USING ACTION AND COPING PLANNING TO SUPPORT SELF-MANAGEMENT OF
HEART FAILURE AMONG VETERANS

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partial fulfillment of the requirements for the degree Master of Science in Nursing.
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Action Plans (AP)

Coping Plans (CP)

Heart Failure (HF)

Theory of Planned Behavior (TPB)

Self-Care of Heart Failure Index (SCHFI)

General Self-Efficacy Scale (GSE)

Veteran's Administration (VA)

Charles George VA Medical Center (CGVAMC)

Computerized Patient Record System (CPRS)

ABSTRACT

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Objective

This descriptive pilot study examines the influence of Action Planning (AP) and Coping Planning (CP) in the veteran population to support self-management of heart failure (HF).

Design

This pilot study used a one-group pretest -posttest time series design that examined the effect of using AP and CP on self management of heart failure

Sample

A convenience sample of 18 veterans who had been hospitalized with heart failure was utilized for this pilot study.

Methods

Participants were provided with a standard educational intervention about self-management of heart failure, and then assisted in making an AP and CP to assist with client directed goals for self-management. Data gathered included pretest and posttest scores on the self-care of heart failure index (SCHFI) and the general self-efficacy scale (GSE); whether or not goals were met; satisfaction level with use of AP and CP; and rates of readmission within 30 days of the original hospitalization. Data on goal achievement was gathered at two week and six week intervals after

the intervention. Posttest responses on SCHFI and GSE were gathered six weeks after the intervention.

Results

Seventy-two percent (72%) of study participants stated they were meeting their goal at the six-week interval. Four of 18 participants did not return second SCHFI/GSE questionnaire. Of those who returned the questionnaire, 28.6% reported no symptoms of shortness of breath or ankle swelling for the past month, indicating heart failure was managed. Overall scores on the SCFHI improved in the maintenance and confidence sections. While the small sample limits the ability to make definitive conclusions, t-test analysis did show significant improvement on mean scores on the maintenance and confidence subscales of the SCHFI. Overall, satisfaction with the use of AP and CP was high. There was no effect on 30 day hospital readmissions. Also, no change in self-efficacy was noted after using AP and CP.

Conclusions

This pilot study indicates that AP and CP may be useful techniques to encourage self-management of HF. Supporting individuals in making self-care goals is a patient-centered approach that, in this small sample, produced high satisfaction with use of AP and CP. Given the small sample size, additional research using a larger sample is warranted.

CHAPTER I: BACKGROUND AND RATIONALE

Heart Failure (HF) is a chronic disease with high mortality and cost of care. While 2.4% of the US population has HF, prevalence increases to 12% among individuals older than 80 years of age. (Heidenreich et al, 2013). The American Heart Association projects that if current trends continue, prevalence of HF will increase by 25% by the year 2030. Furthermore, the cost of the care of HF is projected to increase over the next fifteen years from 20.9 to 53.1 billion (Heidenreich et al, 2013). HF is a chronic, progressive disease that becomes more challenging for individuals to live with as it progresses. Effective self-care of heart failure does improve the patient-reported experience of living with heart failure as well as clinical outcomes (Riegel, Dickson, & Faulkner2015). However, self-care can be complex with behavioral changes recommended that are related to diet, exercise and activities of daily living. Patients being taught how to self-manage their disease are instructed to engage in many lifestyle behaviors such as: weighing themselves daily, restricting fluid intake, restricting sodium use, stopping smoking, adhering to medication regimens, increasing activity levels if possible, decreasing alcohol intake, and consuming a low fat, heart-healthy diet.

Because of the many tasks involved in self-care of HF, this complex disease requires a high level of patient involvement to effectively self-manage. Riegel, Dickson, & Faulkner (2015) indicate that effective self-care of HF involves three different processes: self-maintenance, symptom perception, and self-management. Each of these processes involves different behaviors that contribute to successful HF self-care. Self-care of HF is a complex process requiring the learning of behaviors as well as comprehending mental processes. Accordingly, HF education must include both the explanation of the disease as well as instruction on self-care tasks.

As frontline educators, nurses often provide comprehensive heart failure education. Traditionally, heart failure education has been a process of imparting knowledge, reviewing instructions and answering questions (Shaw, O'Neal, Siddharthan, & Neugaard, 2014). However, as the understanding and emphasis on patient-centered care grows, the need to provide patient-centered educational interventions has become apparent. Patient-centered care is a health care initiative designed to include the patient as part of the care team and empowers him or her to take ownership of their health. In 2001, the Institute of Medicine included patient centered care as one of six quality aims presented in their publication *Crossing the Quality Chasm: A New Health System for the 21st Century* (Institute for Healthcare Improvement, 2016). The Veteran's Administration (VA) has been a strong proponent for patient-centered care and has made significant advances to integrate patient-centeredness into the provision of care. In 2010, the VA began providing primary care through a Patient Aligned Care Team model, based on the patient-centered medical home concept. Additionally, in 2010, the VA created the Office of Patient-Centered Care and Cultural Transformation. The objective of this office is to promote, develop, and assist in the implementation of patient-centered care initiatives (Burkhart, et. al., 2016). The development and study of patient-centered measures to support self-management is recognized as an important component of the delivery of safe and effective health care.

In considering how to make heart failure education both more effective and more patient-centered, different approaches to education interventions need to be considered. The purpose of this paper was to investigate whether assisting patients in making plans for their chosen goals contributing to heart failure care would assist in their self-management of heart failure. One approach to assisting with goal development is known as action planning (AP) and coping planning (CP). Action planning is the process of developing a specific plan for a goal, including

a description of when, where, and how the behavior will be performed. Coping planning is the development of a plan for the barriers that may make the performance of the behavior more difficult (Hagger & Luszczynska, 2014).

Problem Statement

Due to the high cost of providing care to those with heart failure and the overwhelming toll it takes on individuals and families, educational interventions that assist patients in planning how they will incorporate instructions for management into their life are needed.

Justification of Study

Determining effective methods to promote self-care among people who suffer from heart failure is important to improve outcomes and decrease costly hospitalizations for individuals with HF. Providing care that is patient-centered is consistent with goals from the Institute of Medicine and the mission of the Veteran's Administration.

Theoretical Framework

The use of AP and CP stems from the theory of planned behavior (TPB) (Ajzen, 1991). Ajzen proposed that the performance of a specific behavior is influenced by an individual's intention. Further, Ajzen suggested that intentions are influenced by attitudes, perceived social norms, perceived control, as well as the resources and skills necessary to perform the behavior (Nelson, Cook & Ingram, 2013).

Figure 1 illustrates the components of the TPB and how different types of beliefs affect the forming of an intention, which may then form a behavior. By making volitional plans for a behavior, AP and CP attempt to influence the behavioral controls that can assist an intention to become a behavior. The theory thus provides the framework for research on the usefulness of AP and CP in the described population.

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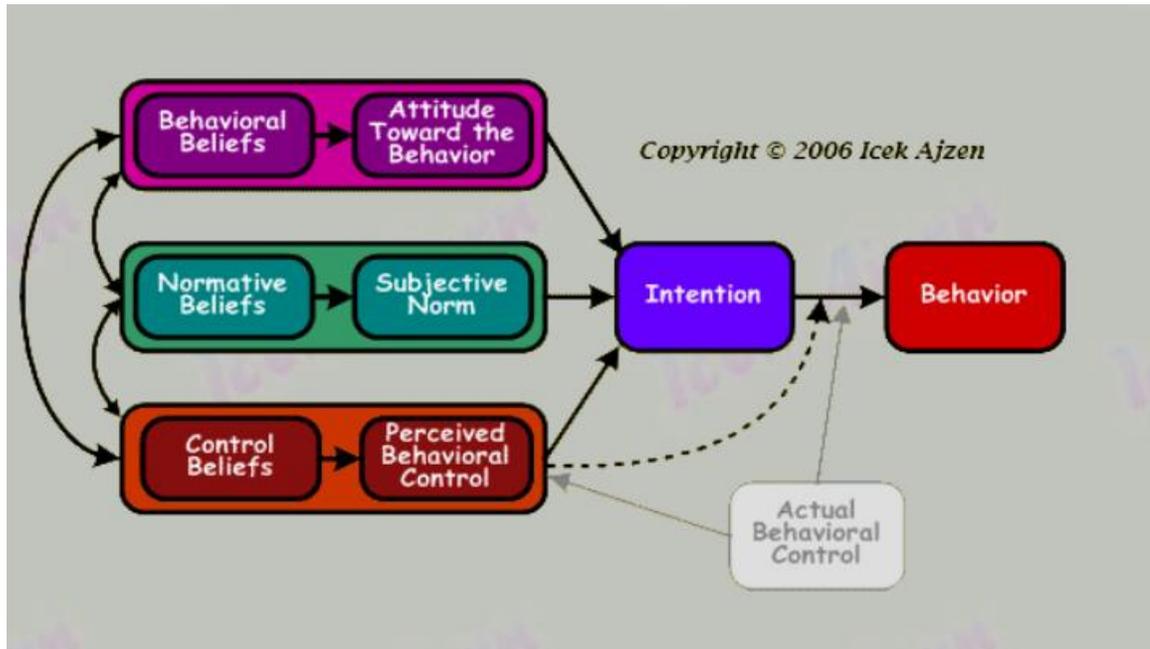
Figure 1. Diagram of the theory of planned behavior (Ajzen, 2006). *Used with open permission*.

The TPB is the basis for volitional planning interventions such as AP and CP. The theory explains how patients may have intentions to follow instructions for taking care of their heart failure exactly as the nurse describes. Yet, when they get home, the scale is located in the laundry room so they have to get dressed and walk past the kitchen. On the way to the scale, they drink a glass of water. A behavior as simple as weighing oneself first thing in the morning suddenly becomes complicated and unreachable. However, the creation of a plan to implement the behavior boosts the perceived behavior control providing the tools to exert actual behavior control. This theory explains that an educational plan that does not address how a patient will achieve the behaviors of self-care is not a complete plan.

Assumptions

Based on the theory of planned behavior, the underlying assumption of this study is that AP and CP will assist with goal attainment in veterans with heart failure. There is an assumption that by making a detailed plan, an action plan, about a behavioral goal, the participant will be better prepared to implement that behavior. Further, the study assumes that planning for potential barriers and how the barriers will be overcome will assist the participant in continuing to perform the behavior. The study also assumes that general self-efficacy is related to the participant's ability to self-manage their chronic disease. Finally, the study assumes that nurses can provide an educational intervention that incorporates action planning and coping planning.

Research Questions

The primary objective of the study was to explore the influence of AP and CP on self management of HF in veterans. The hypothesis was that the use of AP and CP would assist participants in achieving their self-selected goals for HF management. Data were collected before the study intervention was provided, two weeks after the study intervention and six weeks after the study intervention.

In order to examine the potential uses of AP and CP several research questions were examined:

(1) Does the use of AP and CP assist participants in meeting their self-identified goals for HF management?

(2) Does use of AP and CP affect scores on the SCHFI?

(3) What percentage of participants using AP and CP had a 30 day readmission during the study period?

(4) Does use of AP and CP affect self-efficacy as evidenced by increased scores on the GSE?

(5) How satisfied were participants with the use of AP/CP?

Variables in the Study

The independent variable of this study is the educational intervention that includes the formation of an action plan and a coping plan. The dependent variables are: achieved goals; scores on the self-care of heart failure index and the general self-efficacy scale; rate of 30 day readmission; and level of satisfaction.

CHAPTER II: LITERATURE REVIEW

The TPB, proposed by Ajzen (1991), suggests that the enactment of a behavior is influenced by an individual's intention to complete that behavior. Yet, individuals often make intentions that are never implemented. In investigating this process, researchers have identified an intention-behavior gap in which individuals desire to enact positive lifestyle changes but fail to do so (Hagger & Luszczynska, 2014).

For the past decade, increasing research has been directed at exploring how to overcome the intention-behavior gap through volitional planning interventions. The planning techniques used most often to support volitional planning are implementation intentions and action planning (Hagger & Luszczynska, 2014). Implementation intentions are designed to address the gap by developing a cue to perform the desired behavior. Implementation intentions are usually written as an if-then statement (Hagger & Luszczynska). For example, if someone offers me an unhealthy snack, I will say "no, thank you." Action planning is a similar approach, but can involve multiple cues and complex responses. Coping planning is often paired with action planning as it addresses potential barriers to carrying out the specified behavior (Hagger & Luszczynska).

Another factor that may influence individual agency to change or enact behaviors is the concept of self-efficacy. Self- efficacy is a widely studied concept that relates to an individual's belief in their ability to effect change in their own life. People with a high sense of self-efficacy tend to feel optimistic and self-confident about their abilities to achieve and cope with life. In contrast, when people have low self-efficacy, they do not feel capable of achieving their aims

and they may suffer from feelings of helplessness as well. (Scholz, Dona, Sud, & Schwarzer, 2002).

Action Planning and Coping Planning

Two of the most predominant volitional planning interventions, AP and CP are designed to promote behavior changes by creating specific plans. With AP, individuals describe how the desired behavior will be incorporated into their daily lives by stating when, where, and how the behavior is to be done (Hagger & Luszczynska, 2014). Action planning can be utilized to obtain specific behaviors, such as running for 30 minutes, as well as broader and more complex behaviors such as increasing physical activity. Thus, APs can be described as specific behavioral plans that consider the separate components of a desired behavior (Hagger & Luszczynska).

AP is often coupled with CP in which barriers and solutions to barriers are identified. For example, if the plan describes running for 30 minutes on Monday, Wednesday and Friday, a coping plan might identify what the individual would do if it rains or if they have to work late on one of these days. The coupling of AP with CP results in further narrowing of the gap between planning and doing (Hagger & Luszczynska, 2014). Coping plans assist individuals to overcome the barriers to acting upon an intention by establishing a plan to address how they will act in the presence of a barrier to their desired behavior change.

Action Planning and Coping Planning and Heart Health

Research on use of AP and CP has shown that these interventions can encourage the development of specific healthful behaviors, including important behaviors to support effective self-management of heart failure. For example, AP and CP have been found to aid in increasing physical activity (Sniehotta, Scholz, & Schwarzer, 2006); changing dietary habits, such as increasing fruits and vegetables (Stadler, Oettingen, & Gollwitzer, 2010) and lowering sodium

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intake (Agondi, Cornelio, Rodriguez, & Gallani, 2014); and promoting smoking cessation (de Hoog, N., et.al, 2016).

A major contributor to heart health is physical activity. Sniehotta, Scholz, and Schwarzer (2006) found that utilizing AP and CP together increased levels of physical activity and adherence in cardiac rehabilitation patients. In this study, the interventional group received instruction on both AP and CP, instead of just AP. The interventional group engaged in significantly more exercise two months after discharge from the cardiac rehabilitation program. Similarly, Koring et al. (2012) found that completing both AP and CP interventions led to increased physical activity in a voluntary group of participants who participated in an online intervention. This effect was measured three weeks after the intervention was provided. However, one limitation of this study is that the results were based on self-report. Other researchers have found positive effects of AP and CP on increasing physical exercise. Gaston and Prapavessis (2014) compared the use of an informational intervention alone, informational intervention with AP, and the use of informational intervention with AP and CP among pregnant women with the goal of supporting increased exercise. The best results were with the interventional group that received prompting to form both AP and CP.

Another important consideration in HF self-management is reducing salt intake and choosing a heart healthy diet. Agondi, Cornélio, Matheus Rodrigues & Gallani (2014) demonstrated that AP and CP could be used to decrease salt intake in Brazilian women. In this study, the interventional group showed a significant reduction in salt intake as evidenced by a 24-hour urinary-sodium excretion test. Stadler, Oettingen, & Gollwitzer, (2010) demonstrated goal of an increased intake of fruits and vegetables over the course of 2 years when female participants aged 30-50 were provided with both information and instruction on self-regulation.

Self-regulation included describing in detail the goal of increased intake of fruits and vegetables, identifying obstacles to achieving the goal, and forming plans to overcome the obstacle. Another study by Luszczynska, Sutton, and Scholz (2007) found that providing an intervention assisting participants in creating a detailed plan for decreasing saturated fat content aided in sustained dietary changes. The intervention lasted approximately twenty minutes; each participant received personal assistance in creating a plan that met dietary guidelines and addressed obstacles appropriately. Six months later, the interventional group ate less saturated fat than those in the control group. Throughout this research, the ability of AP and CP to effect change in dietary habits is established.

The use of action and coping planning has shown significant effects on other behaviors that contribute to heart health. De Hoog et al. (2016) found that AP and CP had a positive effect among individuals who had been advised to quit smoking while hospitalized on a cardiac ward for some form of heart disease. Follow up after 6 months revealed that 31% had not been smoking for 5 months and 43% had not smoked the previous 7 days. Benyamini et al. (2012) found that providing action planning training to individuals enrolled in a weight loss program assisted in the accomplishment of weight loss goals. In this study, those who received both information about how to plan and those who were assisted in creating AP and CP lost 40% more than those who received no information about behavioral change. Those who had higher weight loss goals and received assistance in creating AP and CP lost more weight than those who only received information. This study only examined weight loss so it was not noted whether or not participants achieved the behavioral goals that they set. Lourenço et al. (2013) found that a nursing intervention that prompted the creation of AP and CP for medication adherence succeeded in achieving adherence in 71% of the intervention group. Those in the control group

were only 32% adherent at follow up. Thus, prior evidence demonstrates that AP and CP can have positive effects on a variety of behaviors that contribute to heart health.

Though not widely explored, the use of AP and CP can be helpful to specifically contribute to self- management of HF because HF is a condition that often requires many behavioral changes related to diet, exercise and activities of daily living. Patients being taught how to self-manage their disease are instructed to engage in many lifestyle behaviors such as: weighing themselves daily, restricting fluid intake, restricting sodium use, stopping smoking, adhering to medication regimens, increasing activity levels if possible, decreasing alcohol intake, and consuming a low fat, heart-healthy diet. Research on use of AP and CP has shown support for an increase in specific healthful behaviors, including important behaviors to support effective self-management of heart failure as described above. While AP and CP have been well researched for specific behaviors, use of AP and CP and its impact on patient's ability to self-manage heart failure has not been explored. Based on a review of the extant literature, no studies specific to the veteran population regarding use of AP and CP were found. Determining effective methods to promote self-care among this population is important because these interventions can improve outcomes and decrease hospitalizations for individuals with HF.

CHAPTER III: METHODOLOGY

Design

This pilot study used a one-group pretest -posttest time series design that examined the effect of using AP and CP on self management of heart failure as indicated by scores on the SCHFI, GSE, by readmissions, and by self report of attainment of goals. Using the pretest-postest design, particpants first completed the SCHFI and GSE questionaire and then received an educational intervention which included the setting of goals using AP and CP. At two weeks and six weeks, follow up occurred by phone call to establish whether or not goals were met and the participant's satisfaction level. At five to six weeks, follow up by mail occurred for the final results on the SCHFI and GSE questionaires.

Setting

This study was conducted at the Charles George VA Medical Center in Western North Carolina. Data were collected from June 2016 through September 2016.

Sampling Plan and Inclusion Criteria

Using convenience sampling over the course of three months, 20 veterans were recruited to participate in the study. Participants were identified after being admitted to the hospital with a primary or secondary diagnosis of heart failure. The following inclusion criteria were established for this study: age 45 to 75 with a diagnosis of HF; receive care at the CGVAMC; hospitalized for HF exacerbation in the past year; and live independently at home. Exclusion criteria included: not able to live independently; illiterate status with no literate support person in the home; and non-English speakers. Data from the Veterans Administration's computerized health

record, computerized patient record system (CPRS), was used to ascertain if veteran met inclusion criteria.

The ethics of excluding illiterate participants were considered carefully by the primary investigator and the study coordinator. However, due to Veteran Administration research guidelines, veterans cannot be required to travel to the VA solely for the purpose of research, instead any follow up has to be completed in conjunction with existing clinic appointments. Thus, in order to complete secondary measurements on the SCHFI and GSE, participants needed to be able to read and write, or have someone in the home who could help them with this task. In practice, no potential participants were turned away from the study based on illiterate status, all those who otherwise qualified were also literate. Initially, 20 participants agreed to participate in the study. One participant voluntarily withdrew from the study and a second participant was removed due to inability to reach for follow up. Thus, this pilot study had a sample of 18.

Protection of Human Subjects

This study was first approved by the Institutional Review Board and the Research and Development Committee of the Charles George Veteran's Administration Medical Center. Once this approval was obtained, it was submitted to the Institutional Review Board of Western Carolina University and approved, WCU IRB number: 2016-0194. Informed consent was designed to properly inform participants and give them time to consider participation. Veterans who met the inclusion criteria were approached by the study coordinator, provided with and explanation of the study, and given the opportunity to participate. Ample time to discuss participation with family or support person as well as ask questions of the study coordinator was provided. If the veteran opted to participate, written informed consent was obtained. After initial agreement to participate was received, each individual was assigned a study ID number. No

personally identifiable information was used as part of this study. No risks, other than those of everyday life living with heart failure were anticipated for the participants of this study. No adverse events during the study timeframe for any of the participants were reported. Confidentiality protections were provided to the subject by removing patient identifiers, using subject numbers instead of names, and access-protected data spreadsheets.

<center>**Instruments Used in the Study**</center>

The following instruments were used to measure the variables explored in this study.

Self-Care of Heart Failure Index (SCHFI)

The SCHFI is a self-report instrument based on the situation-specific theory of HF self-care put forth by Riegel and Dickson in 2008 (Vellone et al, 2013). The theory proposes that self-care maintenance is obtained through symptom monitoring and treatment adherence while self-care management is a complex process that is accomplished when HF patients take certain actions when symptoms of HF exacerbation arise. The SCHFI measures a patient's ability to achieve self-care maintenance (following prescribed behaviors) and self-care management. The SCHFI has 22 items in three sections, each section reflects the three "stages" of self-care as defined by the situation-specific theory of HF (maintenance, symptom perception, and management). Each item uses a four point Likert scale from Never or Rarely to Always or Daily (Vellone et al., 2013). As directed, participants were asked to consider the past three months of behaviors when completing the questionnaire the first time. The second time, the participants were asked to consider the five to six weeks after the educational interventional was provided.

Because the SCHFI contains three sections, the reliability of each section has been tested. The Cronbach alpha scores initially reported for reliability were .55 for self-care maintenance, .60 for self-care management and .83 for self-care confidence (Barbaranelli, Lee, Vellone, &

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Riegel, 2014). Of these scores, only the score for the section on self-confidence are good. The authors explain the multidimensionality of the scale affects its Cronbach alpha score. The authors maintain that Cronbach alpha scores relate more specifically to unidimensional measurements and that only the self-care confidence section is unidimensional. Thus, the researchers tested the dimensionality of each section and then looked at different measures of internal consistency based on dimensionality. Testing on the psychometric properties using indices designed for multidimensional measures, internal consistency measurements were .75 to .83 for self-care maintenance, .66 to .77 for self-care management and .84 to .90 for self-care confidence (Barbarnelli, Lee, Vellone, & Riegel, 2014). These scores indicate sufficient reliability of the SCHFI.

Construct validity of SCHFI has been established by previous research as well. Each individual scale was measured separately: the self-care maintenance was rated CFI = .92, RMSEA = .05; self-care Management component revealed CFI = .95, RMSEA - .07, self-care confidence component achieved CFI = .99, RMSEA = .02. Researchers found that the internal consistency, test-retest reliability, and validity all supported the use of this instrument in research investigating self-care of heart failure (Barbarnelli, Lee, Vellone, & Riegel, 2014).

The SCHFI yields a separate score for each of the three sections of the instrument. Instructions for scoring the SCHFI require calculation of three scores based on questions in each section on the instrument. The result is a confidence score, a maintenance score, and if symptomatic, a management score. Scores range from 0 -100, with high scores indicating higher levels of maintenance, confidence and management. Riegel (n.d.) advises that the management score is not reliable if the individuals did not experience heart failure symptoms of swelling of their ankles or difficulty breathing in the recent past. The SCHFI is available for use without

permission; it is in the public domain. Riegel (n. d.) states explicitly that permission to use the SCHFI is not required. Directions for use and scoring as well as instructions for administration were followed (Riegel, n.d.).

General Self Efficacy Scale (GSE)

The general self-efficacy scale (GSE) was first developed in 1979 in German and since that time it has been adapted to 26 other languages (Schwarzer & Jerusalem, 1995). This unidimensional scale has a Cronbach's alpha that ranges from .76 to .90 in samples from 23 nations, indicating a high level of reliability (Schwarzer & Jerusalem, n. d.). Research has shown that the GSE is internally consistent, reliable and homogenous across 25 nations (Scholz, Dona, Sud, & Schwarzer, 2002). No permission is required to use this scale for non-commercial research or development purposes (Schwarzer & Jerusalem, n.d.).

Satisfaction with AP and CP

Participant satisfaction with using AP and CP was measured using a one item researcher-developed instrument using a Likert scale with 1 being not satisfied and 5 being very satisfied. Satisfaction levels were collected at the first and second follow up phone calls at the two week and six week interval following the intervention.

<div align="center">

Data Collection Procedure

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After informed consent was obtained, participants then completed the pretest questionnaire, which included the SCHFI and the GSE. Participants were then provided with the educational intervention that included the standard heart failure education used at the CGVAMC for inpatients admitted with heart failure. As part of this standard intervention, specific lifestyle changes needed to self-manage heart failure were explained and instructional materials were provided to the patient. As part of the study intervention, the study coordinator discussed

participant strengths, weaknesses, and personal feelings about what they wanted to do to manage

their disease. Together, the study coordinator and participant completed the Goalsetting

Worksheet (Appendix A), designed to assist individuals in forming goals using AP and CP. A

copy of the goalsetting worksheet was made for study coordinator and the participant. The

participant also received copies of informed consent paperwork and educational material. If the

individual opted not to participate in the study, the educational intervention was provided

without the inclusion of the goalsetting worksheet.

Approximately two weeks after the intervention was provided, each participant was

called by the study coordinator and asked the following questions:

(1) Over the past two weeks, have you been successful with meeting your goal(s)?

(2) On a scale of 1 to 5, how satisfied are you with the use of action and coping planning?

Responses to these questions were recorded in a data gathering spreadsheet under the study

identification number. This spreadsheet was maintained in a protected file on the VA server,

which could only be accessed by the study coordinator, the primary investigator, and the research

coordinator.

Five weeks following the baseline assessment, each participant was mailed a copy of the

SCHFI and the GSE with a self-addressed, stamped envelope and a request to fill out the forms

and return to the study coordinator. Six weeks following the intervention, the study coordinator

called the participants and asked two questions:

(1) Over the past four weeks, have you been successful with meeting your goal(s)?

(2) On a scale of 1 to 5, how satisfied are you with the use of action planning?

Participants were enrolled in the study on a rolling basis over the course of three months. The study coordinator kept track of the date of intervention for each participant and timeframe for follow-up on the data collection spreadsheet.

Data Analysis

The consideration of whether the participant was assisted in meeting his or her goal using AP and CP was based on the percentage of those who self-reported that they had met goals at the two and six week intervals following the intervention. Whether or not AP and CP affected ability to self manage heart failure was measured by pretest and posttest results of the SCHFI collected prior to the intervention and six weeks following the study intervention. The pretest and posttest scores on the GSE collected before the intervention and six weeks following the intervention were used to measure whether AP and CP had an effect on self-efficacy. Analysis of pretest and posttest of both SCHFI and GSE was achieved using a one sample t- test.

To consider the effect of the provision of AP and CP on hospital readmissions, data from hospital records was used to determine the percentage of study participants who experienced a readmission within thirty days from hospital discharge and was compared with national heart failure readmission rates. Data on participant satisfaction with use of AP and CP was analyzed by finding the mean level of satisfaction at two weeks and six weeks and overall.

Limitations

The small, convenience sample of this study considerably limits any inferences that can be drawn from the results. However the considerable percentage (72%) of those who continued to meet their goals at the study's end, the improved scores for maintenance and confidence on the SCHFI, and the four participants who reported no shortness of breath or ankle swelling on

the posttest SCHFI questionnaire, do suggest that further study would potentially contribute to heart failure education and treatment plans.

In addition to the small, convenience sample, this study was limited by its reliance on self-report measures for both completion of goals and through the use of validated questionnaires. Further, the lack of a control group makes it impossible to determine the contribution of the educational intervention alone towards the completion of the behaviors. Finally, while satisfaction was considered, participants were not asked if they used their coping plan when they encountered barriers.

CHAPTER IV: RESULTS

Sample Characteristics

The original sampling plan for the study included inviting Veterans who had been hospitalized for heart failure in the last year to participate by mailed invitation. However, the study coordinator learned through the process of the study that the difficulty in finding a space to provide the intervention combined with the necessity of scheduling the intervention to coincide with another appointment, made the inclusion of outpatients unfeasible. Therefore, all participants were drawn from veterans who were hospitalized at the time of recruitment.

Twenty participants were consented to participate in the study. One participant asked to withdraw and a second was unable to reach for follow up. Thus, the final sample size was 18. The average age of participants was 69. No other demographic data was collected for this study.

Instrument Reliability

To measure reliability in this study, Cronbach's alpha was determined and found to be sufficient. As shown in Table 1, the first time it was administered, Cronbach's alpha was .762. The second and final yielded a Cronbach's alpha of .985. This indicates acceptable internal consistency and reliability. Cronbach's alpha for the GSE also reflected an acceptable level of reliability. For the pretest measure, GSE reliability was .857; for the posttest measure, GSE reliability was .865.

Table 1

Study Instrument Reliability

Scale	# Items	Cronbach's alpha
SCHFI 1	23	.762
SCHFI 2	23	.985
GSE 1	10	.857
GSE 2	10	.865

Client-Established Goals

Participants' goals included self-monitoring goals, such as weighing themselves daily; increasing physical activity; tobacco cessation; restricting salt intake and medication adherence. These goals were organized into categories for analysis. Of all participants, 38.9% (n=7) made a self-monitoring goal, such as "I will weigh myself every day." Four participants (22.2%) made a goal to increase physical activity. Three participants (16.7%) made a goal to stop smoking. Two participants (11.1%) made a goal to restrict salt. Two participants (11.1%) set a goal to take their medications as ordered.

Table 2 lists the different types of goals chosen by popularity and the percentage of participants who choose each type of goal that met their goal after the two time intervals.

Table 2

Percent Goals Met (n=18)

Type of Goal	%	% who met goal at 2 weeks	# who met goal at 6 weeks
Self- Monitoring	38.9% (n=7)	85.7%	85.7%
Physical activity	22.2% (n=4)	50.0%	75.0%
Smoking cessation	16.7% (n=3)	66.7%	0.0%
Salt restriction	11.1% (n=2)	100.0%	100.0%
Medication adherence	11.1% (n=2)	100.0%	100.0%
All participants	100% (n=18)	77%	72%

The small sample size reduces the ability to draw conclusions about goal completion. Nevertheless, the different categories of goals did seem to indicate that some goals were more likely to be achieved that others. For individuals who set goals related to self-monitoring, 85.7% (n=7) reported meeting their goal at the six week interval. Of those who set a goal of physical activity (n=4), 75% had continued to meet this goal at 6 weeks. Those who set a goal for medication adherence (n=2) and those who set a goal for salt restriction (n=2) had all continued to meet this goal at the 6 week interval. In contrast, 0% (n=3) of those who made a goal to stop smoking stated that they had met this goal at the 6-week interval. Overall, 77% of the 18 participants stated they had met their goal. Six weeks after the intervention, 72% stated they had met their goal.

Changes in SCHFI and GSE between Time Intervals

Table 3 presents the scores for maintenance, confidence, and management subscales from before the intervention was provided and at the six week follow-up time interval. Mean scores increased for both maintenance and confidence indicating improved ability to care for self. Scores for management showed a 0.02 point decrease in the mean, as shown in Table 4. The management section begins with the question, "In the past month, have you had trouble breathing or ankle swelling?" All participants (n=16) answered yes to this question at the pretest interval. At the six week interval, four participants answered "no" to this question. Thus, according instrument instructions, those participants who answered "no" were removed from analysis comparison of mean scores.

Table 3

SCHFI Mean Scores and Change

_____

	M Pre-intervention	M 6-week follow-up	Change
SCHFI Maintenance	66.4 (n=16)	72.1 (n=14)	+5.7
SCHFI Confidence	63.6 (n=16)	66.3 (n=14)	+2.4
SCHFI Management	58.8 (n=16)	58.6 (n=11)	-0.2

Table 4 presents the mean GSE scores before intervention and at the six week follow up. Scores on the GSE range from 10 – 40 with a higher score indicating a higher level of self-efficacy. Results indicated a slight decrease in self-efficacy from the pretest measure to the posttest at the 6 week follow up.

Table 4

GSE Mean Scores and Change

_____
	M Pre-intervention (n=18)	M6-week follow-up (n=14)	Change
GSE	31.79	30.4	-1.5

A one sample paired t-test was conducted to examine whether differences in means on the subscales of the SCHFI and GSE were statistically significant between the two time intervals. Table 5 depicts results of the t- test analysis for the maintenance, confidence, and management subscales of the SCHFI. These results indicate significant differences between mean scores on the maintenance and confidence SCHFI subscales baseline and six week intervals. However, this finding must be approached with caution, given the small sample size of the pilot study. Participants with missing data were excluded for analysis.

Table 5

SCHFI Scores t-test and p-value

	df	t	Sig (2-tailed)
Maintenance 1 (n=14)	13	15.2	0.0
Maintenance 2 (n=14)	13	23.0	0.0
Confidence 1 (n=14)	13	5.4	0.0
Confidence 2 (n=14)	13	12.5	0.0
Management 1 (n=14)	13	12.3	0.0
Management 2 (n=10)	9	9.5	0.0

Table 6 depicts the results of the t-test analysis for GSE scores before the intervention and at the six week follow up. As discussed above, these scores did decrease in that time interval. Again, the significance of this finding must be tempered with an understanding of the small sample size.

Table 6

GSE Scores t test and p-value

	df	t	Sig (2-tailed)
GSE-1 (n=18)	17	29.7	0.0
GSE-2 (n=14)	13	23.4	0.0

Hospital Readmission Rates

Of the 18 participants in the study, four (4) were readmitted for heart failure within 30 days following their hospital discharge during which the intervention occurred, reflecting a 22% readmission rate. Nationwide, the average percentage for heart failure readmissions is 25% (Desai & Stevenson, 2012). While the rate of readmission for this study is lower than the national average, the descriptive nature of this study does not allow inferences of whether or not use of AP/CP had any effect on readmission rates.

Participant Satisfaction with Use of AP and CP

Participants were asked about their satisfaction with using AP and CP at the two week check in and the six week check in. Specifically, participants were asked, "On a scale of 1-5, with 1 being very unsatisfied and 5 being very satisfied and 3 being neither unsatisfied or satisfied, how would you rate your level of satisfaction with using the AP/CP for making a self-

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care goal?" The average response at two weeks was 4.1 and at 6 weeks was 4.4. The average

overall was 4.3, indicating high levels of satisfaction with using AP and CP.

CHAPTER V: DISCUSSION

This study sought to describe how AP and CP could potentially contribute to self-care in individuals with heart failure. Our findings are consistent with the existent literature demonstrating that the setting of goals using AP and CP assist individuals in achieving their goals. Additionally, the improved SCHFI scores and the participants who did not report shortness of breath and swelling of ankles on their posttest SCHFI do indicate that further investigation of the use of AP and CP in heart failure care is warranted.

In order explore the use of AP and CP with the heart failure diagnosis, several research questions were considered. First, did the use of AP and CP assist veterans in achieving their self-identified goals for HF management? Overall, 72% of participants reported that they were still meeting their goal at the end of the study. This may indicate that making AP and CP did assist these participants in meeting their goals. Secondly, did the use of AP and CP affect scores on the SCHFI? On average, scores on the SCHFI maintenance improved 5.7 points and scores on confidence improved 2.4 points. The scores on the management section were adversely affected by the four participants that did not experience shortness of breath or ankle swelling during the month prior to their completion of the final SCHFI questionnaire. According to instrument directions, scores for participants in the management section that do not report symptoms should not be used in the analysis. However, this finding does indicate that 28.6% of participants were able to manage heart failure to the extent that for the six week interval after intervention was provided, they did not experience shortness of breath or ankle swelling.

Use of t-tests to examine differences between mean scores on the three subscales of the SCHFI and the GES total score were performed and found to be statistically significant (p=.000).

However, given the small sample size in this study, a high risk of a Type II error is likely and these findings should be approached with caution. Repeating the study with a larger sample is warranted to be able to fully examine these differences.

The third research question asked whether AP and CP would affect readmission rates of study participants within thirty days of discharge. Hospital readmission rate for participants was 22% and the national average is estimated to be 25% (Desai & Stevenson, 2012). Due to the small sample of this study, it is not possible to determine the influence AP and CP had on readmission rates.

The fourth research question sought to explore whether the use of AP and CP affected the participants' self-efficacy as determined by scores on the GSE. In a review of the literature on action and coping planning, Hagger and Luszcynska (2014) explain that some research has found that high self-efficacy contributes to positive outcomes from AP and CP. Research suggests that the presence of self-efficacy helps individuals to engage in action planning and thus achieve behavior changes. The existent research does not indicate that forming AP and CP has an effect on self-efficacy (Hagger & Luszcynska, 2014). Consistent with those prior findings, no improvement in self-efficacy was found, however, the small sample size presents a high risk for error. Thus, the impact of use of AP and CP on self-efficacy in this study cannot be fully examined.

The study also investigated participants' satisfaction with the use of AP and CP. Satisfaction scores did indicate a high level of satisfaction with using AP and CP. Overall, participants ranked their satisfaction with AP and CP as 4.4 on a one to five Likert scale at the end of the study.

Conclusion

This study sought to examine the benefit of using AP and CP to support self-management of heart failure in the veteran population. In this small, convenience sample, 72% of participants were meeting the goals they set using AP and CP at the final 6 week interval of the study. Overall, SCHFI scores for maintenance and confidence improved from pretest to posttest. Scores on GSE indicated no improvement in self-efficacy. Overall, participant satisfaction with the use of AP and CP was high. The effects of AP ad CP on 30-day readmission could not be extrapolated from this sample.

Implications and Recommendations

While the small convenience sample and the lack of a control group limit the proposal of specific recommendations for practice, the positive results do indicate that further study is warranted. The primary question asked in the study was whether an educational nursing intervention could assist those with heart failure in taking steps to manage their disease. This intervention focused on working with the participant to choose a goal, which is a patient-centered approach. Patients were not prescribed a set of behavior changes that they needed to implement in order to manage their disease. Instead, the study coordinator educated on the behaviors needed to manage heart failure and asked participants what behaviors they felt they would like to implement.

This study describes one way to incorporate a patient-centered care approach into one of the largest tasks faced by frontline nurses today, how to educate patients on the management of chronic disease. Both because of the positive results indicated by this pilot study and because it relies on a patient-centered approach, the use of AP and CP to assist with self-management of

HF deserves further study. Innovative ways to implement patient-centered approaches into patient education are needed.

Recommendations for Further Research

In order to effectively explore results and differentiate between the effects of education and the effects of AP and CP, an experimental design with the use of both intervention and control groups are recommended. A larger sample is needed to increase the potential for practice implications. For this study, the age spread of 45 -75 was intended to identify those veterans who were not in advanced heart failure and could most benefit from behavioral changes. In retrospect, the study coordinator did identify several veterans during the course of the study timeframe who were over 75 and not in advanced heart failure who would have been appropriate for study participation. These veterans were provided with educational intervention but not invited to participate in the study because of the pre-established inclusion criteria. Future studies may consider inclusion criteria based on stage of disease or ability to complete activities of daily living as more appropriate to the research than age of participant. In order to assure the inclusion of all possible participants, future studies may consider how to follow up with telehealth or primary care managers in order to include individuals with literacy or English language deficiencies.

To increase understanding of the experience of using AP and CP, a qualitative component that explores how participants used their action plan and their coping plan would be useful. Questions such as: Did you use your action plan? How did it help? Did you use your coping plan? How did it help? Can you describe one instance when your coping plan helped you enact the behavior change that you were working on? These questions would help bring greater definition to the practice of assisting with AP and CP development. A final recommendation is to

study the intervention itself. What modifications are needed so this nursing intervention that can be easily provided by practicing nurses? In order to truly utilize AP and CP in the provision of care, a simple nursing intervention that can be delivered efficiently would be necessary. Defining the intervention itself so that it can be standardized and repeated by a large number of practicing nurses is part of the process of realizing the potential positive results of AP and CP. Further research in developing this intervention would be useful to the practice of assisting patients to make action and coping plans.

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APPENDICES

Appendix A: Goalsetting Worksheet

Goals for Self-Care of Heart Failure Worksheet

Study ID Number _____

There is a lot you can do to take care of yourself when you have heart failure. The

American Heart Association makes these recommendations:

- Quitting smoking
- Losing or maintaining weight
- Tracking your daily fluid intake
- Avoiding alcohol
- Avoiding or limiting caffeine
- Eating a heart-healthy diet
- Being physically active
- Managing stress
- Keeping track
- Monitoring your blood pressure
- Getting adequate rest
  (American Heart Association,
  2015)

While the list is long, you can take small steps now to support yourself.

Make a goal. Choose one or two things to start on. I want to _____

now to help myself? When writing your goal, be specific. What will you do? When

and how will you do it? Where will you be?

_____

_____

_____

_____

_____

Thing about the reward. When I do this for _____

(time frame). What will happen when you work on this? I will experience:

_____

_____

_____

_____

Consider the barriers. What might get in the way of your goals? I might face

challenges in achieving my goal. They are:

_____

_____

_____

_____

Make a plan. What can you do when you face a barrier? How can you overcome

challenges to your goal?

If _____

(something gets in my way)

Then _____

(what I will do to succeed anyway).

If _____

(something gets in my way)

Then _____

(what I will do to succeed anyway).

If _____

(something gets in my way)

Then _____

(what I will do to succeed anyway).

All answers are confidential.

Think about how you have been feeling in the last month or since we last spoke as you complete these items.

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?	1	2	3	4
2. Check your ankles for swelling?	1	2	3	4
3. Try to avoid getting sick (e.g., flu shot, avoid ill people)?	1	2	3	4
4. Do some physical activity?	1	2	3	4
5. Keep doctor or nurse appointments?	1	2	3	4
6. Eat a low salt diet?	1	2	3	4
7. Exercise for 30 minutes?	1	2	3	4
8. Forget to take one of your medicines?	1	2	3	4
9. Ask for low salt items when eating out or visiting others?	1	2	3	4
10. Use a system (pill box, reminders) to help you remember your medicines?	1	2	3	4

SECTION B:

Many patients have symptoms due to their heart failure. <u>Trouble breathing and ankle swelling</u> are common symptoms of heart failure.

In the past month, have you had trouble breathing or ankle swelling? Circle <u>one</u>.

    0) No

    1) Yes

11. If you had trouble breathing or ankle swelling in the past month…

(circle **one** number)

	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?	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
12. Reduce the salt in your diet	1	2	3	4
13. Reduce your fluid intake	1	2	3	4
14. Take an extra water pill	1	2	3	4
15. Call your doctor or nurse guidance	1	2	3	4

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

<div align="right">(circle one number)</div>

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

SECTION C:

In general, how confident are you that you can:

	Not Confident	Somewhat Confident	Very Confident	Extremely Confident
13. Keep yourself <u>free of heart failure</u> symptoms?	1	2	3	4
14. <u>Follow the treatment advice</u> you have been given?	1	2	3	4
15. <u>Evaluate the importance</u> of your symptoms?	1	2	3	4
16. <u>Recognize changes</u> in your health if they occur?	1	2	3	4
17. <u>Do something</u> that will relieve your symptoms?	1	2	3	4
18. <u>Evaluate</u> how well a remedy works?	1	2	3	4

Appendix C: General Self-Efficacy Scale

	Not At All True	Hardly True	Moderately True	Exactly True
1. I can always manage to solve difficult problems if I try hard enough.	1	2	3	4
2. If someone opposes me, I can find the means and ways to get what I want.	1	2	3	4
3. It is easy for me to stick to my aims and accomplish my goals?	1	2	3	4
4. I am confident that I could deal efficiently with unexpected events.	1	2	3	4
5. Thanks to my resourcefulness, I know how to handle unforeseen situations.	1	2	3	4
6. I can solve most problems if I invest the necessary effort.	1	2	3	4
7. I can remain calm when facing difficulties because I can rely on my coping abilities.	1	2	3	4
8. When I am confronted with a problem, I can usually find several solutions.	1	2	3	4
9. If I am in trouble, I can usually think of a solution.	1	2	3	4
10. I can usually handle whatever comes my way.	1	2	3	4

VAMC ASHEVILLE, NC (637)		VA RESEARCH CONSENT FORM Page 1 of 6	
Subject Name:		Date:	
Principal Investigator:	Dr. Kae Livsey	Subj. #:	
Title of Study:	Using Action and Coping Planning to Support Self-Management of Heart Failure among Veterans		

Why am I being asked to participate?

You are being asked to be a subject in a research study about how setting specific goals can help you to make lifestyle changes that you may want to make. These specific goals are called Action Planning and Coping Planning. You have been asked to participate in the research because you have been diagnosed with heart failure and in the last year this disease has caused you to be admitted to the hospital. Therefore, you may be eligible to participate. We ask that you read this form and ask any questions you may have before agreeing to be in the research. Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with CGVAMC. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Purpose of the Study

This research is being done to better understand *how Action Planning and Coping Planning (setting specific goals) may help individuals manage heart failure.*

→ *The study is designed to evaluate the influence that setting specific goals has on individuals who want to make changes to help manage the chronic condition called heart failure.*

→ *Heart failure can be a difficult disease to manage because it can be so complex. Many different behaviors contribute to successful management. If someone has trouble making lifestyle changes, we want to know if setting specific goals helps them achieve the behaviors that they want to make.*

→ *Action and Coping Planning have been used to help many people make specific lifestyle changes.*

Approximately 75 subjects may be involved in this research at the CGVAMC.

Procedures

If we do not meet with you while you are in the hospital, you will need to come to the study site one (1) time over the next 4 months. The visit will take about 45 minutes. This visit will be scheduled to coordinate with a scheduled medical appointment.

IRB APPROVAL: 4/12/2016	IRB EXPIRATION: 4/11/2017

[Subject's Identification (Name - Last, First, Middle, SSN :)]

Version Date 3-16

What happens in this study?

1. The study procedures are that you will first fill out two questionnaires.
2. After that, Sabrina Thomas, the Study Coordinator, will talk to you about managing heart failure. This will include instructions that you should know about caring for yourself when you have this disease. This education is provided to all patients with heart failure, whether you agree to be in the study or not.
3. Ms. Thomas will work with you to set the specific goals that are called Action Planning and Coping Planning.
4. Two weeks later, Ms. Thomas will call you and ask you questions about the goals that you set. This phone conversation will take 15 to 20 minutes.
5. Five weeks after the education session, Ms. Thomas will send you copies of the questionnaires that you filled out at the beginning of the study. She will also provide you with a self-addressed, stamped envelope. You will fill out the questionnaires and mail them back to Ms. Thomas.
6. Six weeks after the education session, Ms. Thomas will call you the final time. She will again ask you questions about the goals that you set. She will remind you to mail the questionnaires if you haven't already. This is the final step of the study. This phone conversation will take 15 to 20 minutes.

Standard Care and Experimental Procedures

Some of the study procedures might be done as part of your standard care even if you do not take part in this research study. The education about heart failure and instructions for caring for yourself while you have this disease will be provided to you even if you do not take part in the study. The following procedures are performed for research purposes only: filling out the questionnaires in the beginning and the end of the study and setting specific goals for behaviors to help you manage heart failure.

Risks

There are no known risks known to result from the intervention used in this study. Participation in this study carries no danger above and beyond what you may expect to experience in your daily life.

IRB APPROVAL:	IRB EXPIRATION:
4/12/2016	4/11/2017

[Subject's Identification (Name - Last, First, Middle, SSN :)]

Version Date 3-15

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Subject Name:		Date:	
Principal Investigator:	Dr. Kae Livsey	Subj. #:	
Title of Study:	Using Action and Coping Planning to Support Self-Management of Heart Failure among Veterans		

Anticipated Benefits to Subjects

Participation in this study may or may not help you to manage heart failure.

Alternatives to Participation

You have the option to not participate in this research study.

New Findings

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might influence your desire to continue participation in this study. If new information is provided to you, your consent to continue participating in this study may be re-obtained. If your participation is cancelled the reasons will be explained to you.

Compensation for Participation

You will not be paid for participation in this research.

Costs to Patient

You will not be required to pay for research-related treatment you receive as a subject in a VA research program. You do not have to pay for care or transportation received as a subject in a VA research project except in accordance with federal law. However, some veterans still have to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to standard medical care and services provided by the VA that are not part of this study. You will be expected to pay these costs according to your usual method of payment. Except for required co-payments, there are no additional costs to you for being part of this study. If we need to make an appointment for you to come in to the hospital for the educational session, that appointment will be set for when you have a medical appointment scheduled so that you do not have any travel expenses associated with participation in this study.

| IRB APPROVAL: 4/12/2016 | IRB EXPIRATION: 4/11/2017 |

[Subject's Identification (Name - Last, First, Middle, SSN :)]

Version Date 3-16

VAMC ASHEVILLE, NC (637)		VA RESEARCH CONSENT FORM Page 4 of 6	
Subject Name:		**Date:**	
Principal Investigator:	Dr. Kae Livsey	**Subj. #:**	
Title of Study:	Using Action and Coping Planning to Support Self-Management of Heart Failure among Veterans		

Withdrawal and Termination from the Study

Your participation in this research is VOLUNTARY. If you choose not to participate or decide to withdraw your consent and discontinue participation, this will not affect your relationship with CGVAMC or your health care provider, or your right to health care or other services to which you are otherwise entitled. You have the right to leave a study at any time without penalty.

Your participation in the study may also be discontinued at any time without your consent by the investigator, Institutional Review Board, the FDA or other regulatory governmental agencies. Reasons that your participation may be discontinued:

→ They believe it is in your best interests;
→ to protect your health or safety if you experience a study-related injury
→ if you do not follow study procedures
→ if you do not meet study requirements
→ if the study is cancelled

Privacy and Confidentiality

If you participate in the research, your authorization will be required to have access to your private medical records. You will be asked to sign a separate authorization form to allow us to have this access. If you do not provide this authorization, you may not participate in the research.

The people who will know that you are a research subject are members of the research team, individuals who may have access to your medical record and/or informed consent document due to their job function at the CGVAMC, and, if appropriate, your physicians and nurses. Information about this study and the results of any test or procedure done may be placed in your medical records.
A copy of your signed consent form will be included in your medical record. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except:

- *if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or*
- *when the Institutional Review Board, the Research Compliance Officer, or the Research and Development Committee monitors the research or consent process; or*
- when the Office for Human Research Protections (OHRP), the Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), or other governmental regulatory agencies monitor the research; or if required by law.

IRB APPROVAL:	IRB EXPIRATION:
4/12/2016	4/11/2017

[Subject's Identification (Name - Last, First, Middle, SSN :)]

Version Date 3-15

Study information which identifies you and the consent form signed by you will be looked at and/or copied for examining the research by:
- CGVAMC Research and Development Office and representatives of CGVAMC

CGVAMC Research and Development Office and representatives of CGVAMC may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside the research.
→ *To prevent this from happening, all information that identifies you will be stored on a spreadsheet in a protected folder on the VA server. Information that identifies you will not be entered into the data gathering spreadsheet used for the study. Any hard copies of information specific to you will be kept in a locked cabinet.*
→ *Data and/or research records will be destroyed in accordance with the record control schedule.*
→ *Any data not destroyed will be stripped of all direct and indirect identifiers.*

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Emergency Care and Compensation for Injury
If you are injured or harmed from taking part in this research study, necessary medical care (emergency or non-emergency) for the injury will be provided to you at no cost by the VA. The VA has not set aside funds for other payments if research subjects are injured or harmed. You are not giving up any legal rights or release the VA or its agents from liability for negligence by signing this form.

Whom to Contact
The researchers conducting this study are Sabrina Thomas and Dr. Kae Livsey. You may ask any questions you have about this study now. If you have any concerns or questions later about this study, you may contact Dr. Livsey at 828-654-6523 during the day or after hours at 703-403-2468. If you have questions regarding your rights as a research subject, or research related injury you may contact the Charles George Institutional Review Board (IRB) at 828-298-7911, ext. 5525. To obtain answers to questions about the research, to voice concerns or complaints about the research, you may contact the Human Research Protections Program Office at 828-299-5909. In the event the

IRB APPROVAL: 4/12/2016	IRB EXPIRATION: 4/11/2017

[Subject's Identification (Name - Last, First, Middle, SSN :)]

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