into which group you will be assigned.

Group A - receives the normal standard of heart failure and supportive care that would be provided to a caregiver if you did not enroll in this study, including access to palliative care, social work, pastoral, and financial planning services.

Also you will be asked to complete questionnaires (at the beginning and at weeks 8, 16, 24, 32, 40, and 48) about your symptoms, quality of life and mood.

Group B - receives additional supportive services, which includes two components: One In- person comprehensive Palliative Care Team (PCT) Consultation by a palliative care team member with special training in supportive care, as soon as feasible after enrollment, performed at UAB and telephone sessions with a Nurse Coach (NC) who will cover materials found in a guidebook called *Charting Your Course* (CYC) that you will receive. These calls will be scheduled at a day/time that is convenient for you.

Also you will be asked to complete questionnaires (at the beginning and at weeks 8, 16, 24, 32, 40, and 48) about your symptoms, quality of life and mood, and the quality of your medical care.

Timeline:

When	Type of meetin	Description/Topics	Group A	Group B	Approx. Duration
Today	In-person	1) Sign consent 2) Eligibility screening 3) First set of quality of life questionnaires	x	x	1 hour
Ongoing	Ongoing	Normal standard of heart failure management support	x	x	
As soon as feasible	In-person	In-clinic palliative care team assessment (patients only unless they wish for you to be present)		x	1 hour
Week 1	Phone	*Charting Your Course* (CYC) Session 1 Caregiver role and		x	45 min.
Week 2	Phone	*CYC 2:* Caregiver Self-care		x	45 min.
Week 3	Phone	*CYC* 3 Being a partner in symptom management		x	45 min.
Week 4	Phone	*CYC 4:* Communication, support, and decision-making.		x	45 min.
Once per month	Phone	Your nurse coach will check-in with you monthly to follow-up		x	15 min.
Weeks 8 to 48	Phone	Quality of life questionnaires	x	x	25-45 min.

Risks and Discomforts

You may become sad or upset after reflecting on the care you provide the person with heart failure during the questionnaires or the educational sessions with the nurse coach. In our experience of providing supportive care interventions, the risks of these occurrences is quite low. If you become distressed you can discuss this with your nurse coach or we can refer you to a counselor.

There is a chance that people not associated with the study will see your answers to questionnaires and your medical record information. Your name and other identifying information will be removed from study documents. Data will be kept in locked files in the study research offices at UAB. Participant data will be housed in a secure, password protected REDCap database at UAB.

There is a risk related to being placed into a group by chance (randomization, like the flip of a coin). Participants placed in the intervention group may receive benefits associated with the extra support activity. The normal standard of heart failure care group may not have the same benefits as the intervention group. Participants in the intervention group may be more burdened by having to participate in extra intervention activities.

Benefits

You may not personally benefit from being in this research study. We hope to gather information that may help us to provide better care to people in the future.

Alternatives

If you decide not to enroll in this study, you and the individual for whom you provide care will receive the normal standard of heart failure supportive care that is usually provided at UAB.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the National Institutes for Health, National Institute of Nursing Research Staff, and the Office for Human Research Protections (OHRP). The results of the study may be published for scientific purposes. However, your identity will not be given out.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

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.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may skip any questions in the questionnaire sessions you do not wish to answer. You are also free to stop or pause any session at any time and reschedule should you not feel well or become fatigued during a call. Calls are scheduled with you ahead of time for times between 8:00AM and 5:00PM, Monday through Friday or when convenient for you.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There are no fees charged to you for taking part in this study.

Participants using a cell phone for calls related to this study will be responsible for their own cell phone plan charges. The table with the Timeline on page 2 lists the estimated amount of time for phone calls in this study.

Payment for Participation in Research

You will be provided with $10 for each of 7 data collection interviews (at baseline, weeks 8, 16, 24, 32, 40, and week 48). Separate $10 payments will be mailed to you after completion of each data collection interview. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit). If you do not finish the entire study, you will be paid at the time you decide to stop taking part in the study. If you complete the entire study, you will receive a total of $70.

Significant New Findings

You will be told by your doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research including available treatments, you may contact Dr. Marie Bakitas. She will be glad to answer any of your questions. Dr. Bakitas' number is 205-934-5277. Dr. Bakitas may also be reached after hours by calling 603-398-7766.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at 205-934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00AM to 5:00PM CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates you that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant Date

Signature of Person Obtaining Consent Date

Reviewed by:

Signature of Principal Investigator Reviewing Consent Document Date

University of Alabama at Birmingham

AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____ **UAB IRB Protocol Number:** **X140813007**

Research Protocol: Randomized Trial of ENABLE CHF- PC for Heart Failure Patients and Caregivers. **Principal Investigator:** **Marie Bakitas. DNSc. CRNP**

Sponsor: **NIH/National Institute of Nursing Research**

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____

or participant's legally authorized representative: _____ Date: _____

Printed Name of participant's representative: _____

Relationship to the participant: _____

Randomized Trial of ENABLE CHF-PC for Heart Failure Patients & Caregivers
(Comprehensive Heartcare For Patients and Caregivers)

Informed Consent Forms - Patient & Caregiver
Site Specific: VA-last approved version
NCT02505425

October 24, 2017

Marie Bakitas, DNSc, NP-C, FAAN,
Principal Investigator
University of Alabama at Birmingham
Birmingham, AL 35294

Department of Veterans Affairs

VA RESEARCH CONSENT FORM
PATIENT CONSENT

Subject Name _____ **Date** _____

Title of Study Randomized Trial of ENABLE CHF-PC for Heart Failure Patients and Caregivers.

Principal Investigator Kathryn L. Burgio, PhD **VAMC** Birmingham (521)

Sponsor
This research is being sponsored by the National Institutes of Health, National Institute of Nursing Research, University of Alabama at Birmingham School of Nursing and Birmingham VA Medical Center (BVAMC). If you decide to participate you will be asked to participate in telephone assessments as well as possible phone consultations for supportive care that may not normally be required for treatment of your condition. These assessments will be paid for with money provided by the sponsor. Any money remaining at the end of the project will be used by Kathryn L. Burgio, PhD to pay other research expenses.

Introduction and Purpose

You are being asked to take part in a research study. Taking part in research is voluntary.

You are being asked to take part in this study, entitled "ENABLE CHF-PC: Comprehensive Heartcare For Patients and Caregivers," because you have been diagnosed with a condition known as heart failure. Your decision whether or not to take part will have no effect on the quality of your medical care. The purpose of this study is to improve care for patients and caregivers as they live with heart failure. We have developed a telephone-based, supportive care program to help patients and their caregivers have a better quality of life and mood and lower symptom burden, in addition to the care that you currently receive at the BVAMC. The goal of this study is to determine if this additional supportive care program improves patient and caregiver outcomes. Nearly 1,000 patients with cancer and their caregivers have experienced this type of care; however, this approach is relatively new for patients with heart failure.

We expect 190 patients with 190 caregivers at the Birmingham VA Medical Center to enroll. Half of the participants in this study will have access to these additional services and half of participants will have access to supportive services that are currently available at BVAMC.

Procedures
You are being asked to take part in a research study which may last up to 48 weeks (12 months). If you decide to enroll into this study, you will be assigned by chance (like the flip of a coin) by a computer to one of two groups (either Group A or Group B). Neither you nor your doctor can control which group you will be assigned to.

If you are assigned to Group A (see table below), you will receive the usual heart failure and supportive care that you would receive if you did not enroll in this study, including access to palliative care, social work, pastoral care, and financial planning services. Also you will be asked to complete questionnaires about your symptoms, quality of life and mood, and quality of your medical care (at the beginning of the study and at weeks 8, 16, 24, 32, 40, and 48). We will review your medical record for information about your heart condition and its treatment.

VA - IRB
Approved 10-24-2017

Subject Name _____ **Date** _____

Title of Study Randomized Trial of ENABLE CHF-PC for Heart Failure Patients and Caregivers.

Principal Investigator Kathryn L. Burgio, PhD **VAMC** Birmingham (521)

Timeline for Group A

When	Type of meeting	Description/Topics	Approx. Duration
Today	In-person	1) Sign consent 2) Eligibility screening 3) First set of quality of life questionnaires	1 hr.
Ongoing	Ongoing	Normal standard heart failure management support	---
Weeks 8 to 48	Phone	Quality of life questionnaires	25-45 min.

If you are assigned to Group B, you will receive additional supportive services, which will include two care components:

1. One in-person comprehensive Palliative Care consultation at the Birmingham VA Medical Center performed by a palliative care team member with special training in supportive care, as soon as feasible after enrollment, and
2. Telephone sessions with an advanced practice nurse coach who will cover materials with you found in the *Charting Your Course* educational & support guidebook that you will receive. These calls will be scheduled at a time that is convenient for you (see below). These sessions will be digitally-recorded for quality assurance purposes.

Also you will be asked to complete questionnaires about your symptoms, quality of life and mood, and the quality of your medical care (at the beginning of the study and at weeks 8, 16, 24, 32, 40, and 48). We will review your medical record for information about your heart condition and its treatment.

Timeline for Group B

When	Type of meeting	Description/Topics	Approx. Duration
Today	In-person	1) Sign consent 2) Eligibility screening 3) First set of quality of life questionnaires	1 hr.
Ongoing	Ongoing	Normal standard heart failure management support	---
As soon as feasible	In-person	In-clinic palliative care assessment	1 hr.
Week 1	Phone	*Charting Your Course* (CYC) Session 1: Problem-solving	45 min.
Week 2	Phone	*CYC 2:* Self-care management	45 min.
Week 3	Phone	*CYC* 3 Assessing, Prioritizing, and Managing Symptoms	45 min.
Week 4	Phone	*CYC 4:* Communication skills, decision-making, and advance care planning	45 min.
Week 5	Phone	*CYC 5:* Discussion and supportive counseling	30 min.
Week 6	Phone	*CYC 6:* Discussion and supportive counseling	30 min.

VA - IRB
Approved 10-24-2017

Subject Name _____ **Date** _____

Title of Study Randomized Trial of ENABLE CHF-PC for Heart Failure Patients and Caregivers.

Principal Investigator Kathryn L. Burgio, PhD **VAMC** Birmingham (521)

When	Type of meeting	Description/Topics	Approx. Duration
Once per month	Phone	Your nurse coach will check-in with you monthly to follow-up	15 min.
Weeks 8 to 48	Phone	Quality of life questionnaires (every 8 weeks)	25-45 min.

Risks and Discomforts
There are two risks associated with study completion. First, you may become distressed, short of breath, or fatigued when reflecting on your symptoms, mood, and quality of life during the questionnaires or the supportive care sessions with the nurse coach. If you become distressed you can discuss this with a member of the study team. You are also free to stop or pause any session at any time and reschedule should you not feel well or become fatigued during a call. In our experience of providing palliative care interventions, this risk of these occurrences is quite low. The questionnaires and intervention also offer the opportunity to reflect upon strengths and resilience, and participants often express gratitude for the chance to respond to the surveys and share their experiences.

The second risk is the slight chance that people not associated with the project will see your answers to questionnaires. The study team will make every effort to maintain confidentiality of your data. Data will be kept in locked files in the study research office.

Benefits
You may or may not benefit personally from being in this research study. We hope to gather information that may help us to provide better care to people in the future.

Alternative Treatment
If you decide not to enroll in this study, you will receive the normal standard of supportive heart failure care that is usually provided at BVAMC.

Compensation/Payments
You will be provided with $10 for each of the data collection interviews (at the beginning and at weeks 8, 16, 24, 32, 40, and 48). Separate $10 checks will be mailed to you after completion of each data collection interview. The total possible compensation for participation is $70; $10 for each of the seven possible data collection interviews. Checks will be prepared by UAB and mailed to you at the address you provide. You will be asked to complete a 'Request for Taxpayer Identification Number and Certification' W-9 form.

Cost of Participation
There will be no cost to you for taking part in this study; however this study will not pay for the costs of your usual care. Some veterans are required to make co-payments for medical care and services provided by VA.

Subject Name _____ **Date** _____

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Principal Investigator Kathryn L. Burgio, PhD **VAMC** Birmingham (521)

These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

Research-Related Injury
You will be participating in a research project approved by the BVAMC Research and Development Committee and conducted under the supervision of one or more VA employees. If you are injured as a result of your participation as a research subject in this study, the VA medical facility will provide you with necessary medical treatment in accordance with Federal regulations. VA will not necessarily be responsible for treatment for injuries that result from noncompliance with study procedures, although veterans injured as a result of such participation may be eligible for care from VA under other statutory and regulatory provisions.

Any cost of care will be in accordance with your eligibility for care at VA. Care outside VA may not be free and VA may not pay for that care.

If you have any questions regarding this study please call Kathryn L. Burgio, PhD at (205) 558-7064. If you are injured or become ill as a result of participation in this study, please call Keith Swetz, MD at (205) 933-8101 ext. 5481 or Marie Bakitas, DNSc, NP-C, FAAN at (205) 934-5277 during the day. If you are unable to reach Marie Bakitas, DNSc, NP-C, FAAN or Dr. Swetz and need immediate medical assistance for a research-related injury, please call the VAMC Emergency Room at (205) 558-4725 to obtain advice.

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

Confidentiality
The study staff will treat your identity with professional standards of confidentiality. The information obtained in this study may be published, but your identity will not be revealed. The sponsors, NIH, NINR, UAB and BVAMC will only have limited access to research data. Your information will be released to UAB for the purposes of research and for payment.

VA personnel, the VA Institutional Review Board (IRB), and other federal oversight agencies reserve the right to inspect both the research data and your medical records. At the completion of the study, data will be stored or destroyed according to VA policy.

Subject Name _____ **Date** _____

Title of Study Randomized Trial of ENABLE CHF-PC for Heart Failure Patients and Caregivers.

Principal Investigator Kathryn L. Burgio, PhD **VAMC** Birmingham (521)

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

Voluntary Participation and Withdrawal
Participation in this study is voluntary and you may refuse to participate without penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw your consent and discontinue participation at any time. If you decide to withdraw from this study, you are asked to contact Kathryn L. Burgio, PhD at (205) 558-7064.
Discontinuation will in no way affect or jeopardize the quality of care you receive now or in the future at this institution or your opportunity to participate in other studies. The Principal Investigator may also withdraw you without your consent for medical or other reasons.

New Findings
Any significant new findings that develop during the course of the research study that in the opinion of the investigator may affect your willingness to continue to participate will be provided to you as soon as possible.

Questions
If you have any questions about the legitimacy of this study, your rights as a research participant, complaints/concerns about this research, or to discuss problems, obtain information and offer input; please contact the Research & Development Office and the staff will direct you to the appropriate person to handle your situation. The phone number for the Research & Development Office is (205) 558-4747.

If you have any questions, concerns, or complaints about the study, you may contact Kathryn L. Burgio, PhD. She will be glad to answer any of your questions. Dr. Burgio is available at (205) 558-7064.

Department of Veterans Affairs

VA RESEARCH CONSENT FORM
PATIENT CONSENT

Subject Name _____ **Date** _____

Title of Study Randomized Trial of ENABLE CHF-PC for Heart Failure Patients and Caregivers.

Principal Investigator Kathryn L. Burgio, PhD **VAMC** Birmingham (521)

You have read or have had read to you all of the above. Kathryn L. Burgio's designee has explained the study to you and answered all of your questions. You have been told of the risks or discomforts and possible benefits of the study. You were informed that voice recordings will be made during phones sessions with nurses for quality assurance purposes. You have been told of other choices of treatment available to you.

You understand that you do not have to take part in this study. Your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

The results of this study may be published, but your records will not be revealed unless required by law.

In case there are medical problems or questions, you have been told you can call Keith Swetz, MD at (205) 933-8101 ext. 5481 or Marie Bakitas, DNSc, NP-C, FAAN at (205) 934-5277 during the day. If you are unable to reach Marie Bakitas, DNSc, NP-C, FAAN or Dr. Swetz and need immediate medical assistance for a research-related injury, please call the VAMC Emergency Room at (205) 558-4725 to obtain advice.
If any medical problems occur in connection with this study, the VA will provide emergency care in accordance with your eligibility.

You understand your rights as a research subject and you voluntarily consent to participation in this study. You understand what the study is about and how and why it is being done. You will receive a signed copy of this consent form. **Please keep this form because it contains important phone numbers and other information.**

By signing and dating this informed consent, you are not waiving any of your legal rights.

		/ /
Participant's Name (printed)	Participant's Signature	Date (MM/DD/YYYY)
		/ /
Name of person conducting consent discussion (printed)	Signature of person conducting informed consent discussion	Date (MM/DD/YYYY)

ICD Version Template Date: 7/11/14
VA Form 10-1086

VA - IRB
Approved 10-24-2017

Department of Veterans Affairs

VA RESEARCH CONSENT FORM
CAREGIVER CONSENT

Subject Name _____ **Date** _____

Title of Study Randomized Trial of ENABLE CHF-PC for Heart Failure Patients and Caregivers.

Principal Investigator Kathryn L. Burgio, PhD **VAMC** Birmingham (521)

Sponsor
This research is being sponsored by the National Institutes of Health, National Institute of Nursing Research, University of Alabama at Birmingham School of Nursing and Birmingham VA Medical Center (BVAMC). If you decide to participate, you will be asked to participate in telephone assessments related to the care of your family member as well as possible phone consultations for supportive care that may not normally be required for usual caregiver care. These assessments will be paid for with money provided by the sponsor. Any money remaining at the end of the project will be used by Kathryn L. Burgio, PhD to pay other research expenses.

Introduction and Purpose
You are being asked to take part in a research study. Taking part in research is voluntary.

You are being asked to take part in this study, entitled "ENABLE CHF-PC: Comprehensive Heartcare For Patients and Caregivers," because you provide care for someone who has been diagnosed with a condition known as heart failure. Your decision whether or not to take part will have no effect on the quality of your family member's medical care. The purpose of this study is to improve care for patients and caregivers as they live with heart failure. We have developed a telephone-based, supportive care program to help patients and their caregivers have a better quality of life and mood and lower symptom burden, in addition to the care that you currently receive at the BVAMC. The goal of this study is to determine if this additional supportive care program improves patient and caregiver outcomes. Nearly 1,000 patients with cancer and their caregivers have experienced this type of care; however, this approach is relatively new for patients with heart failure.

We expect 190 patients with 190 caregivers at the Birmingham VA Medical Center to enroll. Half of the participants in this study will have access to these additional services and half of participants will have access to supportive services that are currently available at BVAMC.

Procedures
You are being asked to take part in a research study which may last up to 48 weeks (12 months). If you decide to enroll into this study, you will be assigned by chance (like the flip of a coin) by a computer to one of two groups (either Group A or Group B). Neither you nor your family member's doctor can control which group you will be assigned to.

If you are assigned to Group A, you and your family member will receive the usual heart failure and supportive care that you would receive if you did not enroll in this study, including access to palliative care, social work, pastoral care, and financial planning services (see table below). Also, you will be asked to complete questionnaires about caregiver burden, quality of life and mood (at the beginning of the study and at weeks 8, 16, 24, 32, 40, and 48).

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Subject Name _____ **Date** _____

Title of Study Randomized Trial of ENABLE CHF-PC for Heart Failure Patients and Caregivers.

Principal Investigator Kathryn L. Burgio, PhD **VAMC** Birmingham (521)

Timeline for Group A

When	Type of meeting	Description/Topics	Approx. Duration
Today	In-person	1) Sign consent 2) Eligibility screening 3) First set of quality of life questionnaires	1 hr.
Ongoing	Ongoing	Normal caregiver support	---
Weeks 8 to 48	Phone	Quality of life questionnaires (every 8 weeks)	25-45 min.

1. If you are assigned to Group B, you will receive additional supportive care services in addition to the usual heart failure and supportive care that you would receive if you did not enroll in this study, including access to palliative care, social work, pastoral care, and financial planning services. The supportive care program consists of telephone sessions with an advanced practice nurse coach who will cover materials with you found in the *Charting Your Course* educational & support guidebook that you will receive. These calls will be scheduled at a time that is convenient for you (see table below). Calls will be digitally-recorded for quality assurance purposes.

Also, you will be asked to complete questionnaires about caregiver burden, quality of life, and mood (at the beginning of the study and at weeks 8, 16, 24, 32, 40, and 48).

Timeline for Group B

When	Type of meeting	Description/Topics	Approx. Duration
Today	In-person	1) Sign consent 2) Eligibility screening 3) First set of quality of life questionnaires	1 hr.
Ongoing	Ongoing	Normal caregiver support	---
As soon as feasible	In-person	In-clinic palliative care assessment (patients only)	1 hr.
Week 1	Phone	*Charting Your Course* (CYC) Session 1: Caregiver role and problem-solving	45 min.
Week 2	Phone	*CYC 2:* Caregiver self-care	45 min.
Week 3	Phone	*CYC 3*: Being a partner in symptom management	45 min.
Week 4	Phone	*CYC 4:* Communication, support, and decision-making	45 min.
Once per month	Phone	Your nurse coach will check-in with you monthly to follow-up	15 min.
Weeks 8 to 48	Phone	Quality of life questionnaires (every 8 weeks)	25-45 min.

Subject Name _____ **Date** _____

Title of Study Randomized Trial of ENABLE CHF-PC for Heart Failure Patients and Caregivers.

Principal Investigator Kathryn L. Burgio, PhD **VAMC** Birmingham (521)

Risks and Discomforts
There are two risks associated with study completion. First, you may become sad or upset after reflecting on the care you provide the person with heart failure during the questionnaires or the supportive care phone sessions with the nurse coach. If you become distressed you can discuss this with a member of the study team. In our experience of providing palliative care interventions, this risk is quite low. The questionnaires and intervention also offer the opportunity to reflect upon strengths and resilience, and participants often express gratitude for the chance to respond to the surveys and share their experiences.

The second risk is the slight chance that people not associated with the project will see your answers to questionnaires. The study team will make every effort to maintain confidentiality of your data. Data will be kept in locked files in the study research office.

Benefits
You may or may not benefit personally from being in this research study. We hope to gather information that may help us to provide better care to people in the future.

Alternative Treatment
If you decide not to enroll in this study, there is no alternative intervention for caregivers.

Compensation/Payments
You will be provided with $10 for each of the data collection interviews (at the beginning and at weeks 8, 16, 24, 32, 40, and 48). Separate $10 checks will be mailed to you after completion of each data collection interview. The total possible compensation for participation is $70; $10 for each of the 7 possible data collection interviews. Checks will be prepared by UAB and mailed to you at the address you provide. You will be asked to complete a 'Request for Taxpayer Identification Number and Certification' W-9 form.

Cost of Participation
There will be no cost to you for taking part in this study.

Research-Related Injury
You will be participating in a research project approved by the BVAMC Research and Development Committee and conducted under the supervision of one or more VA employees. If you are injured as a result of your participation as a research subject in this study, the VA medical facility will provide you with necessary medical treatment in accordance with Federal regulations. VA will not necessarily be responsible for treatment for injuries that result from noncompliance with study procedures, although caregivers injured as a result of such participation may be eligible for care from VA under other statutory and regulatory provisions.

Subject Name _____ **Date** _____

Title of Study Randomized Trial of ENABLE CHF-PC for Heart Failure Patients and Caregivers.

Principal Investigator Kathryn L. Burgio, PhD **VAMC** Birmingham (521)

If you have any questions regarding this study please call Kathryn L. Burgio, PhD at (205) 558-7064. If you are injured or become ill as a result of participation in this study, please call Keith Swetz, MD at (205) 933-8101 ext. 5481 or Marie Bakitas, DNSc, NP-C, FAAN at (205) 934-5277 during the day. If you are unable to reach Marie Bakitas, DNSc, NP-C, FAAN or Dr. Swetz and need immediate medical assistance for a research-related injury, please call the VAMC Emergency Room at (205) 558-4725 to obtain advice.

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

Confidentiality
The study staff will treat your identity with professional standards of confidentiality. The information obtained in this study may be published, but your identity will not be revealed. The sponsors, NIH, NINR, UAB and BVAMC will only have limited access to research data. Your information will be released to UAB for the purposes of research and for payment.

VA personnel, the VA Institutional Review Board (IRB) and other federal oversight agencies reserve the right to inspect the research data. At the completion of the study, data will be stored or destroyed according to VA policy.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

Voluntary Participation and Withdrawal
Participation in this study is voluntary and you may refuse to participate without penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw your consent and discontinue participation at any time. If you decide to withdraw from this study, you are asked to contact Kathryn L. Burgio, PhD at (205) 558-7064.

Discontinuation will in no way affect or jeopardize the quality of care you receive now or in the future at this institution or your opportunity to participate in other studies. The Principal Investigator may also withdraw you without your consent for medical or other reasons.

New Findings
Any significant new findings that develop during the course of the research study that in the opinion of the investigator may affect your willingness to continue to participate will be provided to you as soon as possible.

Subject Name _____ **Date** _____

Title of Study Randomized Trial of ENABLE CHF-PC for Heart Failure Patients and Caregivers.

Principal Investigator Kathryn L. Burgio, PhD **VAMC** Birmingham (521)

Questions

If you have any questions about the legitimacy of this study, your rights as a research participant, complaints/concerns about this research, or to discuss problems, obtain information and offer input; please contact the Research & Development Office and the staff will direct you to the appropriate person to handle your situation. The phone number for the Research & Development Office is (205) 558-4747.

If you have any questions, concerns, or complaints about the study, you may contact Kathryn L. Burgio, PhD. She will be glad to answer any of your questions. Dr. Burgio, PhD is available at (205) 558-7064.

Department of Veterans Affairs

VA RESEARCH CONSENT FORM
CAREGIVER CONSENT

Subject Name _____ **Date** _____

Title of Study Randomized Trial of ENABLE CHF-PC for Heart Failure Patients and Caregivers.

Principal Investigator Kathryn L. Burgio, PhD **VAMC** Birmingham (521)

You have read or have had read to you all of the above. Kathryn L. Burgio's designee has explained the study to you and answered all of your questions. You have been told of the risks or discomforts and possible benefits of the study. You were informed that digital recordings will be made during phones sessions with nurses for quality assurance purposes. You have been told of other choices of treatment available to you.

You understand that you do not have to take part in this study. Your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

The results of this study may be published, but your records will not be revealed unless required by law.

In case there are medical problems or questions, you have been told you can call Keith Swetz, MD at (205) 933-8101 ext. 5481 or Marie Bakitas, DNSc, NP-C, FAAN at (205) 934-5277 during the day. If you are unable to reach Marie Bakitas, DNSc, NP-C, FAAN or Dr. Keith Swetz and need immediate medical assistance for a research-related injury, please call the VAMC Emergency Room at (205) 558-4725 to obtain advice.

If any medical problems occur in connection with this study, the VA will provide emergency care in accordance with your eligibility.

You understand your rights as a research subject and you voluntarily consent to participation in this study. You understand what the study is about and how and why it is being done. You will receive a signed copy of this consent form. **Please keep this form because it contains important phone numbers and other information.**

By signing and dating this informed consent, you are not waiving any of your legal rights.

		/ /
Participant's Name (printed)	Participant's Signature	Date (MM/DD/YYYY)
		/ /
Name of person conducting consent discussion (printed)	Signature of person conducting informed consent discussion	Date (MM/DD/YYYY)