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The Journey to Heart Transplant: Evaluating A Brief Mindfulness Intervention on Hospitalized
Heart Failure Patients' Stress, Anxiety and Resilience

A dissertation submitted in partial satisfaction of the
requirements for the degree
Doctor of Nursing Practice

by

Elizabeth Vandenberg

2021

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ABSTRACT OF THE DISSERTATION

The Journey to Heart Transplant: Evaluating A Brief Mindfulness Intervention on Hospitalized Heart Failure Patients' Stress, Anxiety and Resilience

by

Elizabeth Vandenberg

Doctor of Nursing Practice

University of California, Los Angeles, 2021

Professor Carol Pavlish, Chair

Background: Patients hospitalized with life-threatening conditions are exposed to constant psychological stressors that can lead to anxiety and poor patient outcomes. Mindfulness stress reduction interventions have been shown to decrease stress and anxiety with sustained effect. **Objectives:** This project aims to evaluate the feasibility and effect of a brief mindfulness intervention (MBI) on stress, anxiety, and resilience in advanced heart failure patients, hospitalized awaiting transplant. **Methods:** A one group, pretest-posttest design over a 4-week period in a single center's cardiac care units was used. The intervention included a one-on-one

mindfulness educational session and a 12-minute audio guided iPad application for daily self-practice. Variables measured at baseline, and every 2 weeks post intervention included stress (The Perceived Stress Scale [PSS]), anxiety (the Generalized Anxiety Disorder [GAD-7]) and resilience (the Brief Resilience Scale [BRS]), with patient demographics and self-reported mindfulness performance collected. Statistical analysis included descriptive statistics, repeated measures ANOVA with Friedman tests verification, Bonferroni post hoc tests and Wilcoxon matched pairs tests applied. **Results:** Statistically significant differences were found from baseline to 2 and 4 weeks after intervention in reduced stress ($p=.001$) and anxiety ($p=.001$) and increased resilience ($p=.001$). The greatest change was seen at 2 weeks post intervention and was maintained at 4 weeks. Additionally, feasibility and acceptability of the MBI were evident from the patient experience survey data and focused interview responses. **Conclusion:** A brief mindfulness intervention holds promise in improving stress, anxiety and resilience for advanced heart failure patients awaiting transplant. Nurses could help to alleviate symptoms of distress through education on use of a mindfulness app in the daily patient care plan. Further study in a larger sample is warranted.

The dissertation of Elizabeth Vandenberg is approved.

Anna Gawlinski

Karen Grimley

Mary Ann Lewis

Carol Pavlish, Committee Chair

University of California, Los Angeles

2021

This dissertation is dedicated to my loving husband Michael, sister Fran and family for their unwavering support, and encouragement to always reach further. This project is in honor of my parents William and Catherine who instilled a determined work ethic and desire for ongoing education and to my sister Josie who's battle inspired the project meaning and concept.

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Questionnaires Utilized:

Perceived Stress Scale (PSS) with permission

Generalized Anxiety Disorder 7 Scale (GAD 7) permission not required

Connor-Davidson Resilience Scale (CD-RISC 10) with permission

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CHAPTER ONE: INTRODUCTION AND BACKGROUND

The patient journey to heart transplantation is arduous. Advanced heart failure (HF) patients who are hospitalized awaiting heart transplant are under continuous stress. These clinically tenuous patients have a high mortality risk of 10-15% on the transplant waitlist given the limited donor heart availability (Fudim, 2017). The uncertainty and threat of survival coupled with the need to be hospitalized for weeks to months with little control or independence intensifies an inherently stressful period. Separation from the home environment and family, particularly during a pandemic, contributes to feelings of isolation. Constant exposure to unavoidable stressors frequently leads to states of anxiety and depression influencing clinical outcomes that include adverse cardiac events and death (Hiriscau & Bodolea, 2019; Li et al., 2020; Pedersen et al., 2017). Thus, stress reduction interventions in this vulnerable patient group are necessary and an evidence-based intervention of mindfulness practice may be one option.

When one's adaptive coping or personal resources are unable to adequately mitigate stressors, anxiety and/or depression can develop (Carangdan, 2015). Swartz and colleagues (2015) examined threat related neural activity in healthy young adults and found when fearful stimuli combine with a major life stressor (e.g., death in the family, medical illness, or financial uncertainty) depression or anxiety can develop as long as 4 years afterward. The incidence of anxiety and depression in the advanced HF patient awaiting transplant is estimated at rates of 20 to 36% and 18% to 50%, respectively (Bui et al., 2019; Easton et al., 2016). Furthermore, in a retrospective study, > 60 % of a cohort of 130 heart transplant recipients, reported anxiety and or depression within the 12 months before transplant (Epstein et al. 2017).

Anxiety and depression have been identified as predictors of negative outcomes such as poor medication adherence, higher rates of hospitalization and reduced quality of life (QOL) in

the post-transplant period (Delibasic et al., 2017). Anxiety has also been associated with higher risk of mortality 2-3 years post-transplant (Epstein et al., 2017). Therefore, addressing stress that influences these psychological variables pre-transplant becomes critically important to success for the patient post-transplant.

Mindfulness has been defined as a practice that involves the purposeful, nonjudgmental focus and awareness on the present moment experience through varying techniques of intentional breathing, meditation, or attention focused on specific body parts in a body scan (Kabat-Zinn, 2013). The theoretical premise of mindfulness practice is that an individual's response to stressors or unpleasant experiences becomes reflective and not reactive. Mindfulness can disrupt negative thoughts, emotions or sensations and increase one's own capacity to regulate a state of acceptance leading to positive psychological outcomes (Hoffman & Gomez, 2017; Kabat-Zinn et al., 1992).

Mindfulness-based stress reduction (MBSR) interventions have gained empirical support since the original work by Jon Kabat-Zinn (1982) which demonstrated efficacy in patients with chronic pain, psoriasis, and immune dysfunction. A concise review by Greeson & Chin (2018), identified benefits of mindfulness-based interventions (MBIs) in decreased subjective measures of stress with sustained effects over time, decreased physical symptom burden, and correlated with improved coping, QOL, and psychological health for a range of chronic diseases, such as diabetes, musculoskeletal and neurodegenerative conditions, cardiovascular disease (CVD), and psychosomatic disorders. Thus, mindfulness practice may be a favorable method to managing chronic stress and fostering mind-body health for the advanced HF patient awaiting transplant.

A sense of optimism, coping techniques and self-efficacy are psychological variables that can affect the post-transplant transition adaptation and influence QOL (Milaniak et al., 2016).

Resilience has been defined as “emotional energy or a positive character trait that alleviates the negative effects of stress and improves adaptation” (Wagnild & Young, 1993, p.165) and as “an individual’s ability to deal with adversities without succumbing to them, and to surpass the negative effects of stressful life events” (Edward, 2013, p.744). The concept of resilience, in a review of patients with chronic illness (cancer, CVD, diabetes), is identified as a protective capability that can be promoted and improves coping during times of extreme difficulty (Kim et al., 2018). Higher measures of resilience have correlated with decreased psychological distress in HF and transplant patients (Chang et al., 2017; Tian et al., 2016). Mindfulness training with practice has been associated with improved psychological resilience for populations experiencing prolonged stressful circumstances such as those in the military (Jha et al., 2016) or after trauma (Thompson et al., 2011). Stress and resilience management may provide HF patients awaiting transplant enhanced coping skills, comfort and well-being and influence adaptation to and outcomes in the post-transplant period (Lemos et al., 2016).

Problem Statement

Advanced HF patients hospitalized for prolonged periods undergoing evaluation and awaiting transplant, experience unavoidable stress that can influence the clinical course, outcomes, and the patient experience. In three cardiac care units in a large metropolitan, quaternary hospital in Southern California, current treatment for this patient population focuses on intensive medical interventions to maintain physiological stability with less attention provided to the psychological aspects of care. While pharmacological options are part of medical management, there is no consistent non-pharmacological stress reduction therapy option embedded into the daily treatment plan, providing an opportunity to improve psychological care and clinical outcomes. Thus, implementation of an evidence-based intervention that augments

medical therapies, facilitates adaptive coping, and may improve outcomes pre-and post-transplant is needed. Healthcare professionals can offer psychological support before transplantation with non-pharmacologic, evidence-based interventions that may decrease stress and anxiety and promote personal resilience.

PICOT Clinical Question

In hospitalized, adult patients with advanced HF, is a brief mindfulness-based intervention, as compared to usual care (with no mindfulness intervention) feasible and effective in reducing stress and anxiety and increasing resilience over a 4-week pre-transplant waiting period.

Purpose and Objectives

Attenuating stress decreases the potential for progression to worsening psychological states that often lead to negative health outcomes. The purpose of this DNP scholarly project was to determine if implementation of a brief evidence-based mindfulness intervention would decrease stress and anxiety and increase resilience in advanced HF patients awaiting heart transplantation. A secondary aim was to assess the intervention's feasibility in the clinical setting. A longer-term goal includes development of a nurse-led mindfulness-based intervention into usual care.

CHAPTER TWO: THEORETICAL FRAMEWORK

Roy's Adaptation Model theory is based on an underlying philosophical union of science and spirituality with a framework that has a natural fit to the holistic approach of the evidence-based mindfulness intervention project. The model defines "a person as a bio-psycho-social being in constant interaction with a changing environment" (Roy & Andrews, 1991, p. 21). The model's central feature is adaptation, understanding that problems occur when a person's

adaptive systems are unable to manage compounding stimuli (Roy & Andrews, 1991). The theory highlights the importance of fostering an individual's repertoire of coping strategies especially during significant life transitions such as advanced HF patients awaiting transplantation (Roy & Zhan, 2006).

Stimuli can be focal, contextual, or residual and is a trigger that evokes a response (Roy, 1999). Applied to the advanced HF population the following stimuli are congruent: 1) Focal stimuli: advanced HF requiring transplant; critical illness with unknown clinical stability; 2) Contextual stimuli: hospitalization requiring continuous invasive monitoring with limited mobility and personal control; and 3) Residual stimuli: role identity change due to illness; inability to work; family dynamic changes; prohibited family visitation during COVID -19 surge. These stimuli influence behaviors psychosocially and can manifest as maladaptive coping. Stimuli can change rapidly over the course of the waiting period particularly for this patient population. The Roy model's concept of stimuli management is the purpose for the mindfulness intervention (see Figure 1).

The model's coping processes include cognitive-emotive channels to physiological links that maintain equilibrium. Mindfulness practice draws the individual to connect mind, body, and spirit. In the nursing process of the Roy Adaptation model, an individual is recognized as an integrative whole, that is interacting and responding as a system. A nurse can evaluate the impact of stimuli on a patient's behavior to then set goals, intervene and evaluate intervention effectiveness. The MBI can be utilized to enhance the coping process and assist the patient to adapt during a stressful time while awaiting heart transplantation. The model's self-concept mode of adaptation is represented by reduction of stress and anxiety and strengthened resilience

measured after the MBI by validated tools. Once learned, patients can utilize an MBI to cope and adapt during other periods of life transitions post-transplant.

CHAPTER THREE: REVIEW OF LITERATURE

Evidence Search

A search of the literature was conducted in several databases including PubMed, CINAHL, PsycInfo and EBSCOhost, using key search words with MeSH and Boolean terms to include HF, mindfulness intervention, anxiety, hospitalized, transplant recipients, heart transplant, stress, and resilience. Forty articles were reviewed to explore clinical relevance to the DNP scholarly project. Studies critically appraised and included in the Table of Evidence (Appendix A) were selected according to one or more criteria including: efficacy of a MBI in the CVD, HF, hospitalized or pre and post solid organ transplant patient populations; use of a brief or web based MBI; and mindfulness as a resilience intervention.

Efficacy of MBIs

The prevalence of psychological distress in patients with CVD that leads to negative outcomes, CV events and death is significant (Tawakol et al., 2017). A meta-analysis by Scott-Sheldon et al. (2020) reviewed the effects of MBIs for adults with CVD. Psychological (distress, anxiety, perceived stress, depression) and physical outcomes (systolic and diastolic blood pressure [BP]) were analyzed. A pretest-posttest, control group design was used in all studies (14 randomized control trials [RTC]; 2 non RCTs) with a total 1476 adults from all samples. The MBI treatment groups described larger improvements in psychosocial outcomes and reduction in systolic BP than in control groups. These were outpatient programs with MBIs typically delivered in groups over an average of nine (60 minute) sessions with 30 minutes of daily self-practice emphasized between sessions. The systematic review highlighted MBIs benefits on

psychological variables and through MBI education, can be an effective adjunct to a patient's stress management by decreasing the sympathetic response to stress and accentuating the calming effect of the parasympathetic system.

In an integrative review, Viveiros et al. (2019) aimed to synthesize the evidence assessing MBIs effect on psychological and physiologic outcomes and QOL for patients specifically with HF. Six studies (2 RCT, 4 prospective cohort) with a sample total of 320 HF patients were included. This review created four outcomes' classifications having significant results: HF symptom affliction, QOL, psychosocial, and physical findings. There was significant improvement after meditation interventions in HF symptom burden, QOL, social support, and depression when compared to controls. Psychosocial factors of anxiety, perceived stress, perceived control had varied results.

Similarly, a prospective study of 208 chronic HF patients, by Sullivan et al., (2009), examined how an MB psychoeducational intervention may influence depression, clinical outcomes and QOL at 3, 6 and 12 months. The intervention included teachings in coping strategies, mindfulness meditation and support group activities over 8 weekly sessions. Post intervention results, compared with the control group, showed reduced depression, anxiety, improved clinical scores and symptoms with sustained effect.

The experience of requiring treatment in an intensive care unit (ICU) often results in anxiety and psychological suffering well beyond hospital release. Cox et al. (2019) explored whether use of a month long innovative, self-administered mindfulness program application (App) was a practical approach to deliver psychosocial support for survivors of cardiorespiratory failure as compared to internet-based education or a telephone mindfulness session provided by a therapist. This pilot, multicenter, RCT assigned 80 participants to either a mindfulness app

program, mindfulness sessions by telephone encounter or education from a web-based platform. Feasibility and acceptability of the mindfulness mobile app was identified and reported similar impact to a therapist-led intervention. At 1 and 3-month follow up, group-based mean values demonstrated clinically significant changes on anxiety, depression, post-traumatic stress, and physical symptom scales.

The complexity of care for solid organ transplant recipients can lead to symptoms of depression, anxiety, and sleep disturbances. In an RCT, Gross et al. (2010) explored how an MBSR intervention may improve these psychosocial variables. Patients were allocated to the mindfulness intervention group or health education group for 2.5 hours weekly for 2 months. Variables data were gathered before the intervention, at 2 months, 6 months and 1 year. At 8 weeks, the MBSR treatment group, showed all measures had improved and were sustained at 12 months as compared to the education group. Medium treatment effects were noted for anxiety and sleep at 12 months.

Comparably, in a prospective study of 31 pre-and post-transplant patients and 18 of their family caregivers, Stonnington et al. (2016) explored the acceptability and consequence of mindfulness-based resilience training (MBRT) on psychosocial outcomes. Core components of the intervention focused on movement through yoga, experiential mindfulness practice and stress and resilience education weekly for six weeks. Patient results post-intervention, at 6 and 12 weeks, showed significantly improved anxiety, perceived stress, depression, and negative affect measures. QOL also improved at follow-up. Caregivers showed non-significant improvements.

Effectiveness of Brief MBIs

Numerous mindfulness intervention studies have been conducted in the ambulatory setting however, limited work exists in the inpatient setting. Among a group of oncology

patients and their family caregivers, Compernelle et al. (2020) described the results of a brief MBI on psychological distress while hospitalized. In the bone marrow transplant unit at a large metropolitan teaching hospital, participants received mindfulness education and learned how to perform a mindfulness activity guided by an experienced facilitator for 20 minutes. An informational handout was provided with further instruction for self-practice. The nursing staff provided protected quiet time for practice. Data collected at baseline and 2-weeks post intervention included a validated checklist to rate symptoms of emotional and physical distress and QOL. Additionally, frequency of practice and qualitative answers to questions regarding the mindfulness activity experience were gathered. Patient participants reported heightened relaxation, and better sleep quality from the experience and expressed interest in continued mindfulness practice as part of usual care. At two weeks post intervention, psychological and physiological distress were significantly reduced. QOL scores were not significantly improved; however self-reports identified mindfulness helped with focus, decreased feelings of tension and stress particularly in times of transition.

Similarly, in a hospital based acute care surgery unit, Miller-Maturo et al. (2019) implemented a pilot study involving a brief MBI and its application to stress and acute pain reduction in 60 randomly selected participants. A trained psychology fellow delivered a 10-minute, scripted, one on one MBI practice to the intervention group participants who then received an instructional handout to follow for later use. A comparison group received 10-minutes of education on Pain Gait Theory. Pre and posttest results demonstrated improvement in both groups, with a decrease in pain after the interventions. A statistically significant reduction in stress was found for the MBI group, however not in the education group. Despite limitations, the

study demonstrated delivering a single, brief, mindfulness intervention may assist with management of stress and pain in diverse patient populations who are hospitalized.

Synthesis of Literature Review

While tremendous interest and research with application of MBIs has escalated in the past decade, researchers have addressed a need for rigorous methodology from which to draw meaningful conclusions. Efficacy of MBIs on reducing symptoms of anxiety and depression was described by Khoury et al., (2013) in a comprehensive analysis of 209 studies (pre/post (72), waitlist controlled (67), treatment controlled (68) including 12,145 patients with various disorders. MBIs were shown to have superior effect in decreasing psychological and physical symptoms than psychotherapy, education, imagery, or relaxation training. The greatest effect sizes noted were for anxiety with sustained benefit for 3 weeks to 3 years post intervention. While the review suggests MBIs may have greater efficacy than non-evidence-based interventions in reducing symptoms of depression and anxiety, it has been noted that the field has been limited by methodological gaps that limit breadth and strength of conclusions from the literature (Dimidjian & Segal, 2015).

The strength of the level of evidence of the studies reviewed were at the highest level I-II with meta-analysis, systematic reviews, randomized control trials, prospective cohort and control group studies included. In this ROL, 6 of the 8 studies demonstrated significant improvement in symptoms of anxiety and depression after the MBI (Cox et al., 2019; Gross et al., 2010; Scott-Sheldon et al., 2020; Stonnington et al., 2016; Sullivan et al., 2009; Viveiros et al., 2019), and while only 5 of the studies measured stress, they identified a significant impact in stress reduction (Compernelle et al., 2020; Cox et al., 2019; Miller-Mateo et al., 2019; Scott-Sheldon et al., 2020; Viveiros et al., 2019). With improved anxiety in 6 studies, one would anticipate

improved stress to have occurred given anxiety is a result of continuous stress; it simply was not measured. Gross et al. (2010), Stonnington et al. (2016) and Viveiros et al. (2019) reported improved QOL after the MBIs, however only Viveiros et al. (2019) and Stonnington et al. (2016) identified improved resilience or perceived control after an MBI. The research demonstrates positive effects of an MBI in improving stress, anxiety, and resilience in cardiac, HF and transplant populations as well as those hospitalized in an acute care setting. Translation of this evidence supports the potential benefits to the DNP project population of hospitalized, pre-transplant HF patients. Given the importance of resilience in adaptive coping, further evaluation of the relationship of MBIs and resilience in these populations is warranted.

Length of time for follow-up data collection with longest timepoints of 2, 3, 6 and 12 months was evident in 6 of the 8 studies (Cox et al., 2019; Gross et al., 2010; Scott-Sheldon et al., 2020; Stonnington et al., 2016; Sullivan et al., 2009; Viveiros et al., 2019). This is an important consideration to identifying the optimal length of time an MBI is needed for sustained effect, as well as knowing if continued self-practice will improve or decrease over time.

Throughout the literature, the larger body of work in MBIs has surrounded implementation of the more established MBSR interventions and its benefits. In this review, all the MBI studies apart from Compernelle et al. (2020) and Miller-Matero et al. (2019) were performed in the outpatient setting. While effective, these studies show outpatient MBSR in a more traditional format performed in groups and for longer periods of 60 minutes for 6-8 weeks with daily self-practice of 30 minutes or more encouraged. However, for hospitalized patients, this rigor is not feasible. Compernelle et al. (2020) and Miller-Matero et al. (2019) demonstrate how a brief 10-20-minute MBI can have a beneficial impact on stress and improved symptoms in the inpatient setting with patient self-practice encouraged for best effect.

Utilization of an MBI in the inpatient setting is an important shift to identifying how an effective, low cost, easy to implement therapy can be put into practice with potential for beneficial outcomes for hospitalized advanced HF patients awaiting transplant. While further study is needed in understanding the benefits of abbreviated MBI programs and efficacy of internet or smartphone application-based mindfulness interventions, a meta-analysis of 15 RCTs showed a small yet significant benefit using technology delivered MBIs for improving anxiety, depression, well-being and noting online “guided” MBIs demonstrate the greatest effect with the largest change noted for stress (Spikerman et al., 2016). Patient mindfulness education and guidance are key facilitators for mindfulness adoption noted across the MBI studies included in this review. The studies also identified the importance of commitment and adherence to the mindfulness program as correlative to benefit.

Findings from the literature appear to support the use of a mindfulness intervention to mitigate stress, anxiety, and promote resilience in advanced HF patients hospitalized awaiting transplant. A paucity in the literature surrounds the feasibility and effectiveness of abbreviated MBIs that are technology delivered in the hospitalized patient setting. The DNP scholarly project has the potential to contribute to the literature on efficacy of a brief MBI in the hospitalized advanced HF patient.

CHAPTER FOUR: METHODS

Ethics / IRB Statement

The DNP project was reviewed and approved by the UCLA general investigational review board (GIRB) administrator and the Center for Nursing Excellence UCLA Health. As an evidence-based, DNP scholarly project, neither certification of exemption from UCLA IRB review nor UCLA IRB approval of the proposed activities were required.

Project Design

This evidence-based project aimed to assess the effect and feasibility of a brief MBI in a target population of advanced HF patients, in a single academic medical center using a one group pretest/posttest design. The design was chosen given the exploratory project approach, a limited number of patients available over a 3-month period and a short timeline of 4 weeks to collect participants' data during the COVID-19 pandemic.

Population Sample and Setting

Over a 3-month period, a convenience sample of adult, advanced HF patients, awaiting heart transplantation at a large academic medical center were recruited for voluntary participation in the project. Initial inclusion criteria were defined as 18 years or older, New York Heart Association (NYHA) HF functional class II-IV, hospitalized, undergoing evaluation for and / or listed for heart or heart-multi organ transplantation, and able to comprehend English or Spanish languages. Inclusion criteria were expanded to include those HF patients home waiting for transplant but admitted to the hospital for cardiac optimization and left ventricular assist device (LVAD) patients awaiting transplant. Patients excluded were those unable to self-report stress, anxiety, or resilience. The transplant center cases average 100 heart transplant evaluations and 55 patients transplanted annually, with most hospitalized prior to transplantation.

The advanced HF and transplant team members assisted in identifying patients for participation. The DNP project lead, who has a decade of clinical experience in advanced HF and transplant, approached the patients to discuss the project and provide an informational flyer describing the mindfulness intervention, a schedule of project steps and assessments for participation (Appendix B). Time was provided for patients to review the information and have their questions answered before enrollment in the project. For those who expressed a willingness

to participate, the project lead described the 4-week commitment while also emphasizing the patient's option to end participation at any time.

Between December 15, 2020, and March 15, 2021, a total of 43 patients were approached and 35 agreed to participate. Of this sample, 20 participants completed all baseline surveys, interventions, 2-week and 4-week post intervention data collection. Five participants completed baseline to 2-week data collection but were unable to complete the 4-week follow up due to serious clinical decline or transplantation prior to project completion. Similarly, in 10 patients interested in participation, four became too ill, four advanced to transplant and three dropped out prior to data collection. There were eight patients who declined participation: six were not interested, and two expressed a sense of conflict with their faith.

Intervention

The DNP project lead conducted educational sessions regarding the mindfulness project purpose and design with staff in the cardiac care units prior to starting the project. Nursing staff were asked to assist in providing the patient with daily reminders and uninterrupted time for the mindfulness practice by placing a sign on the door to prevent others from entering the room. A mindfulness project symbol sign was placed in each participant's room aside their communication board to act as a visual prompt for the patient and nurse. A nurse-to-nurse communication comment was added to the daily nursing task list in the EMR to reinforce the nurse engagement and mindfulness practice prompt. Informational project flyers were posted in the units at staff communication and high staff traffic areas. Staff feedback was gathered weekly through informal brief huddles to evaluate the process, answer questions, and address any necessary changes.

To prepare participants, the DNP project lead delivered an initial, 45 minute, one on one, scripted mindfulness educational session which defined mindfulness and reviewed its concepts, benefits, and overall practice to the participants. A standardized, pre-selected, 12-minute audio-guided mindfulness practice session, for hospitalized patients, delivered by an expert mindfulness facilitator and available as an Application (App) from the UCLA Mindful Awareness Research Center (MARC) website was introduced and its use was demonstrated to the patient.

Participants were then instructed to access and listen to this same standardized 12-minute audio-guided self-practice mindfulness session daily over a 4-week period. The audio guided session begins by inviting the participant to find a comfortable position or posture; the participant is then guided to direct attention toward body awareness and sensations, using the breath as an anchor, addressing ambient sounds, thoughts, and distractions, and to be present and focused while adopting a curious, nonjudgmental attitude.

Each hospitalized patient had access to an iPad which had the UCLA Mindfulness App uploaded for use. Additionally, patients were offered the option to download the free for use UCLA Mindfulness App, with assistance, to their own cellphone. The patients were also provided a project logbook which included a mindfulness information sheet, a short instructional tip sheet on steps to access the UCLA Mindfulness App session and log sheets to track their practice.

The first three days following project initiation, the project lead provided a daily check-in followed by a weekly “check-in” (5-10minutes) to answer any questions regarding the mindfulness self-practice. This was typically done face to face or, if patients preferred, through

technology-based electronic chart patient communication portal, smartphone or email given potential COVID restrictions.

Data Collection and Instruments

In review of the literature, widely used, reliable and valid instruments were identified in MBI studies to measure stress, anxiety, and resilience. These questionnaires were collected at baseline, 2 weeks, and 4 weeks post intervention. At project initiation and prior to the mindfulness intervention, patient participants completed a simple baseline demographics survey and questionnaires regarding stress, anxiety, and resilience (via optional pen and paper or Qualtrics electronic platform) provided by the DNP project lead. Baseline demographic data including ethnicity, gender, age, highest level of education, marital status, etiology and classification of HF, comorbidities, and any previous experience with mindfulness practice was collected from the questionnaire and the electronic medical record (EMR) (Appendix C).

Developed by Cohen et al. (1983), with Cronbach alpha reliability of 0.72, the Perceived Stress Scale (PSS) appraises thoughts and feelings in perception of stress (Appendix D). It is a 10-item scale (score 0-40) with upper scores signifying increased perceived stress. While the aim is to capture stress level, the PSS is used to obtain a patients' perceptions of their own stress.

Anxiety can be considered a result of stress, and a slightly more reliable instrument for screening and measurement of severity symptoms of anxiety, is use of the Generalized Anxiety Disorder (GAD-7) scale with Cronbach alpha reliability of 0.89 (Appendix E). It is a 7-item scale (score 0-21), with acuity distinguished as mild (5–9), moderate (10–14) or severe (15–21) distress (Spitzer et al. 2006). The higher score indicates greater anxiety.

An abbreviated adaptation of the early Connor-Davidson Resilience Scale (CD-RISC) was established by Campbell-Sills and Stein (2007) with Cronbach alpha reliability of 0.91. The

CD-RISC 10 (Appendix F) is a 10-item scale (score 0-40) that measures components of adaptation, coping and recovery in response to stressful events, trauma, or tragedy. The higher scores reflect greater resilience.

Participants were provided a logbook to track their mindful practice frequency. The logbook was reviewed with patient self-report of frequency at 2 weeks and 4 weeks. A comment section allowed the patient to add notations (optional) and patients were invited to keep their logbook.

At week 4 participants were asked to complete a mindfulness patient experience survey containing three 5-point Likert scale statements: 1) I found the mindfulness exercise helpful 2) I found the mindfulness exercise app easy to use 3) I will likely continue to use mindfulness (Appendix G). Additionally, 4 questions regarding the application and barriers to practice were collected through focused patient interviews with audio recorded responses. The four open-ended interview questions included: 1) What do you think about the mindfulness intervention overall? 2) In what ways did you find mindfulness helpful? 3) In what ways did you find it difficult? 4) What do you think we can do in future to improve this mindfulness activity? (Appendix G)

Data Analysis

Data was analyzed using IBM SPSS Statistics (version 26). Descriptive statistics provided assessment of frequency counts for the selected variables including demographics, medical, mental health, and mindfulness variables. To assess effect of the MBI, the repeated measures ANOVA and Friedman tests for statistical verification purposes were used for the three outcome variables measures of stress, anxiety, and resilience with Bonferroni post hoc tests and Wilcoxon matched pairs tests applied.

Feasibility of the MBI was evaluated through frequency of patient reported daily practice using the mindfulness app (0-28 days), number of participants and number of those who completed all surveys. Patient acceptability was also measured through tabulation of three 5-point Likert scale statements regarding benefit, ease of app use and likelihood of continued mindfulness practice. Patient feedback regarding the mindfulness experience was analyzed from the 4-question focused interview responses. Narration on overall impressions, benefits, challenges, and suggested improvements was uploaded into an excel file and coded within each category. Similar codes were clustered, and themes were extracted.

CHAPTER FIVE: RESULTS

The purpose of this DNP scholarly project was to determine if implementation of a brief evidence-based mindfulness intervention would result in decreased stress and anxiety and increased resilience in advanced HF patients awaiting heart transplantation and assess its feasibility in the clinical setting. A complete dataset from a total of 20 participants was analyzed.

Participant Characteristics

Patients ranged in age from 21-64 years old ($M = 50.65$, $SD = 11.01$). There were more men in the sample (70.0%) than women (30.0%). Half the patients were Hispanic with another 25.0% being white. About two thirds the sample (65.0%) were married. Educational background varied. Specifically, 25.0% had completed only grade school, 35.0% had completed high school and 40.0% had completed college/university (Table 1).

Table 1: Frequency Counts for Demographic Variables

Variable	Category	<i>n</i>	%
Age Category ^a	21 to 49 years	5	25.0
	50 to 59 years	10	50.0
	60 to 64 years	5	25.0
Gender	Male	14	70.0
	Female	6	30.0
Race/Ethnicity	Hispanic	10	50.0
	AA/Black	4	20.0
	White	5	25.0
	Asian	1	5.0
Marital Status	Married	13	65.0
	Single	7	35.0
Highest Education	Grade school	5	25.0
	High school	7	35.0
	College/university	8	40.0

^a Age: $M = 50.65$, $SD = 11.01$.

Seventy-five percent of the sample had a non-ischemic cardiomyopathy heart failure etiology. Most (80.0%) had an ejection fraction of 20% or less. Nearly two thirds (65.0%) met New York Heart Association class IV criteria with half the sample (50.0%) requiring renal or cardiac mechanical device support. Most of the sample (85.0%) required a single organ, heart only transplant (Table 2).

Table 2: Frequency Counts for Medical Variables

Variable	Category	<i>n</i>	%
Heart Failure Etiology	ICMY	5	25.0
	NICMY	15	75.0
Ejection Fraction ^a	< 15%	6	30.0
	15-20%	10	50.0
	>20%	4	20.0
New York Heart Association	II-III	2	10.0
	III	5	25.0
	IV	13	65.0
Device Support (IAPB, Impella, ECMO, LVAD, CRRT)	Device	10	50.0
	No Device	10	50.0
Organs Needed (for transplant)	Heart Only	17	85.0
	Heart/Kidney	2	10.0
	Heart/Liver	1	5.0

^a Ejection Fraction: *Mdn* = 17.5%

IABP: Intra-aortic balloon pump, ECMO: Extracorporeal membrane oxygenation, LVAD: Left ventricular assist device, CRRT: Continuous renal replacement therapy.

Mental health variables showed that half the respondents (50.0%) reported having a history of anxiety, depression, or a related mental health disorder (panic attacks) and 25.0% were currently receiving treatment with related medications (Table 3).

Table 3: Frequency Counts for Mental Health Variables

Variable	Category	<i>n</i>	%
History of Anxiety, Depression or Other Mental Health Symptoms	Yes	10	50.0
	No	10	50.0
Currently Taking Associated Medication	Yes	5	25.0
	No	15	75.0

Table 4 displays the frequency counts for the comorbid conditions sorted by highest frequency. Some patients did have multiple comorbid conditions. The most common comorbid conditions, all reported by 35.0% of the sample, were hyperlipidemia (HLD), arrhythmia, diabetes, and hypertension (HTN) (Table 4).

Table 4: Frequency Counts for Comorbid Conditions Sorted by Highest Frequency

Condition	<i>n</i>	%
HLD	7	35.0
Arrhythmia	7	35.0
Diabetes	7	35.0
HTN	7	35.0
CKD	4	20.0
CVA/TIA	3	15.0
Obesity	3	15.0
Substance Abuse	2	10.0
OSA	1	5.0
Thyroid	0	0.0

Note. Multiple responses were given. Percentages add up to more than 100%.

Table 5 displays the frequency counts for the mindfulness variables. Three of 20 patients had previous mindfulness training (15.0%). Patients were asked how many days they had practiced mindfulness. During the first 14 days of this project, the average frequency was $M = 10.25$ days. During the second 14 days, the average frequency was $M = 10.80$ days. Overall, for the 28 days of the project, the average frequency was $M = 21.20$ days.

In response to the three mindfulness experience survey statements that participants completed at the end of the project time period, two thirds of the sample (65.0%) strongly agreed that the experience was helpful and 70.0% strongly agreed that the mindfulness app was easy to use. Queried about their likelihood to continue use of mindfulness, all either agreed (45.0%) or strongly agreed (55.0%) (Table 5).

Table 5: Frequency Counts for Mindfulness Variables

Variable	Category	<i>n</i>	%
Previous Mindfulness Training	Yes	3	15.0
	No	17	85.0
<i>Frequency of Practice:</i>			
Week 1 and 2 Practice Frequency ^a	2 to 7 days	4	20.0
	8 to 11 days	6	30.0
	12 to 14 days	10	50.0
Week 3 and 4 Practice Frequency ^b	4 to 7 days	2	10.0
	8 to 12 days	14	70.0
	13 to 14 days	4	20.0
Four Week Practice Frequency ^c	16 to 21 days	10	50.0
	22 to 24 days	6	30.0
	25 to 28 days	4	20.0
<i>Week 4 Mindfulness Experience Survey:</i>			
Experience Helpful	Agree	7	35.0
	Strongly Agree	13	65.0
Easy to Use	Neither	1	5.0
	Agree	5	25.0
	Strongly Agree	14	70.0
Likely to Continue	Agree	9	45.0
	Strongly Agree	11	55.0

^a Week 1 and 2 Frequency: $M = 10.25$, $SD = 3.09$.

^b Week 3 and 4 Frequency: $M = 10.80$, $SD = 2.65$.

^c Four-Week Frequency: $M = 21.20$, $SD = 3.61$.

Efficacy of the Brief Mindfulness Intervention

The guiding PICOT clinical question for this project was, In hospitalized, adult patients with advanced HF, does an evidence-based mindfulness intervention, as compared to usual care (with no mindfulness intervention) decrease stress and anxiety, and improve resilience over a 4-week pre-transplant waiting period.

To answer this clinical question, Table 6 displays the repeated measures ANOVA and Friedman tests for the three outcome variables (stress, anxiety, and resilience). Given the sample size ($N = 20$), both tests were used for statistical verification purposes. For the stress outcome, baseline stress levels were $M = 24.25$, two-week stress levels were $M = 18.45$, and four-week stress levels were $M = 17.35$. Both the ANOVA and Friedman tests were significant at the $p = .001$ level. Bonferroni post hoc tests found baseline stress levels to be significantly higher ($p = .001$) than the stress levels at two weeks and four weeks. However, there were no significant differences in stress level at two weeks and four weeks. A similar pattern of findings was noted based on the Wilcoxon matched pairs tests (Table 6).

For the anxiety outcome, baseline anxiety levels were $M = 8.45$, two-week anxiety levels were $M = 3.50$, and four-week anxiety levels were $M = 2.35$. Both the ANOVA and Friedman tests were significant at the $p = .001$ level. Bonferroni post hoc tests found baseline anxiety levels to be significantly higher ($p = .001$) than the anxiety levels at two weeks and four weeks. However, there were no significant differences in anxiety level at two weeks and four weeks. A similar pattern of findings was noted based on the Wilcoxon matched pairs tests (Table 6).

For the resilience outcome, baseline resilience levels were $M = 28.00$, two-week resilience levels were $M = 33.53$, and four-week resilience levels were $M = 33.40$. Both the ANOVA and Friedman tests were significant at the $p = .001$ level. Bonferroni post hoc tests

found baseline resilience levels to be significantly lower ($p = .001$) than the resilience levels at two weeks and four weeks. However, there were no significant differences in resilience level at two weeks and four weeks. A similar pattern of findings was noted based on the Wilcoxon matched pairs tests (Table 6).

Table 6: Repeated Measures ANOVA and Friedman Tests for the Outcome Variables

Outcome Variable	Time	<i>M</i>	<i>SD</i>
Stress ^{a, b}	1. Baseline	24.25	5.31
	2. Week 2	18.45	3.82
	3. Week 4	17.35	5.79
Anxiety ^{c, d}	1. Baseline	8.45	4.36
	2. Week 2	3.50	3.22
	3. Week 4	2.35	2.13
Resilience ^{e, f}	1. Baseline	28.00	5.31
	2. Week 2	33.55	3.99
	3. Week 4	33.40	6.15

^a Repeated measures ANOVA: $F(2, 38) = 20.28, p = .001$. Bonferroni post hoc tests: $1 > 2, 3 (p = .001)$; $2 \approx 3 (p = 1.00)$.

^b Friedman nonparametric repeated measures ANOVA test: $\chi^2(2, N = 20) = 28.00, p = .001$. Wilcoxon matched pairs test: $1 > 2, 3 (p = .001)$; $2 \approx 3 (p = .58)$.

^c Repeated measures ANOVA: $F(2, 38) = 25.18, p = .001$. Bonferroni post hoc tests: $1 > 2, 3 (p = .001)$; $2 \approx 3 (p = .54)$.

^d Friedman nonparametric repeated measures ANOVA test: $\chi^2(2, N = 20) = 28.30, p = .001$. Wilcoxon matched pairs test: $1 > 2, 3 (p = .001)$; $2 \approx 3 (p = .39)$.

^e Repeated measures ANOVA: $F(2, 38) = 11.22, p = .001$. Bonferroni post hoc tests: $1 < 2, 3 (p = .002)$; $2 \approx 3 (p = 1.00)$.

^f Friedman nonparametric repeated measures ANOVA test: $\chi^2(2, N = 20) = 19.57, p = .002$. Wilcoxon matched pairs test: $1 < 2, 3 (p = .001)$; $2 \approx 3 (p = .45)$.

Themes in Subjective Reports of the Mindfulness Experience

The mindfulness patient experience focused interviews were completed at week 4, the end of the project with 20 participants (17 audio recorded, three manually recorded). Subjective reports to the project lead answered four focused mindfulness experience questions (Appendix G). Responses were coded line-by-line within each of the four-question categories and assessed for descriptive themes with in vivo commentary extracted (Table 7).

Patient reported benefits of mindfulness included: offers a change in outlook / perspective / state of mind, improves positivity, increases tolerance, provides a sense of calm and being present in the moment, promotes relaxation, lessens stress, decreases anxiety, improves focus, improves sleep, builds inner strength, improves coping and feelings of isolation. Feedback highlighted the mindfulness intervention as beneficial overall with a calming of mind and body reported most.

Overall, patients reported the mindfulness app easy to use and navigate. For the best experience, patients identified the MBI required: an “openness” to trying it, a commitment to practice, availability of quiet uninterrupted time without distractions, and a pause length within the guided session that is brief.

Patients suggested improvements to the MBI experience included: reducing interruptions and provision of dedicated time for practice, developing app practice prompts and a self -tracker, expansion of mindfulness session options, developing complementary therapy options in addition to mindfulness, and expanding its use to the post-transplant phase.

Table 7: Patient Experience Interview Categories, Themes, and Responses

Question / Category	Descriptive Themes	Sample of Supporting Quotes
<p>What do you think about the mindfulness intervention overall?</p>	<ul style="list-style-type: none"> • Beneficial effect 	<p>“Made me feel good.” “It was really good.” “It helped a lot.” “Yeah, I’m definitely going to use it after my hospital.” “I’m pretty sure everybody deserves to know about this. Everybody! Not only when we are sick or something, no. Life is hard. So, it will help you in life.”</p>
<p>In what ways did you find mindfulness helpful?</p>	<ul style="list-style-type: none"> • Offers change in outlook / perspective / state of mind. • Improves positivity. • Promotes inner peace. • Increases tolerance / patience. • Reduces anger /frustration. • Promotes relaxation. • Promotes calm. • Lessens stress, anxiety. • Controls pain • Improves Focus • Improves ability to be present. • Promotes inner strength. • Improves coping. • Improves feelings of loneliness / isolation / boredom / fear. 	<p>“My perspective on life changed. My tolerance changed. My patience, ...I think of the mindfulness thing and just kind of – calm. It changed my whole mental intake or output or whatever. It was a different mind frame.” “It helped me be patient.” “Turn my mind off. ” “My mind is thinking forward, everything is better.” “It helped me find my inner peace.” “It relaxes you and helps you understand things.” “Relaxed me so much I totally felt free.” “You can release all the tension.” “It de-stresses me”. “My anxiety went from constant every day to almost non-existent.” “I did it mostly at night and it helped me decompress from everything.” “My mind and body are better.” “Refocus when we drift away from ourselves.” “Forget and focus in the right way.” “Learn to focus on the reality.” “It taught me one day at a time.” “I don’t feel weak. I don’t feel boring. I don’t feel scary. I feel relaxed.”</p>

Question / Category	Descriptive Themes	Sample of Supporting Quotes
	<p>App utility:</p> <ul style="list-style-type: none"> • Easy to use / learn. • Available anytime • Good tool 	<p>“... they introduce the app and just a few minutes makes it very easy and simple to start. You think it’s hard or you have to go somewhere. No. It’s just very, very simple.”</p> <p>“I thought it was easy to use. I thought it was pretty helpful in the moments that I needed it. And learning how to use it was pretty straightforward.”</p>
<p>In what ways did you find it difficult?</p>	<ul style="list-style-type: none"> • Requires openness to try it. • Requires commitment to practice. • Important to have someone introduce mindfulness. • Interruptions / distractions • Requires quiet place / dedicated time. • Intimidated by length of session or long pauses. 	<p>“As long as you commit yourself to do it then I think it was awesome. Consistency. Trying to do it seven days a week. I tried but sometimes it slipped my mind. There were different experiences almost between day and night. The consistency was the hardest thing for me.”</p> <p>“The most difficult thing I found was finding the quiet place and time where there’s no distractions/noises.”</p> <p>“Sometimes in the actual exercises there are these very long pauses of eternity.”</p>
<p>What do you think we can do in future to improve this mindfulness activity?</p>	<ul style="list-style-type: none"> • <u>Execution</u>: • Reduce interruptions. (use specific signage, staff communication) • <u>App utility</u>: • Develop practice prompts. • Develop app accountability / self-tracker. • Expand session options. • <u>Program development</u>: • Multimodal, complementary inclusions • Expand to post transplant group 	<p>“More regular prompts from the app itself to keep to daily use might be good. Also, if there is any way to include relaxing music or sleep sounds or nature sounds.”</p> <p>“Maybe if the app had a reminder built in but also a tracker of some sort.”</p> <p>“It should be encouraged by nursing.”</p> <p>“I’m looking forward to it expanding.”</p> <p>“I think it would help tremendously in the transition and post-transplant because there’s going to be anger, there’s going to be depression, there’s going to be sadness, there’s going to be—Adjustment.”</p>

Summary

In a sample of 20 patients, this DNP scholarly project addressed the clinical question of whether implementation of a brief MBI would reduce perceived stress and anxiety and improve resilience in a population of advanced HF patients awaiting transplant. Statistically significant differences were found from baseline to 2 and 4 weeks after intervention in decreased stress and anxiety and increased resilience (Table 6). The greatest change was seen at 2 weeks post intervention and was maintained at 4 weeks. Additionally, feasibility and acceptability of the MBI were evident from the patient experience survey data and focused interview responses. These project findings will be compared to the literature, with recommendations, implications for practice and future research offered.

CHAPTER SIX: DISCUSSION

It is well recognized that advanced HF patients on the trajectory awaiting transplantation are confronted with significant physical, psychological, and social stressors that can influence clinical outcomes (Delibasic et al., 2017, Epstein et al., 2017, Hiriscau et al., 2019, Pederson et al., 2017). Utilization of effective complementary, nonpharmacologic interventions that may mitigate stress and promote adaptive coping and psychological adjustment during this hospitalized waiting period is warranted. The primary PICOT clinical question of reductions in stress and anxiety and increased resilience was found, providing preliminary support to mindfulness as a promising adjunctive intervention and a foundation to further inquiry in this population. Additionally, the patient MBI experience feedback endorsed psychological benefits as well as overall feasibility and usability in this clinical setting.

Primary Outcome Measures

In this exploratory pilot project, 20 advanced HF participants receiving the abbreviated MBI reported improvements in psychological outcomes of perceived stress and anxiety over a 4-week pre transplant period. Although a small sample size, significant differences for perceived stress and anxiety were observed post intervention at 2 weeks and 4 weeks from baseline. This is consistent with study findings that reported clinically significant decreased levels of stress after an MBI for patients in acute care (Compernelle et al., 2020; Cox et al., 2019; Miller-Mateo et al., 2019), with cardiovascular disease (Scott-Sheldon et al., 2020), and HF (Viveiros et al., 2019). Anxiety is often a derivative of or reaction to chronic stress and has been associated with negative outcomes after transplant (Epstein et al., 2017). Similar to previous mindfulness intervention studies in CV disease (Scott-Sheldon et al., 2020), solid organ transplant recipients (Gross et al., 2010; Stonnington et al., 2016) and chronic HF patient populations (Sullivan et al., 2009; Viveiros et al., 2019), this MBI project yielded significant reductions in levels of anxiety. The project results suggest use of an MBI in mitigating stress and anxiety may be an important complementary inclusion to the advanced HF patient care plan.

While stress and anxiety can negatively affect clinical outcomes, higher measures of resilience have been associated with lower psychological distress (Tian et al., 2016). Resilience is now considered a dynamic attribute that may be cultivated and can enhance psychological strength and coping (Kim et al., 2018). This has generated interest in resilience promoting interventions, such as mindfulness, to aid in the holistic care of patients with chronic diseases. This project supports that premise by demonstrating significant improvements in resilience scores from baseline to 2 and 4 weeks after the MBI. Similarly, Kemper et al. (2016) presented the greatest improvement from before to after intervention with 8 weeks of mindfulness training

in measures of resilience in a small sample of HF patients. By comparison, a mindfulness training resilience intervention for transplant patients by Stonnington et al. (2016), did not see a significant change in measures of resilience. This difference was thought to be related to the baseline sample score measures already above normal and the possibility that key aspects of resilience targeted in the study were not accurately measured. Seyedoshohadaee et al., (2019) reported significant improvements in resilience scores in patients with HF after a 6-week self-care education intervention. The daily self-directed, audio guided mindfulness app session in this project was used to promote patient self-care, self-efficacy with a potential to improve resilience. Mianiak et al. (2016) reported an individual's coping resource repertoire (optimism, a sense of coherence and self-efficacy) can significantly predict and moderate stress and development of worsening psychological states in heart transplant recipients. A brief MBI that improves resilience, as shown in this project, has potential benefit to expand protective personal resources for adaptive coping during the stressful waiting period prior to transplantation.

Alignment with Theoretical Framework

The positive findings of this DNP project align well with the theoretical framework in Roy's Adaptation Model. The empowering effect of the MBI for advanced HF patients to connect mind and body in the management of stressful stimuli allows for mitigation of psychological variables that can lead to maladaptive coping. In the hospital setting, this patient group is subjected to continuous and often rapidly evolving stimuli over which they have little control influencing physical and psychological well-being. Improved resilience seen through use of an MBI in this project, can potentially foster self-efficacy, improve coping and adaptation during an uncertain time pre transplant and may aid in the transition post-transplant. Patient

comments after the MBI included: “It de-stresses me”; “My anxiety went from constant every day to almost non-existent”; “It definitely helped me cope”.

Within the model, nursing is viewed as an integral part in facilitating patient coping and adaptation. Nurses are in a position to identify stressful stimuli and clinical changes and offer MBI support to the patient as needed. During the scholarly project, cardiac unit nurses provided patient reminders and protected time for mindfulness sessions and assisted patients in identifying challenges and opportunities for benefit such as suggesting practice prior to a procedure to lessen anxiety or in the evening to promote relaxation and sleep. One patient commented: “What I did like about meditation time was being able to say to the staff ‘I’m meditating’ and being given that time to do so. I did really appreciate that.” Nurses encouraging use of mindfulness as a complementary intervention may facilitate adaptive coping during prolonged hospitalizations prior to transplant in the advanced HF population.

Outcome Changes Over Time

While the project demonstrated significant improvement in levels of stress, anxiety, and resilience from baseline after MBI there was no significant difference in the level of improvement between 2- and 4-weeks post intervention, however, these improvement scores were maintained at week 4. This is congruent with findings from similar MBI studies with repeated data follow up periods collected after baseline. Significant improvement in stress and anxiety from baseline to first follow up with sustained scores at subsequent time-points was reported by Cox et al. (2019) at 1 and 3 months and Stonnington et al. (2016) at 6 weeks and 3 months. This was comparable in measures of anxiety by Gross et al. (2010) at 8 weeks, 6 and 12 months and by Sullivan et al. (2009) at 3, 6, and 12 months. This was further substantiated in a review of 209 MBI trials that found post treatment results greatest for psychological outcomes in

reduction of stress, anxiety and depression noting effects remained stable after follow-up periods ranging 3 weeks to 3 years (Khoury et al., 2013).

Further inquiry and study are required as to optimal time necessary for benefit and factors that explain a “levelling off” in improvement over time yet an ongoing benefit remains regardless of follow up time-point variability. Given the mindfulness intervention remained consistent through the project period and in the studies reviewed, this may suggest consideration for an additional mindfulness “dose” or intervention modification after the initial period to assess for increased benefit over time.

Impact of a Brief MBI

Much of the literature supporting the effectiveness of mindfulness interventions in reducing stress and anxiety and promoting resilience is generated from traditional MBSR programs that are typically implemented in eight 2.5 hour long weekly outpatient group sessions with 45-minute daily guided self- practice. For the hospitalized advanced HF population, like many patient groups, this rigor is not a reasonable option. Recognition of this gap has led to development of brief 2–3-week adapted MBSR programs and web based, internet and smartphone MBI options ranging from formal to abbreviated versions. This DNP project utilized an abbreviated MBI comprised of a 45-minute one-on-one mindfulness educational session followed by daily use of a 12-minute audio guided self- practice session via the UCLA Mindfulness App over 4 weeks which proved effective in reducing stress and anxiety and improving resilience in this small sample group of advanced HF patients. Brief face to face, MBIs ranging from 10-20 minutes in length in a single encounter in hospitalized patients have resulted in reports of increased relaxation and improved sleep for those with hematologic malignancies (Compernelle et al., 2020) and have shown to decrease pain and significantly

decrease stress in patients requiring acute pain management (Miller-Matero et al., 2019). Similarly, Chui et al., (2021) found significant reduction in stress among patients with cancer after a provider led educational session on mindfulness with demonstration of 5-minute mindful breathing performed later by participants three times a day for 3 months. However, in a study performed at an “in-center” setting with hemodialysis patients, Thomas et al. (2017) examined effects of individual 10–15-minute provider led mindfulness meditation three times weekly for 8 weeks and found no significant effects on depression or anxiety scores although the intervention was well tolerated and feasible.

A systematic review by McClintock et al. (2019) of brief mindfulness-based interventions (BMBI) across 20 acute and chronic pain studies where 13 used audio/video recordings and 12 were delivered by face-to-face encounters described that although efficacy was mixed, BMBI facilitated by a provider and lasting more than 5 minutes has promise in improved psychologic and pain related outcomes. One explanation may be that research surrounding the effect of BMBIs is relatively new in the past decade. While BMBI has an appeal in practical clinical application, particularly in high medical acuity patient populations such as advanced HF, there continues to be a wide range of variation in rigor, intervention composition and methodology with mixed results necessitating ongoing larger scale control trials to understand best application (McClintock et al., 2019). The DNP pilot project’s positive results invite greater clinical inquiry in this regard.

Impact of a Technology Based MBI

In this project, both face to face mindfulness education and technology-based mindfulness modalities were utilized and yielded positive results in the intended outcome measures. This is supported in a meta-analysis of 15 RCTs that found technology based MBIs

had a significant positive impact on improving stress, anxiety as well as and other psychological variables (Spijkerman et al., 2016). Furthermore, Cox et al., (2019) found that mindfulness training via self-directed mobile app and by telephone for patients previously hospitalized in a critical care setting had clinically significant improvement in anxiety, stress, and psychological distress. These mobile mindfulness options were feasible, acceptable, and shown to have similar impact to a provider led intervention. However, in an 8-week, telephone adapted MBSR for patients awaiting kidney transplant, followed over 6 months, researchers found only small changes in anxiety that provided no clinically meaningful reduction although participants reported it beneficial in stress management (Gross et al., 2017). Contrary to the project findings, an RCT with a 12-week online MBI for patients with heart disease found only positive effects on exercise capacity and heart rate but no significant differences in variables such as stress or psychological well-being from baseline to post intervention follow-up (Younge et al., 2015).

An important consideration, as employed in the DNP project, is understanding that mindfulness develops with practice and the presence of a provider to facilitate initiation and offer support in its early adoption has been associated with its benefit (McClintock et al., 2019). The differences noted may be related to the fact that while there has been a surge in development of technology-based mindfulness interventions, the current literature remains limited in understanding best components, delivery, and effects of this method. The practical application for both patients and clinicians in use of this modality begs for ongoing well-designed studies to guide greatest benefit.

Feasibility of MBI

While several studies have identified MBIs as acceptable, feasible and usable in varied populations (Cox et al., 2019, Heo et al., 2018, Thomas et al., 2017), an additional aim in this

pilot project included evaluation of the feasibility of a brief MBI in the clinical setting of the advanced HF patient awaiting transplant. Over a 3- month period, 43 patients were approached, eight declined (19%), and 35 (81%) agreed to participate, of which 20 patients (57%) were able to complete all components of the project. Attrition was related to the dynamic, rapidly changing clinical course of the advanced HF patient and the unpredictability of the call to transplant. While patients were interested in engaging in the project, reasons for those unable to participate to complete the 4 weeks included six (17%) with clinical deterioration (too ill), six (17%) who advanced to transplantation and three (9%) dropped out. The mindfulness patient experience survey Likert question regarding ease of app use revealed most participants (95%) agreed or strongly agreed it was easy to use. Additionally, subjective reports found the UCLA Mindfulness App session convenient, and easy to use and navigate, particularly while hospitalized. While the app was available to each patient on their room iPad, many patients opted to download the free app to their cellphone to keep it readily available for use. Frequency of patient reported days of mindfulness practice in the project averaged 21 out of 28 days (75%). From a patient perspective, the project demonstrated feasibility, acceptability, and usability.

Feasibility from a provider perspective has several important considerations. This DNP project was cost neutral, however, allocation of provider time can be considerable. In this project, patient recruitment, enrollment, intervention implementation and data collection at baseline, 2 and 4 weeks as well as patient experience interviews were conducted by the project lead. The introductory mindfulness patient education interaction as well as patient “check-in” for the first 3 days then weekly was considered pivotal by patients new to the concept of mindfulness to fully engage in ongoing practice. In offering the intervention to our Spanish speaking patients (5), additional time was necessary for implementation and availability of

interpreter services as well as ensuring Spanish project materials were available. This may not be feasible in future studies, particularly in larger samples, but can be remedied by expanded staff support. One potential option might be to scale out mindfulness education to the clinical staff nurses to facilitate patient introduction to and use of the mindfulness app as a part of usual care. Clinical nursing staff has the ability to evaluate the real time clinical condition, patient psychological needs and best timing and use of the intervention.

Lessons Learned during Project Implementation

Medical Acuity Impact

The medical acuity of the hospitalized advanced HF patient is high and the clinical course dynamic. Consequently, one challenge was timing of the project encounters due to worsening clinical changes, unplanned tests or procedures necessitating frequent alterations in patient interactions. Close communication with the bedside nurse aided in determining best clinical window for capture. Patients were also relocated to various cardiac units depending on level of device support required creating a change in continuity of routines, making contact more difficult. These factors had potential to interfere with the patient self-practice intervention but is a real consequence of their medical frailty.

Mindfulness as A Concept

Despite its growing popularity, most of the participants (80%) were new to the concept of mindfulness. During recruitment, some patients felt mindfulness practice conflicted with their religious beliefs or faith-based practice, some others implied a concern for “mind control” in listening to audio recorded sessions and declined participation. Further examination of specific reasons regarding participation may assist in understanding acceptability. Acknowledging the finesse in onboarding a new idea can present challenges. Allowing time for discussion and

explanation tailored to the patient was an important recruitment approach. Once enrolled, the scripted one on one educational session was essential for patients new to mindfulness. Patients reported daily self-practice was most difficult in the beginning phase until it could become part of a regular routine. A strategy for frequent reminders for daily self-practice is key for best adoption of the intervention.

While a mindfulness practice frequency logbook was provided to participants, few (2) utilized it for tracking, thus relying solely on patient self-reporting. Having a tracking component imbedded into the app would allow greater accuracy in data collection and allow for patient self-assessment.

Nurse Engagement

Despite project overview presentations to the cardiac care units' staff and communication staff huddles from the unit director via Zoom and email circulations, many staff (primarily from nightshift) were unaware of the project at its initiation. Large informational flyers were then strategically placed around the nursing stations with a project summary and contact information for questions. More effective were informal huddles and direct one on one nurse interface as patients were recruited. This allowed for a deeper connection to the project and role in facilitating the patient self-practice intervention. Additionally, several nurses drawn to the concept became mindfulness project champions endorsing nurse engagement further. In appreciation for staff efforts, mindfulness exercise and stress-less cards were handed out to staff several days each week to inspire and promote personal wellness. Considering the additional clinical challenges and responsibilities brought on by COVID 19, this small gesture was well received, appreciated by staff, and generated greater interest and dialogue in the project.

Nursing staff were asked to provide the patient with a daily mindfulness practice reminder and provide 15 minutes of protected time using “do not disturb” door signage. With increased clinical demands in the cardiac units during COVID, nurses did not always have an opportunity to be a gatekeeper, place the sign on the door or remove it. Some patients provided feedback finding a verbal reminder prompt from the nurse did not occur consistently and door signage did not dependably prevent clinical staff interruptions making mindfulness practice more challenging. Specific door signage language such as: “15- minute Mindfulness session in progress – Please do not enter” may be considered for future work. An automatic daily reminder from within the mindfulness app session, or on the patient portal, set by the patient, may be a helpful and reliable addition. Data was not collected on nurse engagement or impact of the intervention upon the nursing staff but may provide additional insight in future work.

Technical Logistics

Most patients reported the mindfulness app easy to use however several notable logistical issues were identified. The bedside patient iPads were not kept charged regularly resulting in a waiting period to practice. The charging station was not easily accessible to the patient. If the patient was transferred to a new room or unit, the iPad required reconfiguration which required several minutes for the bedside nurse to complete. Lastly, patients reported a desire to download the mindfulness app to their smartphone to continue practice after hospital discharge, however some patients encountered technical challenges related to their own password access and could not resolve the issue. Exploring if the app can be accessed on another platform option, such as a computer would be beneficial.

Project Limitations

Identifying confounding factors and limitations that may affect the interpretation and consistency of the results include a small sample size, no control group, and patient adherence to daily mindfulness practice. This pilot project was carried out in a single academic institution with a non-randomized, small 1 group sample over a short period of time with one provider delivering the intervention and collecting data. To decrease these threats to validity and strengthen future work, similar projects should include a larger sample powered to establish effect, use of a non-interventional or control group to optimize causal inference and reduce the potential threat of regression to the mean over time, lengthen time of recruitment and data collection and consider multi-site inclusion with study staff involvement.

Selection bias must be recognized given the convenience sample was recruited from the cardiomyopathy clinical group. Bias must also be considered for those patients who had familiarity with the project lead and as volunteer participants there was an existing interest to join the project.

Internal validity directs examination of potential confounding factors that may influence outcomes beyond the intervention such as patients who may have participated in other interventions during the hospitalization such as spiritual, art, music, or aromatherapy. Similarly, some patients have strong family and friend support contacts, while others do not. The “threat of history” may be demonstrated in the length of time a patient has been on the transplant waitlist, the length of time hospitalized or due to clinical condition deterioration over time, all of which may influence participation or motivation to practice and impact the response to the intervention. Collection of data pre intervention regarding these variables would be helpful in future to add to strength in attributing to cause of the intervention.

Testing threat was unlikely through use of three reliable and validated instruments, however, the potential for the patient to become sensitized from pretest to post-testing must be acknowledged. Attrition poses a threat to validity when several questionnaires are utilized for data collection. This was mitigated by providing clear expectations and minimally burdensome procedures with three short 10-item questionnaires, a simple three statement Likert scale mindfulness experience survey and a recorded focused four question mindfulness experience interview. Frequency of mindfulness practice was solely based on self-report questioning reliability.

The UCLA Mindfulness App is a part of all inpatient room iPad menu offerings and available for use. This mode of technology may not be available at different institutions; however, the app is a free to download to a personal cellphone or tablet.

Given the small sample size, limitations on interpretation of positive findings and the possible translation into practice may surround the lack of generalizability to other HF populations, pre-transplant patients in other settings or other populations beyond pre heart transplant patients.

COVID-19 Impact

The COVID-19 pandemic created an unprecedented pivot in care provision for hospital systems, clinicians, and patients. The crisis mandated an alternative lens to view adaptations that were necessary in the development and implementation of this DNP project. As the project was initiated, Los Angeles County was experiencing an accelerated number of COVID-19 cases reaching hospital capacity under surge protocols with health systems stretched to their limits. This had a profound impact on the advanced HF patients hospitalized awaiting transplant in several ways. For safety reasons and to mitigate the COVID-19 spread, all outside visitation was

prohibited. This restriction lasted from December 2020 through March 2021. For many patients in-person contact with loved ones is vital to enduring a long hospitalization and the uncertainty of the pre-transplant waiting period. Additionally, patients required COVID testing prior to all invasive procedures, which are frequent for this patient group, as well as for periodic surveillance. At times, medical teams were limiting patient contact to essential staff only with increased use of iPad based clinical interactions through Zoom, a new and challenging experience for many. Patients shared feeling “more isolated” and “intimidated” when interacting with staff wearing higher levels of PPE, enforcing strict infection control protocols. Patients also expressed a fear of becoming infected either prior to their transplant, missing their opportunity of a new heart or that the donor heart may carry a risk of the infection.

Nurses and clinical staff developed a heightened technology skillset to assist the patients, their families, and staff in critical communications during this time. This was an important benefit in terms of project implementation as patients were familiar with alternative platforms of communication if unable to meet face to face at any time during the project due to unexpected restrictions. Interestingly, the pandemic did not change the number of hospital referrals, transfers or transplants performed during this period. Given the added pandemic related emotional challenges faced by the advanced HF patients, the mindfulness scholarly project was timely.

Implications for Practice and Research

Supporting the psychological health and well-being of the hospitalized HF patient awaiting transplant is vital to improving pre-and post-transplant outcomes and the patient experience. The DNP scholarly project results demonstrated a reduction in stress and anxiety and improved resilience through a brief MBI in a small sample of this population. These positive results occurred early and were sustained through to the end of the project. This pilot data

provides preliminary foundational work to be expanded in a pragmatic trial that integrates this evidence-based, non-pharmacologic, complementary intervention option as a standard of care that can be nurse-led. It may be a feasible, cost-effective, beneficial adjunct to the institution's acute care clinical "Wellness Bundle" that promotes patient engagement in recovery. If a patient's psychological well-being is supported and resilience promoted during hospitalization, through interventions such as mindfulness, further study may assess the influence on self-efficacy, patient readiness in recovery, and transition to the post-transplant period. Once adopted in the cardiac unit settings as a therapeutic, nurse-led, standard of care treatment option, scaling up to study MBI's effect on other advanced HF patients and other transplant specialties for benefit to patients hospitalized for prolonged periods can be considered to assert generalizability.

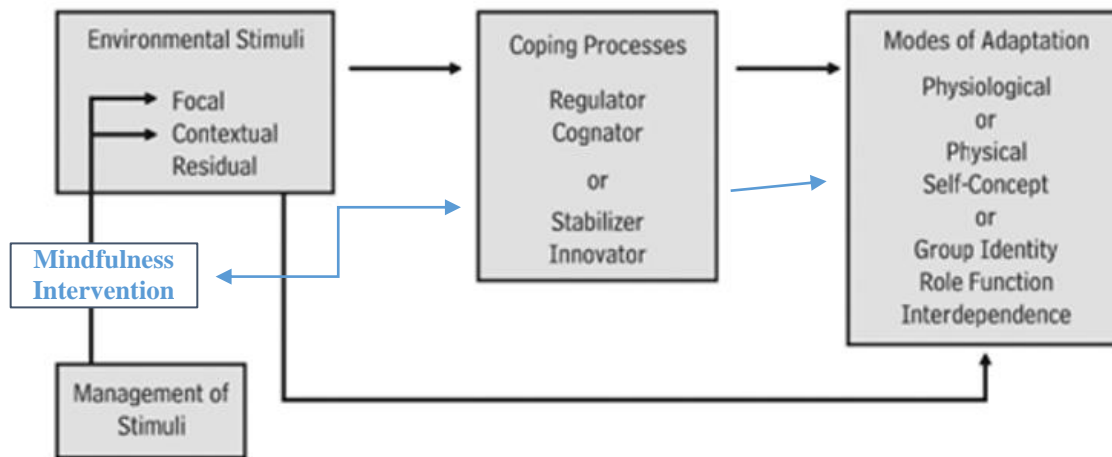
While traditional MBSR programs have established benefit in diverse populations, the time, and resources necessary can be prohibitive for greater use. MBI literature identifies the need for ongoing, rigorous study to be conducted in larger samples, with RCTs in therapeutic application with alternative approaches such as brief, internet and smartphone-based delivery (Hoffman & Gomez, 2017). This DNP scholarly project will add to the existing evidence on the influence of a brief MBI on stress, anxiety, and resilience as it relates to a gap in evidence in a population of hospitalized patients with advanced HF, awaiting transplant in an acute care setting. Studies that are well-designed incorporating what is learned from the project will be necessary. Questions for clinical inquiry and future research would include understanding optimal length and composition of a brief MBI, length of follow up for efficacy and sustainability and whether the intervention is most helpful pre- or post-transplant. Assessment of standardization of features for effective technology based MBIs is needed. Future study

including the impact of an MBI intervention upon the nursing staff would add additional insights to this arena of work.

CONCLUSION

The DNP is a system-wide leader in advancing and integrating holistic, evidence-based strategies to improve patient outcomes. The literature offers evidence regarding the benefits of MBIs in decreasing psychological factors of stress, anxiety, and depression and accentuating resilience and QOL. Translation of this evidence to advanced HF patients awaiting transplant is an important first step to bridging a gap for improved psychological support in the hospital setting. Mitigation of stress is necessary to improve pre-and post-transplant outcomes and use of a brief MBI can be a practical, effective, complementary approach. The DNP project results provide novel insights to the beneficial impact of an evidence-based MBI in small sample of pre-transplant advanced HF patients. It supports the adjunctive role of an MBI in reducing stress, anxiety and promoting resilience that is feasible and acceptable. Larger, well designed, multi-site studies can provide the necessary clinical scrutiny to advance this important field. While further exploration of the efficacy of MBIs in this population is necessary, this project contributes foundational work to a paucity in the literature upon which can be further substantiated. The DNP speaks a language through a theoretical lens, in diverse ways of knowing anchored in evidence to guide necessary system-level change. In collaboration with the healthcare team, the DNP provides important contributions for patient-centered, high-quality, and holistic care while also advancing the nursing profession and its science.

Figure 1: Management of Stimuli in Advanced HF: Mindfulness in The Roy Adaptation Model



Note. Stimuli: Continuous stressors that include:

- Focal: Advanced HF, Critical illness, Clinical instability, Fear of survival
- Contextual: Hospitalization in critical care environment, Limited mobility / Independence, Limited family /social support contact
- Residual: Role identity changes due to illness

Mindfulness may manage or mitigate stimuli through improved coping promoting adaptation.

Adapted from “Using the Roy Adaptation Model to Guide Research and / or Practice: Construction of Conceptual-Theoretical-Empirical Systems of Knowledge,” by J. Fawcett, 2009, *Aquichan*, 9(3), p.299.

APPENDICES

Appendix A: Table of Evidence

CITATION	PURPOSE	SAMPLE/ SETTING	METHODS (Design Interventions Measures)	RESULTS	DISCUSSION, INTERPRETATI ON, LIMITATION OF FINDINGS
<p>Compernelle, M., & Sledge, J. (2020). Effects of a mindfulness intervention on hospitalized patients with hematologic malignancies and their caregivers. <i>Oncology Nursing Forum</i>, 47(1), 70-78. https://doi.org/10.1188/20.0nf.70-78</p>	<p>To describe effects of an MBI for hematology patients who are hospitalized and their caregivers</p>	<p>N=34: N= 29 patients with hematology disorders N=5 caregivers</p> <p>Majority 60-69 years Women (17) White (22)</p> <p>Convenience sample</p> <p>Setting: Bone marrow transplant unit</p> <p>Single Center Hospital St. Louis, Missouri, US</p>	<p>Pre/Post-test design</p> <p><u>Intervention:</u> Education and 1:1 guided mindfulness activity X 20 minutes by / with PI-oncology nurse with meditation experience. Q&A, discussion followed the intervention to summarize experience. Info handout provided and benefit of self-practice encouraged. Protected time for practice by bedside nurses.</p> <p><u>Instruments:</u> Rotterdam Symptom Checklist (RSCL) measures psychological, physiologic distress, QOL.</p>	<p><u>Results:</u> psychological (p<.05), physiological distress (p< .05) was significantly reduced. QOL significant improvement</p> <p>Qualitative theme: helped focus, tension, stress particularly in times of transition.</p> <p><u>Analysis</u> Descriptive statistics- demographics SPSS (22) Wilcoxon signed- rank test.</p>	<p>Nurses may improve distress of hematology patient through incorporating and facilitating mindfulness practice education into usual care.</p> <p><u>Limitations:</u> small sample size, self-selection bias, intervention at different timepoints in treatment and hospitalization/ generalizability</p> <p><u>Future:</u> further study with use of mobile app for</p>

CITATION	PURPOSE	SAMPLE/ SETTING	METHODS (Design Interventions Measures)	RESULTS	DISCUSSION, INTERPRETATION, LIMITATION OF FINDINGS
			Baseline, 2-week post intervention. Qualitative questions regarding experience. Debriefing / in person data collection		
Cox, C.E., Hough, C.L., Jones, D.M., Ungar, A., Reagan, W., Key, M.D., Gremore, T., Olsen, M., Sanders, L., Greeson, J., & Porter, J.M. (2019). Effects of mindfulness training programs delivered by a self-directed mobile app and by telephone compared with an education program for survivors of critical illness: a pilot randomized clinical trial. <i>Thorax</i> , 74, 33-42. https://doi.org/10.1016/j.copsyc.2018.12.014	To compare ease of use and impact of a self-administered mindfulness app versus telephone-delivered or ICU education program on symptoms of psychological distress	N; 80 randomized Adult - ICU patients treated for cardio-respiratory failure. 49.5 years (m) 44% Female, 66% White Mobile app (n=31), Wed based Education (n=18) Therapist / Telephone (n=31),	Pilot RCT - 3-month follow-up <u>Intervention:</u> Randomized after discharge to a group. 1) self-directed mobile app-based mindfulness (weekly 5 min video + 6-8 min guided meditation 2) therapist-led telephone-based mindfulness (30min weekly x 4) 3) web-based critical illness education (patient self -directed, received call at week 1&3 to answer questions)	<u>Results:</u> Surpassed target benchmarks for: <u>Usability:</u> Systems Usability Score (M 89.1, SD 11.5) <u>Acceptability:</u> Client Satisfaction Questionnaire (M 27.6, SD 3.8) <u>Feasibility:</u> consent 74%, randomization 91%, retention 83% Clinically significant changes on	A mobile mindfulness app may be a feasible and effective option and shown to be as effective as a program therapist led. <u>Limitations:</u> -small sample size -generalizability -pilot not designed to assess efficacy -post randomization dropout higher in mobile mindfulness group prior to first use <u>Future:</u>

CITATION	PURPOSE	SAMPLE/ SETTING	METHODS (Design Interventions Measures)	RESULTS	DISCUSSION, INTERPRETATION, LIMITATION OF FINDINGS
		conducted at two academic medical centers, NC, US	<u>Instruments:</u> -PHQ9 depression -GAD-7 anxiety -PTSS Post-Traumatic Stress Scale -PHQ -Patient Health Questionnaire (symptoms) -VAS-QOL -CAMS-R-mindfulness -Brief Cope-coping Study surveys collected via ePRO system at baseline, 1 month, 3 months	depression, anxiety, the PTSD, physical symptom scales (mean values and 95% CIs). <u>Analysis</u> Benchmark %: 1 sample z-test Acceptability: CSQ Usability: SUS Linear models: SAS PROC MIXED	Larger study of app-based intervention further to assess impact.
Gross, C., Kreitzer, M.J., Thomas, W., Reilly-Spong, M., Cramer-Bornemann, M., Nyman, J., Frazier, P., & Ibrahim, H. (2010). Mindfulness-based stress reduction for solid organ transplant recipients: A randomized controlled trial. <i>Alternative Therapies in Health and Medicine, 16,</i>	To describe results of a MBSR on anxiety, depression, and sleep quality for transplant patients as compared to health education or usual care	N: 150 pts Adults Solid-organ transplants: kidney 90 pancreas 3 lung 10 liver 23 heart 11 54 years (m)	<u>RCT:</u> a 2-staged randomization. 72 in MBSR 66 in Health Education {43 usual care on waitlist-later randomized} <u>Intervention:</u>	<u>Results:</u> Treatment group: <u>8 weeks:</u> all measures better (P <0.01, all) <u>12 months:</u> Benefits preserved. (P<0.05, all).	First RCT of MBSR in transplant recipients -showed statistically significant improvement in anxiety, depression, sleep and QOL.

CITATION	PURPOSE	SAMPLE/ SETTING	METHODS (Design Interventions Measures)	RESULTS	DISCUSSION, INTERPRETATI ON, LIMITATION OF FINDINGS
30-38. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3076132/		55% Male 91% White Single Medical Center, MN, US	Both: group classes, 2.5-hour weekly x 8 -MBSR program -Health Education (control) <u>Instruments:</u> PSQI -sleep quality CES-D- depression STAI – anxiety SF-12 –symptoms VAS- QOL Self-reported Collected baseline, 8 weeks, 6 months, 12 months.	Medium treatment effects (0.51 and 0.56) for anxiety and sleep at 12 months Control Education group with small, non- sustained symptoms reduction <u>Analysis:</u> Intention to treat principle used. Use of SAS, SPSS, t tests, chi square, Wilcoxon, linear mixed model regression	MBSR is inexpensive, safe, effective intervention. Consider MBSR program as standard part of care for organ transplant recipients. <u>Limitations:</u> Unblinded trial, primary outcomes were self-reports. Attrition and missing evaluations -same for both groups - did not prefer one program over the other. <u>Future:</u> Larger RCTs warranted

CITATION	PURPOSE	SAMPLE/ SETTING	METHODS (Design Interventions Measures)	RESULTS	DISCUSSION, INTERPRETATI ON, LIMITATION OF FINDINGS
<p>Miller-Matero, L. R., Coleman, J. P., Smith-Mason, C. E., Moore, D. A., Marszalek, D., & Ahmedani, B. K. (2019). A Brief Mindfulness Intervention for Medically Hospitalized Patients with Acute Pain: A Pilot Randomized Clinical Trial. <i>Pain Medicine</i>, 20(11), 2149-2154. https://doi.org/10.1093/pm/pnz082</p>	<p>To explore how a brief MBI may influence acute pain and stress for hospitalized patients.</p>	<p>60 pts Intervention (29) Comparison (30) - acute care surgery inpatient medical setting</p> <p>55.2 years(m) 50% Male 42.3% White</p> <p>Single center Urban hospital MI, US</p>	<p>RCT, pilot Pre/post-test</p> <p><u>Intervention:</u> Treatment group :10-min MBI 1:1, script, led by trained psych postdoc fellow. Patients given instructional info self-practice guide. Comparison group:10-min psychoeducation of Gate Control Theory of Pain.</p> <p><u>Instruments:</u> pain severity: Brief pain Inventory (BPI), stress: one item scale measure 0= no stress, 10= worst stress</p>	<p><u>Results:</u> Pain reduction in both groups MBI: (P=0.002) Education: (P=0.005)</p> <p>MBI: significant reduction in stress pre/post (P=0.001), but not in Education (P=0.32)</p> <p>Pain and stress: Effect sizes small to medium</p> <p><u>Analysis</u> Descriptive statistics, SPSS (25), Independent sample t test, paired sample t tests, effect sizes Cohen's D</p>	<p>A brief MBI shows promise and benefit for use in reducing stress and acute pain in the inpatient setting.</p> <p><u>Limitations:</u> small sample size, use of a one item measure of stress, short intervention time - outcomes measured immediately post intervention so sustained effects unknown.</p> <p><u>Future:</u> need for larger sample for power and test efficacy</p>

CITATION	PURPOSE	SAMPLE/ SETTING	METHODS (Design Interventions Measures)	RESULTS	DISCUSSION, INTERPRETATION, LIMITATION OF FINDINGS
<p>Scott-Sheldon, L., Gathright, E., Donahue, M., Balletto, B., Feulner, M., DeCosta, J., Cruess, D., Wing, R., Carey, M., Salmoirago-Blotcher, E. (2020). Mindfulness-Based interventions for adults with cardiovascular disease: A systematic review and meta-analysis. <i>Annals of Behavioral Medicine</i>, 54 (1), 67–73. https://doi.org/10.1093/abm/kaz020</p>	<p>Meta-analysis to describe outcomes of MBIs on physical & psychosocial variables in adults with CVD</p>	<p>PRISMA method – 16 accepted studies</p> <p>N=1,476 across studies 56 years (m) 40% Women 76% White</p> <p>Coronary heart disease (10); HTN (2), HF (1), multiple CVD conditions (3)</p>	<p>Systematic review / Meta- Analysis 14 RTC, 2 cohort</p> <p><u>Methods:</u> MBI with CVD, included comparison condition, assessed psychological or physiological outcomes Design/quality interventions coded. All Pretest/posttest design with control group</p> <p><u>Intervention:</u> Outpatient MBI, average of nine (60 minute) sessions with 30 minutes of daily self-practice emphasized between sessions.</p> <p><u>Measures:</u> Psychological: depression, perceived</p>	<p><u>Results:</u> Relative to controls, MBI: showed improved perceived stress, anxiety, distress, depression, d: (d+s = 0.49 to 0.64). MBI: reduction in systolic BP (d+ = 0.89, 95% [CI] = 0.26, 1.51; k = 7) No effect on diastolic BP</p> <p><u>Analysis:</u> Difference in mean between groups with calculated effects sizes Heterogeneity assessed by Q.</p>	<p>Improved psychological and physiological measures after MBI shows benefit for patients with CVD.</p> <p><u>Limitations:</u> publication bias and lack of long-term impact data</p> <p><u>Future:</u> Longer follow up studies to examine if benefits further impact disease outcomes over time</p>

CITATION	PURPOSE	SAMPLE/ SETTING	METHODS (Design Interventions Measures)	RESULTS	DISCUSSION, INTERPRETATION, LIMITATION OF FINDINGS
			stress, distress, anxiety Physiologic: BP	Outcome consistency across studies - I2 index. All analyses - Stata 15.1	
<p>Stonnington, C., Darby, B., Santucci, A., Mulligan, P., Pathuis, P., Cuc, A., Hentz, J., Zhang, N., Mulligan, D., & Sood, A. (2016). A resilience intervention involving mindfulness training for transplant patients and their caregivers. <i>Clinical Transplantation</i>, 30, 1466–1472. https://doi.org/10.1111/ctr.12841</p>	<p>To examine the practicality and impact of a 6-week MBRT class on stress associated variables for transplant patients and caregivers</p>	<p>N: Patients 31 Caregivers 18</p> <p>Age (22-79 years) Gender 20M, 29F</p> <p>Patients & caregivers of Pre- or post-solid organ or bone marrow transplant</p> <p><u>Patients:</u> Pre:10 / Post 21 Breakdown: Bone M 3/1 Heart 6 /11 Kidney 1/ 5</p>	<p>Pilot study Pre/post test</p> <p><u>Intervention:</u> 3 rounds of MBRT over 1 year. Each round 6 weeks long. 15-20 per group.</p> <p>3 components of mindfulness used ACT, SMART, MBSR 6 wk. program: Session1 led by SMART trained facilitator. Session 2-6 lead by psychologist & yoga therapist: included educational, experiential practice</p>	<p><u>Results:</u> At 6wks & 3 months, significant (P<.005) reduction in anxiety, depression, perceived stress, and QOL negative affect (P=.006)</p> <p><u>Analysis:</u> Conservative Bonferroni correction for multiple comparisons, showed significant improvements</p>	<p>Innovative MBRT program showed significant improvements in psychological variables sustained over 3months.</p> <p>Participant’s feedback: wish intervention had been available pre transplant.</p> <p><u>Limitations:</u> No control group, missing data at 3 months Program rigor /commitment:</p>


CITATION	PURPOSE	SAMPLE/ SETTING	METHODS (Design Interventions Measures)	RESULTS	DISCUSSION, INTERPRETATI ON, LIMITATION OF FINDINGS
		Liver 1/ 5 Single center, Mayo Clinic AZ, US	and mindful movement. No control groups. <u>Instruments:</u> Stress: (PSS), Resilience (CDRISC), Health-related QOL (HRQOL), Anxiety (GAD-7), Depression (PHQ-9), Subjective sleep quality Mindfulness (MAAS) Positive and negative Affect scale (PANAS) Collected baseline, 6 weeks, 3 months post intervention. Self- reported - mailed in.	(P<.005) over time (6weeks and 3months) from baseline in anxiety, depression, negative affect, and stress. Caregivers: improved but not significant for mindfulness, anxiety, perceived stress	80% attended 3 or more sessions. Selection bias motivated from support groups. Combined organ transplant groups may have different outcomes versus single organ. <u>Future:</u> Larger sample size, RTC design, assess impact on morbidity, mortality, specific transplant types and whether more useful pre or post - transplant, Further study with caregivers to assess efficacy.

CITATION	PURPOSE	SAMPLE/ SETTING	METHODS (Design Interventions Measures)	RESULTS	DISCUSSION, INTERPRETATION, LIMITATION OF FINDINGS
					Offer virtual internet options?
<p>Sullivan, M. J., Wood, L., Terry, J., Brantley, J., Charles, A., Mcgee, V., Johnson, D., Krucoff, M., Rosenberg, B., Bosworth, H., Adams, K., & Cuffe, M. S. (2009). The Support, Education, and Research in Chronic Heart Failure Study (SEARCH): A mindfulness-based psychoeducational intervention improves depression and clinical symptoms in patients with chronic heart failure. <i>American Heart Journal</i>, 157(1), 84–90. https://doi.org/10.1016/j.ahj.2008.08.033</p>	<p>To describe the effect of a psychoeducation MBI on clinical and psychosocial outcomes in CHF patients</p>	<p>N: 208 adults with LVEF $\leq 40\%$</p> <p>Control grp: N:100 Avg 61years 73% Male</p> <p>Tx grp: N:108 Avg 61years 66% Male</p> <p>Multiple locations recruitment geographical to Duke University MC, US</p>	<p>Prospective Cohort study Treatment or control groups assigned geographically.</p> <p><u>Intervention:</u> Treatment groups: 2.5hrs weekly x 8 Training: 3 components: coping skills, support group, mindfulness meditation led by experienced facilitators. Daily self-practice of 30 minutes encouraged, resources provided.</p> <p><u>Instruments:</u> KCCQ- health status measure for HF</p>	<p><u>Results:</u> MBI group: lower depression ($P = .05$), anxiety ($P = .003$), clinical scores ($P = .024$), and improved symptoms ($P = .033$) over time compared to controls</p> <p>At 1 year, no effect on rehospitalization or death</p> <p><u>Analysis:</u> Comparison of Kaplan Mier</p>	<p>An 8-week MB psychoeducational intervention can be effective in decreasing depression, anxiety and significantly improving CHF symptoms at 12 months.</p> <p>Consistent results with other studies</p> <p><u>Limitations:</u> Small sample size Not powered for effect of mortality or morbidity. Bias: Use of a geographic control grp-80% were managed by same cardiology practice</p>

CITATION	PURPOSE	SAMPLE/ SETTING	METHODS (Design Interventions Measures)	RESULTS	DISCUSSION, INTERPRETATI ON, LIMITATION OF FINDINGS
			(clinical and symptoms) POMS – mood/anxiety CES-D – depression Collected baseline, follow-up at 3, 6, and 12 months. Self-reported - mailed in	Curves by Log rank test SAS	<u>Future:</u> Larger, RCT design, assess effects of reducing anxiety depression on morbidity and mortality
Viveiros, J., Chamberlain, B., O’Hare, A., & Sethares, K. A. (2019). Meditation interventions among heart failure patients: An integrative review. <i>European Journal of Cardiovascular Nursing</i> , 18(8), 720–728. https://doi.org/10.1177%2F1474515119863181	A literature review to describe the effect of meditation interventions on HF patient outcomes.	58 studies reviewed. N: 6 studies in final sample -320 HF pts Avg age range 56.9-76 years 4- US 1-Brazil 1-Sweeden Studies assessed using Hawker and colleagues’ guideline protocol for	Systematic review <u>Method:</u> Created classifications of outcome measures: -Psychological/social -Bio/Physical -HF symptom burden -QOL that demonstrated significant findings. <u>Interventions:</u> Facet to face: (all) 1 hr. group based to 90 min in home training. Weekly meeting/ meditation (all)	<u>Results:</u> design and length varied -20 different dependent variables noted. Treatment groups showed: significant improvement QOL (p<.05), bio physical / HF symptom burden (p<.05), social support (p<.05), depression (p<.05)	Patient meditation with self-practice may offer HF symptoms relief and increase emotional wellbeing, and QOL. <u>Limitations:</u> Comparisons difficult due to large variations in study designs, reporting methods, definitions, intervention dose. 5/6 studies, small sample (<50)

CITATION	PURPOSE	SAMPLE/ SETTING	METHODS (Design Interventions Measures)	RESULTS	DISCUSSION, INTERPRETATION, LIMITATION OF FINDINGS
		critical appraisal	<p>Self- reported practice from home (all): 15min (1), 20min (3) 30 min (2) with daily aid to support meditation (audio or manual script)- all.</p> <p>Length: 8 weeks (3), 3- month (2), 6- month (1) Trained Facilitator -all</p> <p>Instruments/Measures: CED-depression PHQ-symptoms PROMIS depression PSS-perceived stress Anxiety Social support MLHFQ-QOL, symptom burden, BNP, 6MW, CPX, echo</p>	when compared to controls.	<p>Over 20 different measures used to measure outcome variables.</p> <p><u>Future:</u> Need for detailed comparative analysis of larger RCTs with consistency in design, interventions, instruments used</p>

Appendix B: Sample Participant Information Flyer



Can mindfulness help reduce stress, anxiety and build resilience for heart failure patients awaiting transplant?

If you participate you will :

At Project Start : Complete general information about yourself and questionnaires about your current level of stress, anxiety and resilience.
Have a one-on-one educational session about mindfulness and learn how to follow a guided mindfulness practice session.

- You will be asked to practice mindfulness DAILY using a 12-minute audio guided mindfulness app. and keep a logbook of how often you do it.
- The project lead will check in with you WEEKLY to answer questions.

At 2-weeks : Complete questionnaires about your level of stress, anxiety and resilience.


At 4-weeks : Complete questionnaires about your level of stress, anxiety and resilience. Complete a short end of project experience survey. Answer 4 questions about the mindfulness experience.

The Mindfulness Project

Deep Breaths, Less Stress

You are invited to participate!

Mindfulness is
a way to calm the mind, free of distractions, without thinking about the past or the future.



For more information and participation please contact :
Beth Vandenberg, MSN, CNS, ACNP-BC
310-497-6927, evandenberg@mednet.ucla.edu

Image: [Openclipart - Clipping Culture](#)

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Appendix C: Demographic Survey

Age: ___ years

Gender: Male Female Prefer not to answer

Highest level of education completed: Grade school High school College University.

Race: African American Asian American Indian/Alaska native Hispanic/Latino

Pacific islander White/Caucasian

Previous experience with mindfulness practice: Yes No

Appendix D: Perceived Stress Scale (PSS)

PSS-10

INSTRUCTIONS:

The questions in this scale ask you about **your feelings and thoughts during THE LAST 2 WEEKS**. In each case, you will be asked to place an X on the answer of how often you felt or thought a certain way.

<u>In the LAST 2 Weeks:</u>	Never	Almost Never	Sometimes	Fairly Often	Very Often
	0	1	2	3	4
1. How often have you been upset because of something that happened unexpectedly?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. How often have you felt that you were unable to control the important things in your life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. How often have you felt nervous and “stressed”?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. How often have you felt confident about your ability to handle your personal problems?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. How often have you felt that things were going your way?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. How often have you found that you could not cope with all the things that you had to do?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. How often have you been able to control irritations in your life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. How often have you felt that you were on top of things?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. How often have you been angered because of things that happened that were outside of your control?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. How often have you felt difficulties were piling up so high that you could not overcome them?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

References The PSS Scale is reprinted with permission of the American Sociological Association, from Cohen, S., Kamarck, T., and Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior*, 24, 386-396. Cohen, S. and Williamson, G. Perceived Stress in a Probability Sample of the United States. Spacapan, S. and Oskamp, S. (Eds.) *The Social Psychology of Health*. Newbury Park, CA: Sage, 1988

Appendix E: General Anxiety Disorder (GAD 7)

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

GAD-7				
Over the last 2 weeks , how often have you been bothered by the following problems? <i>(Use "✓" to indicate your answer)</i>	Not at all	Several days	More than 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 is 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

(For office coding: Total Score T___ = ___ + ___ + ___)

Appendix F: Connor Davidson Resilience Scale (CD-RISC 10)

Resilience - (CD-RISC 10)

Please indicate how much you agree with the following statements as they apply to you **over the last month**. If a particular situation has not occurred recently, answer according to how you think you would have felt. *Mark (X) in the most appropriate response.*

Question	Not true at all 0	Rarely True 1	Sometimes True 2	Often true 3	True nearly all the time 4
1. I am able to adapt when changes occur.					
2. I can deal with whatever comes my way.					
3. I try to see the humorous side of things when I am faced with problems.					
4. Having to cope with stress can make me stronger.					
5. I tend to bounce back after illness, injury, or other hardships.					
6. I believe I can achieve my goals, even if there are obstacles					
7. Under pressure, I stay focused and think clearly.					
8. I am not easily discouraged by failure.					
9. I think of myself as a strong person when dealing with life's challenges and difficulties.					
10. I am able to handle unpleasant or painful feelings like sadness, fear, and anger.					

All rights reserved. No part of this document may be reproduced or transmitted in any form, or by any means, electronic or mechanical, including photocopying, or by any information storage or retrieval system, without permission in writing from Dr. Davidson at mail@cd-risc.com. Further information about the scale and terms of use can be found at www.cd-risc.com. Copyright © 2001, 2018 by Kathryn M. Connor, M.D., and Jonathan R.T. Davidson, M.D. This version of the scale was developed as a work made for hire by Laura Campbell-Sills, Ph.D., and Murray B. Stein, M.D

Appendix G: Mindfulness Experience Survey and Focused Interview Questions

Mindfulness Experience Survey

Please circle your answer:

1. I found the mindfulness exercises helpful:

Strongly Agree Agree Neither Agree or Disagree Disagree Strongly Disagree

2. I found the mindfulness exercise app easy to use:

Strongly Agree Agree Neither Agree or Disagree Disagree Strongly Disagree

3. I will likely continue to use / practice mindfulness:

Strongly Agree Agree Neither Agree or Disagree Disagree Strongly Disagree

Mindfulness Experience Focused Interview Questions

Audio recorded (with permission):

- 1) What do you think about the mindfulness intervention overall?
- 2) In what ways did you find mindfulness helpful?
- 3) In what ways did you find it difficult?
- 4) What do you think we can do in future to improve this mindfulness activity?

Appendix H: Institutional Review Board Approval

From: Lillig, Paul
Sent: Wednesday, October 7, 2020, 10:34 AM
To: Vandenberg, Elizabeth
Subject: UCLA IRB Review Not Required

Hi Beth,

Thank you for the confirmation.

I can confirm your DNP project does not meet the definition of human subjects research as defined by federal regulations for human subject protections (45 CFR 46.102(d) - <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102>).

Therefore, neither certification of exemption from UCLA IRB review nor UCLA IRB approval of the proposed activities is required.

Please retain this email as formal documentation of this determination.

Please contact our office for an update to this determination if the scope or aims of the activities are revised.

Thank you,

Paul Lillig
GIRB Administrator

Appendix I: Perceived Stress Scale Permission

PERMISSION FOR USE OF THE PERCEIVED STRESS SCALE

I apologize for this automated reply. Thank you for your interest in our work.


PERMISSION FOR USE BY STUDENTS AND NONPROFIT ORGANIZATIONS: If you are a student, a teacher, or are otherwise using the Perceived Stress Scale (PSS) without making a profit on its use, you have my permission to use the PSS in your work. Note that this is the only approval letter you will get. I will not be sending a follow-up letter or email specifically authorizing you (by name) to use the scale.

PERMISSION “FOR PROFIT” USE: If you wish to use the PSS for a purpose other than teaching or not for profit research, or you plan on charging clients for use of the scale, you will need to see the next page: “Instructions for permission for profit related use of the Perceived Stress Scale”.

QUESTIONS ABOUT THE SCALE: Information concerning the PSS can be found at <https://www.cmu.edu/dietrich/psychology/stress-immunity-disease-lab/index.html> (**click on scales on the front page**). Questions about reliability, validity, norms, and other aspects of psychometric properties can be answered there. The website also contains information about administration and scoring procedures for the scales. Please do not ask for a manual. There is no manual. Read the articles on the website for the information that you need.

TRANSLATIONS: The website (see URL above) also includes copies of translations of the PSS into multiple languages. These translations were done *by other investigators*, not by our lab, and we take no responsibility for their psychometric properties. If you translate the scale and would like to have the translation posted on our website, please send us a copy of the scale with information regarding its validation, and references to relevant publications. If resources are available to us, we will do our best to post it so others may access it.

Good luck with your work.



Sheldon Cohen
Robert E. Doherty University Professor of Psychology
Department of Psychology

Appendix J: Connor-Davidson Resilience Scale (CD-RISC) Permission

Dear Elizabeth:

Thank you for your interest in the Connor-Davidson Resilience Scale (CD-RISC). We are pleased to grant permission for use of the English and Spanish CD-RISC-10 in the project you have described under the following terms of agreement:

1. You agree (i) not to use the CD-RISC for any commercial purpose unless permission has been granted, or (ii) in research or other work performed for a third party, or (iii) provide the scale to a third party without permission. If other colleagues or off-site collaborators are involved with your project, their use of the scale is restricted to the project described, and the signatory of this agreement is responsible for ensuring that all other parties adhere to the terms of this agreement.
2. You may use the CD-RISC in written form, by telephone, or in **secure electronic format whereby the scale is protected from unauthorized copying, distribution or the possibility of modification. In all presentations of the CD-RISC, including electronic versions, the full copyright and terms of use statement must appear with the scale. The scale should be accessed by password at a secure link, should not appear in any form where it is accessible to the public and should be removed from electronic and other sites once the project has been completed. The scale should not be accessed more than one time by the respondent. The RISC is not to be sent as an email attachment, and can only be made accessible after subjects have logged in with a password and given consent.**
3. Further information on the CD-RISC can be found at the www.cd-risc.com website. The scale's content may not be modified, although in some circumstances the formatting may be adapted with permission of either Dr. Connor or Dr. Davidson. If you wish to create a non-English language translation or culturally modified version of the CD-RISC, please let us know and we will provide details of the standard procedures.
4. Three forms of the scale exist: the original 25 item version and two shorter versions of 10 and 2 items respectively. When using the CD-RISC 25, CD-RISC 10 or CD-RISC 2, whether in English or other language, please include the full copyright statement and use restrictions as it appears on the scale.
5. A **student-rate** fee of \$ 30 US is payable to Jonathan Davidson at 2434 Racquet Club Drive, Seabrook Island, SC 29455, USA either by PayPal (www.paypal.com, account mail@cd-risc.com), cheque or bank wire transfer (in US \$\$). Money orders are not accepted.
6. Complete and return this form via email to mail@cd-risc.com.
7. In any publication or report resulting from use of the CD-RISC, you do not publish or partially reproduce items from the CD-RISC without first securing permission from the authors.

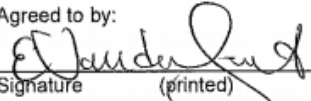
If you agree to the terms of this agreement, please email a signed copy to the above email address. Upon receipt of the signed agreement and of payment, we will email a copy of the scale.

For questions regarding use of the CD-RISC, please contact Jonathan Davidson at mail@cd-risc.com. We wish you well in pursuing your goals.

Sincerely yours,

Jonathan R. T. Davidson, M.D.

Agreed to by:


Signature (printed) 11/23/20
Date

Nurse Practitioner - UCLA Cardiomyopathy
Title UCLA School of Nursing DNP student

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