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The Outcomes of COPE, a Cognitive Behavioral Therapy Program, in Patients Awaiting LVAD
Implantation

Submitted in Partial Fulfillment of the Requirements for the Degree of Doctor of Nursing
Practice at the University of Kentucky

By

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2021

Abstract

PURPOSE: The purpose of the Doctor of Nursing Practice (DNP) project was to pilot Creating Opportunities for Personal Empowerment (COPE), an evidence based cognitive behavioral therapy (CBT) intervention, with patients diagnosed with advanced heart failure who are awaiting Left Ventricular Assist Device (LVAD) implantation or those who have had one recently implanted before they are discharged home.

METHODS: A cross-sectional study design was used for this Pilot project. Patients were identified for potential participation by LVAD coordinators and represent a convenience sample. The patients were screened for anxiety and depression using the GAD-7 and PHQ-9 screening tools. If patients scored a 5 or greater on either tool, they received the COPE CBT intervention. COPE is a 7 session CBT intervention with each session lasting 20-30 minutes, delivered every three to four days during the patient's hospitalization following LVAD implantation when patient was able to participate. After the sessions were completed, patients were re-evaluated for depression and anxiety symptoms with GAD-7 and PHQ-9 tools.

RESULTS: Five patients were able to participate during the timeframe of this Pilot Project. The average scores for depression and anxiety symptoms pre-intervention were 10.6 and 10.2, respectively. Post intervention, the scores decreased to an average of 5.4 and 3.2, respectively. Due to the small sample size the results did not reach statistical significance. Qualitative data reported from the participants suggests that they felt the intervention was helpful.

CONCLUSION: Though the results did not achieve statistical significance, the decreases in average score represent clinically-significant decreases in depression and anxiety symptoms. More research is needed to confirm statistical and clinical significance of these findings. This

project does show that it is possible to implement a multi-session CBT intervention with advanced heart failure patients who have recently received LVAD implantation.

Acknowledgements

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Dedication

I would like to dedicate this project to Jesus Christ in whom all my hope and strength is found. May this mark the first of many new steps to bring people the best of medicine and faith and to bring people back to healing and wholeness. This project is also dedicated to my wife, Brooke, who has sacrificed, supported, believed, cried with, and pushed me through this marathon journey; and to my two girls, Kyla and Darah, Daddy loves you very much! I want you both to know that you can do anything if you are willing to work hard for it. Thank you to my parents and in-laws who have prayed for, encouraged, watched children, bought books, and brought food. Thank you to my friends and coworkers who have helped keep me going- there are too many to name. I could not have completed this journey without all of you. "Five years will come and go." Well Marilyn, it's gone now!

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Background and Significance

Problem Statement

The National Institutes of Mental Health (NIMH), reported in 2017 that Major Depression affects roughly 7.1% of adults and is the leading cause of disability in the United States. Approximately, 31.1% of adults in the United States have been diagnosed with an anxiety disorder (NIMH, 2017). Patients with advanced heart failure are at an increased risk for developing symptoms of depression and anxiety (Celano et al., 2018).

Context, Scope, and Consequences of Problem

In 2014, there were over 1 million emergency room admissions and just under 1 million hospitalizations related to heart failure with each admission costing around \$11,000 (Jackson et al, 2018). The incidence of depression in patients with heart failure is approximately 20%, which is 2-3 times greater than the general population (Rustad et al., 2013; Celano et al., 2018). Depression is also associated with increased hospitalizations, arrhythmias, increased inflammation and increased mortality. According to Ghosh et al. (2016), the high 30-day readmission rates (~17%) for patients with heart failure is partially related to the effects of depression and anxiety. Anxiety is also a problem for patients with heart failure with nearly 13% meeting diagnostic criteria for generalized anxiety disorder and 30% having clinically significant symptoms (Celano et al., 2018).

Current Evidence Based Strategies

A recent meta-analysis by Das et al. (2019) considered 21 randomized control trials (RCT) comprising over 4,500 patients. The findings from their analysis suggest that exercise therapy followed by cognitive behavioral therapy (CBT) are more effective than anti-depressant

therapy, though the results are not strongly conclusive (Das et al, 2019). Multiple studies suggest that CBT is effective for addressing the problem of depression and anxiety in patients with heart failure (Celano et al., 2018; Dekker et al., 2011; Dekker et al., 2012; Gary et al, 2010; Jeyananatham et al., 2017; Lungren et al, 2016).

The primary population that Creating Opportunities for Personal Empowerment (COPE), a CBT intervention, has been studied with is school-aged children and high school students. Several studies that implemented COPE did show positive results with reducing depression and anxiety symptoms (Melnyk, Jacobson, Kelly, Belyea et al, 2015; Melnyk, Kelly, & Lusk, 2014; Melnyk, Kelly, Jacobson, Arcoleo, 2013; Lusk & Melnyk, 2011). Dr. (Melnyk, et al., 2013 has also developed a version of COPE program for adult patients, which was used in this DNP pilot study.

There are significant gaps in the literature concerning the use of CBT in patients with heart failure. While there are multiple studies that suggest that it is of some benefit for reducing anxiety and depression symptoms, especially in the short term (Freeland et al, 2015; Lundgren, Dahlström et al, 2016; Lundgren, Andersson & Johansson, 2015; Rustad et al, 2013; Tully et al, 2015), there are questions about factors that contribute to the success or failure of CBT for these patients such as the severity of heart failure, activity level, and sleep schedule (Smagula et al, 2019). Das, Roy, Schwarzer et al, 2019; Hundt et al., 2018; Jevenatham, 2017; Lundgren, Andersson, & Johansson, 2015 suggest that further study is needed to assess the factors which could improve the longitudinal gains from CBT. A combination of CBT, exercise therapy, and pharmacologic agents are helpful useful for treating depression and anxiety in patients with heart failure (Das et al, 2019; Gary et al, 2010; Rustad et al, 2013).

People with cardiovascular disease have an increased incidence of co-morbid psychiatric conditions, specifically depression and anxiety. Several studies have substantiated that CBT is helpful for treating depression and anxiety symptoms (Dekker et al., 2012; Freedland et al., 2015; Lundgren et al., 2016). One recent DNP project completed at the University of Kentucky demonstrated that patients with cardiovascular disease had a high incidence of depression following their heart surgery but a short cognitive behavioral therapy (CBT) intervention was beneficial for helping to address some of the post-operative depression and anxiety (Coles, 2018). Coles found that a short CBT intervention was possible to employ and effective for this population even while they were convalescing in the hospital. This current DNP project applies some of these findings to patients with heart failure.

Purpose

The purpose of this DNP Project was to pilot Creating Opportunities for Personal Empowerment (COPE), an evidence based cognitive behavioral therapy (CBT) intervention, with patients diagnosed with advanced heart failure who are awaiting Left Ventricular Assist Device (LVAD) implantation or those who have had one recently implanted before they are discharged home.

Objectives

The objectives of this DNP project are two-fold. The first objective was to identify patients with advanced heart failure who are experiencing depression and anxiety symptoms to capture the scope of the problem in this population. The second was to pilot COPE in patients who are recovering from LVAD implantation surgery. The third was to evaluate their symptoms of depression and anxiety pre and post intervention. At this time, the current practice at this

institution is for the clinical social worker to screen the prospective LVAD recipients for anxiety and depression, using the PHQ-9 and GAD-7 tools, as part of the initial work up. However, beyond documenting these scores very little is done in terms of psychiatric care. The goal of piloting the COPE CBT intervention with this population was to determine if CBT is effective in reducing anxiety and depressive symptoms as demonstrated through pre-post PHQ-9 and GAD-7 scores. This intervention addresses a current gap in the overall care of this patient population.

Theoretical Framework

There are two related theories that inform the theoretical framework of this DNP project: Theory of Reasoned Action (TRA) which is the progenitor of the Theory of Planned Behavior (TPB). Both of these theories were developed by Azjen and Fishbein. The Theory of Reasoned Action was developed in 1975 to explain behavioral choices (Fishbein and Azjen, 1975). In the TRA, attitudes and subjective (societal) norms determine intentions to act which lead to behaviors (Fishbein and Azjen, 1975). Attitudes are an individual's perceptions regarding the consequences of a choice (Azjen, 2020). Societal norms are the understood values of "everyone else" (Azjen, 2020). Societal norms may not necessarily mean the culture at large but could be the family, friend circle, or people of importance surrounding an individual (Azjen, 2020). TPB adds to TRA by incorporating the idea of perceived behavioral control as a third factor that influences behavior. Perceived behavioral control is the degree to which an individual feels they can change a situation. In TPB, the sum of these three factors influence the individual's intention to act in one way or another (Azjen, 2020).

The Theory of Reasoned Action and the Theory of Planned Behavior guided this DNP project because CBT, which COPE is based on, suggests that how one thinks determines feelings which

lead to behaviors (Anxiety and Depression Association of America, 2021). Therefore, if behavior is to be influenced, changing thoughts regarding a behavior is essential if a positive outcome is to be achieved. Depression and anxiety symptoms can cause people to feel poorly and, consequently, they may be less likely to be compliant with their treatment regimen. COPE is a tool to help people develop more perceived behavioral control and a better attitude for dealing with these challenging problems so that they can achieve better health outcomes. An illustration of TRA and TPB is included in figure 1.

Review of Literature

A literature review was performed in order to assess the level of knowledge regarding the treatment of anxiety and depression with CBT in adult patients with heart failure. A search of the CINAHL with full text database using the search terms CBT and Heart failure was conducted. 18 articles were found in the initial search. The results were further filtered by peer reviewed and research articles which left 11 articles. Articles older than 10 years were excluded leaving nine. One more was excluded because it focused on sleep disturbance leaving eight articles that were included in this review. The types of articles that were found were: one secondary analysis, one review, four randomized control trials, one meta-analysis, and one quasi-experimental study.

A PubMed search was also conducted using the same search terms which yielded 46 articles. These results were further filtered by looking at those published in the last 10 years which left 38. Next full free text filter was applied which yielded 20 results. Finally, only those articles that were randomized control trials or meta-analysis were included which left seven. Of

those seven, three additional articles were excluded because they focused on the use of CBT for insomnia in patients with heart failure leaving four to be included from the PubMed search. However, all four of these articles were duplicate findings from the CINAHL search.

A literature search was also conducted on the APA PsycInfo database using the search terms CBT and heart failure. 25 articles were initially returned using those terms. Articles outside the years of 2010-2020 were excluded which left 22. Peer reviewed article filter was applied yielding 20 articles. Those articles that were duplicates from the other searches were excluded as well as ones that did not include the target population of patients with heart failure leaving five additional articles to be included in this review. The five articles that were added from this search were comprised of one quantitative study, one qualitative study, a meta-analysis, a review, and a randomized control study. A total of 13 articles were used from these three database sources for this literature review.

The literature was also reviewed on the utilization of COPE. A search of the APA Psycinfo database was conducted using the search terms COPE, CBT, and Melnyk. Ten articles were returned from this search. Five of the articles focused on the use of COPE with pediatric and adolescent patients (Kozlowski et al., 2015; Lusk & Melnyk, 2011, 2013; Mazurek Melnyk et al., 2014; McGovern et al., 2019). In three articles COPE was used with adults (Buffington et al., 2016; Hart et al., 2019; Melnyk, Amaya et al., 2015) and one article reported about training graduate psychiatric advanced practice nursing students (Lusk et al., 2018). The final article discussed lessons learned from implementing COPE in one of the pediatric studies (Lusk & Melnyk, 2011). Pubmed and CINAHL searches were also completed using the same search terms. No new articles were returned from these searches.

Synthesis of the Literature

The most important finding from this literature review was that CBT is an effective treatment modality for treating symptoms of anxiety and depression in patients with advanced heart failure. Two of the reports were meta-analysis, concerning the use of CBT in patients with heart failure from 2017 and 2019. The most recent meta-analysis by Das et al. (2019) considered 21 randomized control trials (RCT) comprising over 4,500 patients. In addition, they reported that exercise therapy and CBT had therapeutic benefits in treating depression and anxiety in patients with heart failure (Das et al, 2019). Jeyantham et al (2017) reported that CBT improved depression scores on the Beck Depression Inventory, PHQ-9, and the Ham-D scales, both initially and at three months follow up. Five RCTs reported that CBT is effective in reducing anxiety and depression symptoms in patients with heart failure (Cockayne et al., 2014; Freeland et al., 2015; Hundt et al., 2018; Lungren et al., 2016; Smagula et al., 2019). In addition, Hundt et al (2018) reported that patients who had greater limitations on physical function and decreased self-efficacy experienced less benefit from CBT. Tully et al. (2015) reported that the use of CBT was significantly associated with improvements in GAD-7 and PHQ-9 scores as well as better participation with a community-exercise program.

Three of the articles in this literature review reported ambivalent findings regarding the utility of CBT for patients with heart failure. Smagula et al (2019) reported that about half of patients with advanced heart failure who received CBT did not improve with their depression and anxiety symptoms. Mejia et al (2014) reported a secondary analysis of Cockayne et al (2014) considering the cost effectiveness of nurse guided outpatient CBT compared to self-

guided outpatient CBT. There was no significant difference in cost effectiveness or improvement in QALY (Quality Adjusted Life Years). Gary et al (2010) reported that CBT reduced depression scores on HAM-D scale however they were not statistically significant.

It was also found that more studies were needed to further evaluate the use of CBT in patients with advanced heart failure. Cockayne et al., 2014; Mejia et al., 2014; Lungren et al., 2016; Freedland et al., 2015; Gary et al., 2010 reported offering web-based, discussion board type, self-directed, or specialist delivered CBT to their patients. Celano et al (2016) reports that depression and anxiety are underdiagnosed in patients with heart failure and that further study was needed as did several others (Das et al., 2019; Hundt et al., 2018; Jevenatham et al., 2017; Lungren et al., 2016; Smagula et al., 2019).

There were two significant findings from the literature regarding COPE. The first finding that was consistent in nearly all the articles was that it was effective at reducing depression and anxiety symptoms. In one adult study, Hart et al (2019) found that depression and anxiety symptoms, as measured by Beck Depression Inventory and State- Trait Anxiety scale, showed statistically significant improvement following the COPE intervention. The five studies in pediatric and adolescent patients all found statistically significant improvements in anxiety and depression symptoms as measured by Beck Youth Inventory and SCARED assessment tools.

One that did not show statistically significant decreases in both anxiety and depression symptoms was Melynk et al. (2015). This study was focused on college freshmen and delivered the COPE intervention via online modules (Melynk et al., 2015). However, students that did have severe anxiety symptoms before COPE did show statistically significant improvements post intervention as indicated by GAD-7 scores (Melynk et al., 2015). The other article that did

not show statistically significant improvement in anxiety symptoms was Buffington et al (2016). This study evaluated the effect of COPE in female student athletes experiencing stress and anxiety while trying to maintain body composition, nutritional status, and improve knowledge. Following the COPE intervention, students did experience a decrease in GAD-7 scores but it was not statistically significant. However, students in the control group actually experienced an increase in their GAD-7 scores, indicating benefit for the COPE intervention.

The other important finding was that COPE is an intervention that can be applied across a broad range of population and by several different means. Hart et al., 2019; McGovern et al., 2019; Kozlowski et al., 2015; Melnyk et al., 2014; Lusk et al., 2011 show that COPE can be applied to children, adolescents, and adults. It is also an intervention that can be shared and learned by others as seen in Lusk et al (2018). COPE can be used in the outpatient setting (Lusk et al., 2011) delivered by self-guided online modules (Melnyk et al., 2015) and even in schools as a lunch group therapy session (McGovern et al., 2019).

Gaps in Practice

There are a significant number of gaps in the literature concerning the use of CBT in patients with heart failure. There are multiple studies that suggest that it is of some benefit for reducing anxiety and depression symptoms, especially in the short term (Freeland et al, 2015; Lundgren, Dahlström et al, 2016; Lundgren, Andersson & Johansson, 2015; Rustad et al, 2013; Tully et al, 2015). There are questions about factors that contribute to the success or failure of CBT for these patients such as the severity of heart failure, activity level, and sleep schedule (Smagula et al, 2019). Nearly all of the studies found in this search suggest the need for further

study especially for factors to improve longitudinal gains from CBT (Das, Roy, Schwarzer et al, 2019; Hundt et al., 2018; Jevenatham, 2017; Lundgren, Andersson, & Johansson, 2015).

It is likely that a combination of CBT, exercise therapy, and pharmacologic agents are effective treatment modalities for depression and anxiety in patients with heart failure (Das et al, 2019; Gary et al, 2010; Rustad et al, 2013). However, it is important to more fully explore each of these components individually.

Patients with advanced heart failure have an increased risk for co-morbid psychiatric illness. Accessing mental health providers and therapeutic modalities such as CBT in the non-psychiatric acute inpatient setting can be challenging for those presenting with an exacerbation of advanced heart failure (Bopp, 2017). Since most CBT interventions take place over many weeks, few multi-session interventions have been studied with patients who are hospitalized related to heart failure.

Methods

This was a quasi-experimental pretest and posttest design with patients who were awaiting Left Ventricular Assist Device (LVAD) implantation or had one recently implanted. These patients were screened for interest in participating by the LVAD coordinators. If the patient expressed interest, the PI approached and explained about the study and obtained informed consent. Subjects were not randomized in this project. Patients are screened with PHQ-9 and GAD-7 tools during their LVAD workup by a social worker. It may be an extended period of time before the patient is admitted to the hospital for surgery, thus obtaining a new baseline score was needed.

COPE is a seven-session, workbook guided, cognitive behavioral therapy (CBT) intervention. The individual sessions take approximately 20-30 minutes to complete and the patient is given a workbook to practice skills learned in the sessions. Sessions can be spaced out to every three to four days for people who are in the hospital. They can also be completed in the outpatient setting or via telehealth if they are discharged before being able to complete all sessions. Offering CBT to hospitalized patients is an innovative idea because traditionally it is offered in the outpatient setting over the course of 12-16 weeks.

Setting

This DNP project was conducted at the University of Kentucky Chandler Medical Center, the main campus of UK Healthcare (UKHC). This facility is an academic medical center with over 800 beds, certified as a Level 1 trauma center and has achieved Magnet nursing status. Patients with advanced heart failure are placed in cohorts on the cardiovascular (CV) service line which is comprised of two units, a 32-bed intensive care unit and 32 bed progressive unit, with an additional 40 telemetry beds in another section of the hospital. Every Friday, there is an outpatient clinic for patients with advanced heart failure who have received an LVAD. UKMC performs an average of 20-30 LVAD implantations per year. At any given time, there are two to ten patients with LVADs admitted to the hospital. The average length of stay according to the coordinators is two to six weeks following implantation of a new device.

Congruence with organization mission, goals, and strategic plan

UK Healthcare (UKHC) presents its core values through the DIRect acronym which stands for Diversity, Innovation, Respect, Compassion, and Teamwork. Deploying an intervention to address the mental health needs of a population of patients that has a known,

largely unmet need fits well with this mission statement. Increasing access to mental health services in the acute care setting is in the interest and values of the UK Healthcare enterprise. This DNP project is congruent with the mission and goals of the UKHC as it evaluates the use of a CBT based intervention in the treatment of symptoms of depression and anxiety in hospitalized patients with advanced heart failure. Currently, there is minimal screening of these patients for depression and anxiety due to limited resources.

Stakeholders

The key stakeholders for this DNP project include:

Patients and their families. The research in this area is clear that this patient population have increased rates of depression and anxiety (Celano et al., 2018)

Dr. Lacey Buckler- Chief Advanced Practice Officer.

Dr. Buckler is a panel member as well as a supporter of the implementation of this DNP project.

Dr. Andrew Kolodziej- Medical Director Heart Transplantation

Dr. Kolodziej is one of the primary physician champions of the implementation of this DNP project. He has also committed to serve as a panel member for the DNP panel.

Dr. Rajasekhar Malyala- Cardiothoracic Surgeon

Dr. Malyala is the primary surgeon who implants LVADs at UKHC. He expressed support for this project because of the need to holistically support these patients and address their mental health needs.

LVAD Coordinators

The LVAD coordinator team is comprised of four BSN-prepared registered nurses who serve as the primary contact point for these patients. Together they support approximately 80 patients who have received LVADs. The coordinators are the first people on the medical team to address any issues that these patients experience. The issues they take care of range from psycho-social issues to medication management and obtaining various resources needed by these patients. One of the themes that they have shared is that a significant number of the issues are psycho-socially because these issues affect all areas of care.

Julia Akhtarekhavari BSN- Mechanical Circulatory Support (MCS) Director

Julia is the manager over the MCS program and her support of this project is crucial both for helping to identify patients that may benefit from participating in this project as well as being a champion for the project.

Bedside nurses

Nurses are the hands, ears, and eyes of the healthcare team. Before formalized screening occurs, they may recognize patients that are exhibiting signs of depression and anxiety. With additional training, bedside nurses could be trained to deliver this CBT intervention.

Facilitators and Barriers

There are several facilitators for the implementation of this project. One of the most important is that this project matches well with the UKHC Enterprise goals of providing innovative and wholistic care for each patient. This DNP project includes an innovative

application of cognitive behavioral therapy to address the known problem of depression and anxiety in this population.

One potential barrier is related to the stigma associated with mental illness and mental healthcare. Patients may not participate because they do not recognize the symptoms of depression and anxiety or the value of mental healthcare. Another barrier could be the time commitment of the patients to participate in the project.

The COPE CBT intervention is an innovative approach to addressing the psychiatric needs of patients with advanced heart failure. This intervention has great potential to be applied to many other patient populations should this project prove to be successful. COPE has been shown to decrease the severity of depression and anxiety symptoms in adults (Hart et al, 2019).

Sample

The DNP project sample was a convenience sample at a single academic medical center. Since the PI did not have direct access to the potential participants of this project, the LVAD coordinators approached the patients who were going to have an LVAD implanted to determine their interest in participating in this DNP project. LVAD coordinators are BSN prepared nurses who organize the care for these patients and have established access to them. If the patients expressed interest in learning more about the project, LVAD coordinators informed the PI who approached the patients and offered the option of participation in the study. Once informed consent was obtained, patients were screened for depression and anxiety

symptoms using the PHQ-9 and GAD-7 screening tools. If the patients screened positive for at least mild symptoms of depression or anxiety, they were offered the COPE intervention.

Procedure

IRB Approval

Approval for this project was first received from the UK Healthcare Nursing Research Council in October of 2020. Before implementation of this DNP project, an expedited application was submitted to the Institutional Review Board (IRB) at the University of Kentucky. The IRB was approved in December 2020. The project was implemented soon after and was completed on March 15, 2021.

Description of Evidence-Based Intervention

COPE was delivered over the course of seven 20 to 30-minute sessions utilizing the manual for adults. The sessions were organized by topic in the manual: Thinking, feeling, and behaving; Self-esteem and positive thinking/self-talk; Stress and coping; Problem solving and setting goals; Dealing with your emotions in healthy ways; Coping with stressful situations/valuable Sleep; and Pulling it all together for a healthy you. The sessions were conducted every three days while the patients were recovering in the hospital as they were ready to participate. Patients were assessed for readiness based on a glasgow coma scale of 15 and stating they were ready to participate. Most of the patients completed the first session before their surgery. If the patients were discharged before all the sessions could be completed, zoom calls were scheduled at convenient times at the same interval in order to complete all the sessions. Following the final session, the participants received follow up screening for depression and anxiety using the PHQ-9 and GAD-7 tools.

Measures and Instruments

Demographic data (age, gender, highest level of education, employment status, marital status, and New York Heart Failure classification score) was collected from participant chart. In order to assess depression and anxiety symptoms in patients with heart failure, it is important to use valid and reliable screening tools. The tools that were used in this DNP project were the GAD-7 and the PHQ-9. The GAD-7 tool was developed by Spitzer et al (2006) because there was a need for a simple assessment for generalized anxiety disorder. It is a seven-question assessment where patients rate how frequently various symptoms have bothered them in the past two weeks. It has been shown to have reliable sensitivity and specificity for identifying generalized anxiety disorder (Spitzer et al., 2006). The rating options are “not at all, several days, more than half the days, and nearly every day”, which correspond to scores of 0,1,2,3 respectively (Spitzer et al., 2006). The scored responses to the seven questions are summed which yields an overall score from 0 to 21, score cut offs at 5, 10, and 15 represent mild, moderate, and severe symptoms (Spitzer et al., 2006). The GAD-7 tool has good internal consistency with a Cronbach’s alpha of between 0.79-0.91 (Dear et al., 2011).

The PHQ-9 was developed by Kroenke et al (2001) from the PRIME-MD diagnostic tool. The PHQ-9 scores nine criteria from the DSM IV for depression. Patients are asked to consider the nine questions in the timeframe of the past two weeks. They rate how often they experience various symptoms from not at all to nearly every day. The responses are given a score of zero to three and summed together for a total of zero to 27. The scoring cutoffs for the PHQ-9 tool are 5, 10, 15, and 20 which correlate with mild, moderate, moderately severe, and

severe depression (Kroenke et al., 2001). According to the American Psychological Association, the PHQ-9 tool has Cronbach's alpha between 0.86-0.89 (2011).

Data Collection

Data was collected pre intervention included: demographic information, PHQ-9 and GAD-7. Post intervention data was collected on the PHQ-9 and GAD-7. All data was entered into the REDcap application via the PI's mobile device for secure data storage. Data was de-identified and assigned random subject ID.

Data Analysis

All data was analyzed using SPSS statistical software version 25 with an alpha of 0.05. Frequency distributions were used to summarize the demographic characteristics of the participants. Pre-intervention and post intervention scores were evaluated using the paired t-test.

Results

Demographics

The demographic characteristics are shown in table 1. Six patients were identified during the timeframe of this study; five were included based on their screening scores on the PHQ-9 and GAD-7 tools. A score of 5 or greater on either tool was needed for inclusion to the intervention. One was excluded due to not scoring 5 or higher on either tool. The gender characteristics of the participants were four male and one female. Three of the participants were married and two were single. The educational level that the patients had achieved was either high school or college degree. Sixty percent had completed high school and forty percent

had completed a college degree. All of the participants were Caucasian and unemployed between 28 and 71 years of age. The average age of the patients was 57 years old.

Findings

The average initial PHQ-9 and GAD-7 scores for the participants were 10.6 and 10.2, respectively. The PHQ-9 tool has been shown to have 88% sensitivity and 88% specificity for identifying major depressive disorder at scores greater than or equal to 10 (Kroenke et al., 2001). The GAD-7 tool has been shown to have 89% sensitivity and 82% specificity for identifying generalized anxiety disorder at scores 10 or above (Spitzer et al., 2006). These initial scores suggest that the participants likely were experiencing moderate depression and anxiety before implantation of their LVAD device.

Following the COPE CBT intervention, the average scores decreased to 5.2 and 3.4 (PHQ-9 and GAD-7). These scores indicate that the depression and anxiety symptoms decreased to mild or minimal at the end of the intervention. Unfortunately, the p-value for the differences in these pre-post scores did not reach a level of statistical significance, likely due to the small sample size. Frequency distributions were used to summarize the demographic characteristics of participants. Pre-intervention and post-intervention scores were evaluated using the paired t-test. All analysis was conducted using SPSS, version 25 with an alpha of .05. The results can be viewed in table 3.

There were some important qualitative results from this study. All of the patients expressed appreciation for the study intervention and felt that it was valuable and helpful. A family member of one of the participants reported that their loved one's mood improved significantly after they began participation with this DNP project. They noted that "since having

two counseling meetings, his mood has been less labile, he has been getting out of the house to go visit friends, sleeping better, and just shown an overall improvement in his mental health.”

This participant had initially not scored high enough before implantation of the LVAD to receive the intervention while he was in the hospital. However, his LVAD coordinator and a family member became concerned about him after he was discharged from the hospital. During his first follow-up appointment 2 weeks after discharge, he was re-screened for depression and anxiety and found to be experiencing mild symptoms by both PHQ-9 and GAD-7 tools. He participated in the intervention via zoom appointments and experienced benefit from the therapy sessions.

Another patient, during the final session of the CBT intervention, cried and hugged the PI. “You don’t know how much this has meant to me.” He reported that he had felt scared about going home but was grateful to have some new strategies to get through future challenges.

Discussion

The findings from this DNP project support the implementation of the COPE program for adults for reducing both depressive and anxiety symptoms in patients who have received an implanted LVAD. The results of this project are similar to those reported by Ishak et al (2020) in their meta-analysis of depression in heart failure. They report that depressive symptoms have a prevalence in up to 85% of patients with heart failure (Ishak et al., 2020). The prevalence of mild to moderate depressive symptoms in this DNP project was 83%. It is possible that this finding is due to concerns regarding their impending surgery and hospitalization. However, this result does support recommendations by the American Heart Association that patients with

advanced heart failure should be screened for depression (Lichtman et al., 2008; Merschel, 2020).

"Depression and depressive symptoms are not just in the brain," Celano said. "Your brain is connected to every other part of your body. We know more and more that these connections between the brain and the rest of the body go both ways. So things that happen in your body can affect how you think and feel. And changes in your brain can affect many different parts of your body, including your heart." (Merschel, 2020)

Most of the patients, who participated in this DNP project, screened positive for mild to moderate anxiety. Both anxiety and depression are associated with poor outcomes for patients with heart failure (Celano et al., 2018) and this DNP project highlights the need both for further study and continued intervention to address these conditions.

Implications

Offering short CBT interventions to patients with advanced heart failure and cardiovascular disease while they are hospitalized has shown positive results (Coles, 2018; Dekker et al., 2012). Most patients with hospital admissions related to heart failure have an average length of stay less than 6 days (Tashtish et al., 2017). However, patients who receive implantation of LVAD are usually hospitalized for 2-6 weeks at this institution. This timeframe provides an excellent opportunity to offer patients CBT while they are recovering from their surgery. This DNP project presents some interesting findings regarding the use of CBT with patients in the acute hospital setting. The reduction in anxiety and depressive symptoms aligns with previous findings that CBT is effective for patients with advanced heart failure.

Future studies could also consider enrolling the primary caregiver in addition to the patient receiving the LVAD. According to Bidwell et al (2016), caregivers experience a decrease in quality of life following LVAD implantation, despite improvement for the patient. Some of the decreased quality of life was related to stress, anxiety, and depression. COPE could be beneficial for the primary caregiver as well as the patient.

Further research is needed to see if the benefits are sustained such as reduced readmission rates, decreases incidence of gastrointestinal bleeding, decreased incidence of drive line infection, and decreased depression and anxiety symptoms. If these benefits persist then further investment in this kind of intervention is warranted. It is also important to assess for longitudinal benefits such as effects on readmission rates, other quality indicators such as driveline infection rates, incidence of gastrointestinal bleeding, and one-year survival rate. An embedded psychiatric nurse practitioner could be the ideal way to solidify the implementation of CBT at this institution. In addition to offering therapy, a psychiatric nurse practitioner could also work in conjunction with the medical team to provide medication management for anxiety and depressive symptoms which are common in this population. A systematic review by Oldham et al (2019) concluded that there appears to be some benefit to a collaborative care model incorporating psychiatric services with the primary medical management of general hospital patients. Their review showed a decrease in length of stay and favorable cost-benefit for the enhanced care (Oldham et al, 2019).

Limitations

There are several limitations related to this project. One of the most significant was the sample size (n=5). Due to the small sample size the effects of the intervention did not reach statistical significance though they did show clinical significance with the reduction in average scores on the PHQ-9 and GAD-7 tools. A larger sample size performed at multiple centers with follow up at 6 and 12 months could help solidify the hypothesis that these results would become statistically significant and potentially lead to long-term benefits for the participants.

The participants were homogenous with regard to ethnicity and gender. All of the patients were Caucasian and five were male. A larger sample set with greater diversity of participants both in terms of gender and ethnicity would make findings more generalizable especially considering heart failure has an increased prevalence in other ethnicities and races compared to Caucasians (Virani et al., 2020).

Another limitation of this project is the lack of randomization with regard to who received the pilot intervention. Some might suggest that the improvements in the depression and anxiety scores are related to the patient's general recovery and adjustment to the LVAD rather than benefits of the CBT. By randomizing patients to receive standard care and CBT, the effects of the CBT could be compared to the general improvement and alleviation of heart failure symptoms that patients generally experience once the device is implanted.

Conclusion

The purpose of this DNP project was to pilot Creating Opportunities for Personal Empowerment (COPE), an evidence based cognitive behavioral therapy (CBT) intervention, with patients diagnosed with advanced heart failure who are awaiting Left Ventricular Assist Device

(LVAD) implantation or those who have had one recently implanted before they are discharged home. These patients have an increased risk for anxiety and depression especially considering the 5-year survival rate after first hospital admission is only 25% (Jeyantham et al., 2017). In addition to the high risk for mortality, patients with LVADs also have the stress of managing an implanted device which requires significant lifestyle modifications and additional stressors including worries about pump failure, burdening their families and loved ones, not being able to participate in activities that they previously enjoyed (Costello, 2019). All participants demonstrated symptoms of depression and/ or anxiety and the COPE program was successfully implemented for all five participants. This project demonstrated that using a multi-session CBT based intervention, such as COPE, was effective in decreasing the severity of depression and anxiety symptoms in hospitalized patients with an LVAD. Although the results were not statistically significant, they indicated that the COPE intervention could be beneficial. Participants experienced clinically significant decreases in severity of anxiety and depressive symptoms. In addition, the patients consistently stated that they felt better after participation in this project.

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Tables and Figures

Table 1. Demographic characteristics of participants (*N*)

	<i>n</i> (%)
Gender	
Male	4 (80)
Female	1 (20)
Marital Status	
Married	3 (60)
Single	2 (40)
Highest Educational Level	
High School	3 (60)
College Degree	2 (40)
Ethnicity	
Caucasian	5 (100)
Employment Status	
Unemployed	5 (100)
New York Heart Association Heart Failure Score	
Class II	2 (40)
Class III	3 (60)

Table 2.

Descriptive Statistics					
	N	Minimum	Maximum	Mean	Std. Deviation
Age	5	28	71	57.20	16.814
Valid N (Listwise)	5				

Table 3. Pre-and post-intervention scores ($n=5$)

	Pre-intervention Mean (SD)	Post-intervention Mean (SD)	p
PHQ-9	10.6 (6.3)	5.2 (3.3)	.21
GAD-7	10.2 (6.6)	3.4 (4.9)	.1

Figure 1

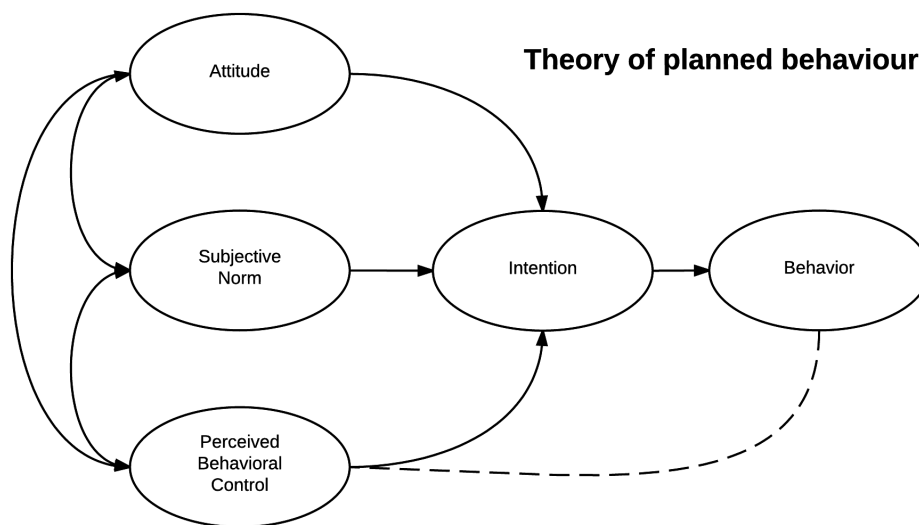


Image obtained from: https://en.wikipedia.org/wiki/Theory_of_planned_behavior

Appendices

Appendix A

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME: _____ DATE: _____

Over the last 2 weeks, how often have you been bothered by any of the following problems?
(use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself	0	1	2	3

add columns + +

(Healthcare professional: For interpretation of TOTAL, TOTAL:
please refer to accompanying scoring card).

10. If you checked off <i>any</i> problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all	_____
	Somewhat difficult	_____
	Very difficult	_____
	Extremely difficult	_____

Appendix B
Generalized Anxiety Disorder 7-item (GAD-7) scale

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all sure	Several days	Over half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
<i>Add the score for each column</i>	+	+	+	

Total Score (*add your column scores*) =

Retrieved from: <https://www.oma.noaa.gov/find/media/images/generalized-anxiety-disorder-7-item-gad-7-scale>