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Feasibility and Efficacy of an App-Based Mindfulness Intervention For Anxiety and Depression Amongst Patients With Metastatic Non-Small Cell Lung Cancer

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Feasibility and Efficacy of an App-Based Mindfulness Intervention For Anxiety and Depression Amongst Patients With Metastatic Non-Small Cell Lung Cancer

A dissertation submitted in partial satisfaction of the

requirements for the degree

Doctor of Nursing Practice

by

Melody Ann Mendenhall

2024

ABSTRACT OF THE DISSERTATION

The Utility and Feasibility of an App-Based Intervention in Anxiety and Depression Amongst Patients with Metastatic Lung Cancer

by

Melody Ann Mendenhall

Doctor of Nursing Practice

University of California, Los Angeles, 2024

Professor Su Yon Jung

Background: Lung cancer ranks as the second most prevalent form of cancer in the United States, excluding non-melanoma skin cancers. Despite a noticeable decline in the incidence of new lung cancer cases and associated mortality rates, lung cancer remains the leading cause of cancer-related deaths. Patients with metastatic (stage IV) lung cancer often experience severe psychological distress, with high rates of anxiety and depression. These mental health challenges can exacerbate physical symptoms, reduce treatment adherence, and negatively impact overall survival and quality of life. **Objectives**: This Doctor of Nursing Practice (DNP) project aims to investigate the effectiveness of an app-based mindfulness intervention designed to support

patients with metastatic (stage IV) lung cancer who are struggling with anxiety or depression. The central question of this study is whether utilizing a mobile application can significantly reduce the levels of anxiety and depression in this patient population. Quality of life (QOL) and feasibility were listed as secondary outcomes. **Methods:** Patients from a single institution were screened for anxiety and depression and offered to participate in the project if they exhibited at least mild depression, anxiety, or both. Patients were invited to use the daily intervention, effectiveness and feasibility were evaluated through patient feedback and clinical outcomes, including measures of psychological well-being and overall health status. **Results:** The app-based intervention was implemented with a sample of 4 patients with metastatic lung cancer. Over an 8-week period, participants showed a decrease in anxiety (p=.374, d=1.06) and depression scores (p=.25, d= .93), as well as improvement in QOL (p=.125, d=1.06). Results were not statistically significant but did show a large effect size. Qualitative feedback highlighted the app's usability and the value of meditation. **Conclusion:** Lung cancer patients, particularly those with metastatic disease, experience significant psychological distress that impacts their overall health and treatment outcomes. This DNP project highlighted the importance of addressing the mental health needs of these patients. By improving the resources and support available, it is possible to enhance the overall well-being and clinical outcomes, including overall survival and cost of care, for patients with metastatic lung cancer. Further research is needed to refine these interventions and ensure their effectiveness across broader lung cancer populations.

The dissertation of Melody Ann Mendenhall is approved.

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This dissertation is dedicated to my family, especially to my brothers, who have stood by me through all of life's ups and downs and everything in between. Thank you to my family of friends who put up with my absence for the past two years and have supported me throughout. And finally, this is dedicated to my two orange feline boys. They bring me incredible joy and entertainment every day. They help me to remember to keep balance in my life.

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VITA

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CHAPTER ONE: INTRODUCTION

In the United States (U.S.), lung cancer is recognized as the second most prevalent form of cancer apart from non-melanoma skin cancers and is the most common cause of cancer-related deaths (American Cancer Society, 2023). Although there has been a noticeable decline in the incidence of new lung cancer cases and associated mortality (American Cancer Society, 2023), the survival rate after diagnosis is still low. In particular, the five-year survival rate for non-small cell lung cancer is approximately 28%, while for small-cell lung cancer, the rate declines significantly to 7% (American Cancer Society, 2023).

Many individuals diagnosed with lung cancer also suffer from comorbidities of anxiety and depression, with estimated prevalence rates of 19% and 23%, respectively (Zeilinger et al., 2022). There are detrimental effects of depression and anxiety on the overall survival outcomes among individuals with lung cancer. This includes overall survival and time to progression for those patients on treatment (Andersen et al., 2021). In addition, patients with increased psychological burden have an increased personal cost of care over the lifespan of their disease process (Mausbach et al. 2018). In particular, the mental well-being of individuals experiencing lung cancer is complex, influenced by various factors, including the physiological and therapeutic consequences of the disease, psychological burden arising from guilt and societal stigma related to smoking, difficulties in breathing, and a decline in functional capacity (Gonzalez-Ling et al., 2022). The DNP project aimed to add to the resources available to patients with metastatic (stage IV) lung cancer with anxiety or depression.

For the purposes of this paper, metastatic will be used interchangeably with stage IV, as defined by the American Joint Committee on Cancer (AJCC) 8th edition, Tumor, Node Metastasis (TNM) staging for lung cancer (Lababede and Meziane, 2018).

Background

Lung cancer, a pervasive and life-threatening malignancy worldwide, imposes not only physical but also significant psychological distress on affected individuals. A systematic review and meta-analysis by Yan et al. (2019) underscored the substantial burden of depression in this population. Importantly, these psychological symptoms are not confined to the post-diagnostic phase but often persist throughout the cancer journey.

Anxiety and depression exact a heavy toll on the quality of life (QOL) of individuals with lung cancer. Brown-Johnson et al. (2014) highlighted the role of lung cancer stigma in intensifying psychological distress, eroding patients' overall well-being. These symptoms are associated with a myriad of challenges, including social isolation, disrupted sleep, reduced physical activity, and difficulties adhering to treatment regimens. Of interest is the potential influence of anxiety and depression on disease morbidity and mortality. Andersen et al. (2021) employed a joint model analysis, linking psychological symptom trajectories with the survival of non-small cell lung cancer patients. Their study revealed that patients with persistently high levels of psychological symptoms experienced poorer survival rates than those with lower symptom burdens. This suggests a bidirectional relationship between mental health and cancer progression, where psychological distress might contribute to deteriorating physical health in this population.

Psychosocial stress, encompassing anxiety and depression, significantly impacts immune responses in the general population, and more specifically in cancer patients (Antoni & Dhabhar, 2019). Chronic stress may disrupt the immune system, potentially influencing tumor growth and treatment response. This emphasizes the importance of holistic care in cancer management,

where addressing psychological distress not only enhances patient comfort but also may have implications for disease control.

Duan et al. (2022) emphasized that addressing frailty, defined as diminished physiological function affecting various organs and systems and often associated with psychological distress, can improve outcomes in lung cancer patients undergoing chemotherapy. Additionally, McFarland et al. (2021a, 2021b) reported prognostic implications of depression and inflammation in metastatic lung cancer patients, further supporting the notion that psychological well-being is intertwined with disease progression.

Su et al. (2022) explored the interplay between cancer fear, emotion regulation, and emotional distress in newly diagnosed lung cancer patients. Their findings highlight the importance of addressing fear and providing tools for effective emotion regulation to enhance the psychological well-being of patients.

Talk therapy and medication have demonstrated efficacy in managing cancer patients; however, the accessibility of such interventions may be hindered by financial limitations. The issue of cost-prohibitive care is further exacerbated by an increasing number of psychiatrists and psychologists discontinuing acceptance of insurance coverage (Bishop et al., 2014). Further studies examining the efficacy of antidepressant interventions in patients diagnosed with cancer have produced inconclusive outcomes, highlighting the need for a more nuanced and adaptable therapeutic approach (Ostuzzi et al., 2015).

Mindfulness

Mindfulness is a deliberate and nonjudgmental practice that centers on the present moment. It involves techniques such as intentional breathing, meditation, and focusing attention on specific areas of the body through body scans (Kabat-Zinn, 2013). The underlying concept of

mindfulness shifts an individual's response from reactive to reflective when experiencing stressors or discomfort. By doing so, mindfulness can potentially disrupt negative thoughts, emotions, and sensations, enabling better self-regulation and positive psychological outcomes.

The effectiveness of mindfulness-based stress reduction (MBSR) interventions has been supported by research building on the pioneering work of Jon Kabat-Zinn (1982). This initial research showcased the efficacy of MBSR in individuals dealing with chronic pain, psoriasis, and immune dysfunction. A literature review by Chayadi et al. (2022) showed that mindfulness-based interventions (MBIs), including MBSR, mindfulness-based cognitive therapy (MBCT), and mindfulness-based cancer recovery (MBCR), can be effective in reducing symptoms of depression, anxiety, and cancer-related fatigue (CRF) in multiple cancer types, with these benefits often lasting beyond the intervention period. Considering these findings and a lack of evidence-based application of the MBIs to patients with metastatic cancer, incorporating mindfulness practices in their care plan could serve as a beneficial approach to managing chronic stress and promoting overall mind-body health for individuals with metastatic cancer.

Problem Statement

Patients diagnosed with metastatic lung cancer necessitate a highly intricate approach to their care. Within this complex landscape, the integration of mental health care assumes significance, often being overlooked during the complicated process of treatment planning. Specifically, anxiety and depression manifest as significant psychological comorbidities, exhibiting associations with unfavorable outcomes, thereby underscoring the imperative to incorporate mental health interventions into the comprehensive oncology care plan. Given the underutilization and limited effectiveness of conventional treatment modalities, a compelling

exigency exists to expand available interventions to address the multifaceted needs of patients with lung cancer.

PICOT Question

The DNP project aimed to answer the following PICOT question: (P) In metastatic lung cancer patients (I) does an app-based mindfulness intervention (C) compared with no mindfulness intervention (O) have an impact on anxiety and depression (T) over an 8-week period?

CHAPTER TWO: THEORETICAL FRAMEWORK

Guided by Roy's Adaptation Model (RAM), a holistic bio-psycho-social approach to care., the RAM theoretical foundation draws on philosophical, scientific, and cultural assumptions rooted in systems theory and adaptation-level theory. The core concepts of RAM, as described by Andrews and Roy (1991), encompass an individual viewed as an adaptive system, the surrounding environment, health, and the nursing goal. As an adaptive system, an individual is defined holistically, with interconnected parts functioning in unity for a purpose. The environment includes all conditions and influences affecting human development, focusing on human and earth resources. Health is perceived as a state and process of integration and wholeness. The nursing goal is centered on enhancing life processes to foster adaptation, where adaptation involves conscious awareness and choice for human and environmental integration (Roy & Andrews, 2008)

The first central construct, adaptation, recognizes that problems arise when an individual's adaptive systems cannot effectively handle multiple stimuli (Roy & Andrews, 1991). Stimuli can include a variety of stressors, including physical and mental health ailments, as well as major life changes, all of which can occur in the face of a cancer diagnosis. The theory

emphasizes the significance of nurturing an individual's coping strategies, particularly during significant life transitions such as coping with metastatic lung cancer (Roy & Zhan, 2006).

The model's coping processes encompass cognitive-emotive channels that establish physiological connections to maintain homeostasis. Mindfulness practice fosters an individual's integration of the mind, body, and spirit. In the nursing application of the RAM, the individual is acknowledged as an interdependent whole, engaging in reciprocal interactions and responses as a cohesive system. By assessing the impact of stimuli on the patient's behavioral patterns, nurses can discern the effects, establish objectives, intervene, and evaluate the efficacy of interventions. The purpose of employing mindfulness in this context is to bolster the coping process and facilitate adaptive responses while adjusting to living with metastatic lung cancer.

CHAPTER THREE: REVIEW OF LITERATURE

Literature Search

The literature search was conducted using the four databases (1) PubMed; (2) Cumulative Index in Nursing and Allied Health Literature (CINAHL); (3) EMBASE; and (4) Google Scholar, and the primary search period spanned from January 2023 through August 2023. Searches were restricted to English-language publications and peer-reviewed journals from 2017-2023, with exceptions for seminal articles. Keywords encompassed various combinations of terms related to mindfulness, meditation, app-based mindfulness, anxiety, depression, and lung cancer. All pertinent research articles were reviewed, categorized, and appraised for relevance to the PICOT topic. The initial broad searches yielded 7,234 articles. Subsequent searches utilized Boolean operators and search terms, such as "lung cancer AND mindfulness" and "anxiety OR depression in lung cancer," reducing the total to 246 studies. These were then evaluated for relevance and scientific rigor, excluding duplicates. Among the 246 articles, 13

articles were selected and discussed in this review of the literature. Specific results from selected articles can be found in the Table of Evidence (TOE).

Mindfulness-Based Interventions

MBIs have been a subject of interest, albeit with varying degrees of exploration across different cancer types. Previous literature is limited in studying patients with lung cancer, other than one study by Millbury et al. (2020) that focused on patients grappling with metastatic non-small cell lung cancer (NSCLC) and their spouses. In the context of this often-incurable disease, which can evoke profound psychological and spiritual distress for both patients and their families, those researchers embarked on a pilot study. The researchers aimed to evaluate the feasibility and preliminary efficacy of a couple-based meditation (CBM) intervention. This intervention, delivered through videoconferencing, encompassed meditation and emotional sharing exercises. The findings were encouraging, demonstrating that the CBM intervention was not only feasible but also well-received by the participants. Moreover, it displayed preliminary efficacy, with individuals in the CBM group reporting lower levels of depressive symptoms and cancer-related stress compared to those in the usual care (UC) group. Remarkably, spouses in the CBM group also experienced improvements in their spiritual well-being. While the study's participant pool was relatively homogeneous, these outcomes point toward the potential value of mindfulness-based interventions in ameliorating psychological symptoms within palliative care settings, underscoring the necessity for further research involving larger and more diverse populations.

Shifting the focus to breast cancer, Janusek et al. (2019) conducted a study involving women newly diagnosed with early-stage breast cancer. In their investigation, they sought to determine the impact of an 8-week Mindfulness-Based Stress Reduction (MBSR) program on

various facets of participants' well-being. A total of 192 women were randomized into either the MBSR program versus an active control condition (ACC), which involved cancer recovery and health education classes. The results unveiled substantial benefits in the MBSR group, including reduced perceived stress, fatigue, sleep disturbances, and depressive symptoms over time. Importantly, this intervention also expedited the restoration of natural killer cell activity (NKCA), reduced circulating TNF-alpha and IL-6 levels, and enhanced interferon-gamma (IFN-gamma) production. These immunological changes suggested an improved immune function that could support cancer control. Collectively, these findings advocate for the early provision of MBSR to women newly diagnosed with breast cancer as it not only delivers psychological benefits but also optimizes immune function, potentially aiding in cancer management.

Park et al. (2020) conducted a randomized trial among stage I-III breast cancer patients (N=74) which compared an 8-week MBCT intervention as compared to a wait-list control group (WC). The outcomes unequivocally favored the MBCT group, with significantly better results in terms of psychological distress, fear of cancer recurrence, fatigue, spiritual well-being, and overall QOL compared to the control group. Importantly, these positive effects persisted for up to four weeks after completing the intervention. This study suggests that MBCT could potentially holistically enhance the well-being of breast cancer patients, addressing psychological, physical, and spiritual dimensions.

Würtzen et al. (2013) undertook a population-based randomized controlled study among 336 patients who had undergone breast cancer surgery to evaluate the effects of an 8-week group MBSR intervention on anxiety and depression levels. Participants were randomly assigned to receive either usual care or MBSR in addition to usual care. The study employed questionnaires administered at multiple time points, ultimately revealing statistically significant and clinically

meaningful reductions in anxiety and depression levels immediately following the intervention and after 12 months in the MBSR group, marked by medium-to-large effect sizes. These findings support the wider adoption of MBSR as an effective intervention for alleviating anxiety and depression in women with breast cancer, underscoring its relevance before, during, and after cancer treatment.

One of the few studies which enrolled patients in the metastatic setting, Eyles et al. (2014) used a mixed methods design to explore the feasibility and acceptability of providing MBSR to women living with metastatic breast cancer. This study employed a mixed methods design, integrated qualitative interviews with patients and staff and questionnaires to gauge various outcomes. Out of 100 women approached, 20 participated in the study (80 percent attrition rate), with recruitment proving to be a slow process. While participants found the course acceptable and reported positive outcomes such as reduced anxiety and enhanced QOL, the 8-week commitment posed challenges for some individuals. This study illuminates the potential of MBSR as a valuable resource for MBC patients, emphasizing the need for tailored interventions that are less time-intensive and more feasible for patients in similar circumstances.

App-Based Mindfulness Interventions

The use of technology-based MBIs has gained prominence in recent years, offering a promising avenue for improving the mental well-being of patients experiencing health challenges. Several studies have shed light on the potential of app-based interventions, each contributing valuable insights into their feasibility and effectiveness.

In a study by Vandenbogart et al. (2023), an app-based MBI was implemented to help heart-failure patients manage psychological distress. This 4-week program involved daily mindfulness practices facilitated through a mobile app, which was also used in the present DNP

project. The participants in this study comprised a small group of patients dealing with advanced heart failure while awaiting transplants. The results of this investigation were noteworthy, as they demonstrated that individuals who engaged in mindfulness practices through the app experienced significant reductions in stress and anxiety levels. Furthermore, these participants exhibited increased resilience, highlighting the potential of this brief technology-based MBI to enhance the mental well-being of patients facing similar circumstances. However, the study underscores the need for additional research to corroborate and expand upon these findings, emphasizing the importance of continued exploration in this domain.

Mikolasek et al. (2018) delved into the feasibility of a mindfulness and relaxation using a smartphone app as an intervention for multiple cancer patients, across several disease types. Their prospective observational study incorporated quantitative and qualitative methods and engaged 100 cancer patients. The study aimed to assess patient characteristics, adherence to the app-based intervention, factors influencing adherence, and patient feedback regarding the use of the app. The results unveiled a nuanced picture. In detail, while 54 patients demonstrated continuous engagement with the app exercises up to week 10, a decline in exercise frequency was observed over time. Various factors were identified as predictors for better adherence, including gender, personality traits such as openness to experience, resistance to change, and the presence of depressive symptoms. Importantly, patient feedback on the app was predominantly positive, although there were suggestions for potential enhancements. Given the acceptable adherence rates and favorable patient responses, this study underscores the feasibility of employing app-based mindfulness and relaxation intervention for cancer patients. It also highlights the importance of tailoring such interventions to the specific needs and characteristics of the target population.

Rosen et al. (2018), in a RCT, contributed to the exploration of mobile app-delivered mindfulness training (AMT) in the context of breast cancer. Their study involved 112 participants, randomized into either the AMT group or a WC group over eight weeks, with an additional four weeks of follow-up. The results of this investigation were encouraging, as participants in the AMT group reported higher QOL and dispositional mindfulness compared to the WC group throughout the study period. However, it is worth noting that fewer participants in the AMT group completed all study assessments, indicating some challenges related to app utilization and study completion. Nevertheless, these findings suggest that commercially available AMT has the potential to offer tangible benefits for enhancing QOL in individuals following a cancer diagnosis. This suggests there may be a benefit to utilizing technology in delivering mindfulness interventions and improving cancer patients' well-being while highlighting the need to address issues related to engagement and completion in future research and intervention design.

Synthesis of the Literature

MBIs have emerged as a compelling approach to addressing the psychological distress prevalent among oncology patients. One recurring theme in the literature is the high prevalence of anxiety and depression among cancer patients. Notably, Chayadi et al. (2022) conducted a systematic review and meta-analysis, emphasizing the substantial burden of these psychological symptoms. This highlighted the urgent need for effective interventions to alleviate the mental health challenges individuals face navigating the complexities of cancer.

MBIs, as explored in various studies, offer a ray of hope in addressing the psychological distress experienced by cancer patients. For example, Eyles et al. (2014) investigated the utility of mindfulness in managing fatigue, anxiety, and depression in women with metastatic breast

cancer. Their findings suggest that mindfulness holds promise as a self-management tool, positively impacting overall well-being. Another pivotal study by Yu et al. (2023) conducted a systematic review and meta-analysis, focusing on the impact of MBSR on loneliness, anxiety, and depression in cancer patients. Their results further bolstered the case for mindfulness interventions, providing evidence of their potential to alleviate the emotional challenges associated with cancer diagnosis and treatment.

The study by Janusek et al. (2019) stands out for its unique emphasis on immune function restoration in women newly diagnosed with breast cancer. This randomized trial revealed psychological benefits and hinted at the possibility that mindfulness-based stress reduction might positively influence immune function, a critical aspect of overall health in cancer patients.

Despite these promising outcomes, the literature reveals specific gaps that warrant attention. Firstly, the diversity of cancer types and stages and variations in mindfulness intervention protocols pose challenges in drawing definitive conclusions across studies. Standardization in intervention design and reporting is essential to enhance the comparability and replicability of studies. Secondly, the long-term effects of mindfulness interventions on cancer patients' psychological well-being and overall quality of life are an area ripe for exploration. Most studies have concentrated on short-term outcomes, leaving a gap in understanding the sustainability of benefits over extended periods. Moreover, the influence of mindfulness interventions on specific cancer-related symptoms, such as cancer-related fatigue, sleep disturbance, and fear of cancer recurrence, demands more in-depth investigation. Han et al. (2023) addressed the issue of sleep disturbance in early-stage cancer patients, demonstrating the potential for more targeted inquiries into symptom-specific outcomes.

Overall, MBIs offer promise as effective strategies for alleviating anxiety and depression in oncology patients. While the literature showcases strengths in demonstrating short-term psychological benefits and potential immune system modulation, there are notable gaps in standardization, long-term effects, symptom-specific outcomes, and real-world implementation. Addressing these gaps through ongoing study will contribute to a more comprehensive understanding of the role of mindfulness in supporting the mental health and well-being of cancer patients, potentially ushering in a new era of holistic care in oncology.
Specifically, there are gaps in the literature in the metastatic setting for all cancer types and in patients with lung cancer at any stage. To meet these gaps, this DNP project addressed patients with metastatic lung cancer, while drawing from existing literature on other disease types/settings.

CHAPTER FOUR: METHODS

Project Design

This study was a quasi-experimental study with a pre-test and post-test analysis. This DNP project aimed to evaluate the efficacy and feasibility of an eight-week app-based Mindfulness intervention in anxiety and depression for patients with metastatic non-small cell lung cancer. QOL was included as a secondary measure. All measures were evaluated before and following the eight-week intervention.

Screening

Over a three-week period, all metastatic lung cancer patients with appointments during the screening window were assessed for anxiety and depression. Those who screened positive for at least mild anxiety and/or depression and met the eligibility criteria were invited to participate in an eight-week MBI delivered through the institution's existing mindfulness app. Although a

sample size of 10-15 was anticipated, time constraints resulted in a final sample size of four participants. These participants also underwent baseline QOL assessments

After screening positive for anxiety and/or depression, five patients consented to participate in the trial. One patient (Participant 3) did not proceed due to a rapid clinical decline. A final sample size of four has been analyzed. Out of the four patients in the final sample, two were followed for depression only (participants 1 and 5), one for anxiety only (participant 4), and one patient was followed for both (participant 2).

Sample Population and Setting

Participants were enrolled using a convenience sample from a single outpatient oncology clinic at a major medical center in Santa Monica, California. Participants were included if they met the following inclusion criteria: (1) metastatic non-small lung cancer diagnosis; (2) Eastern Cooperative Oncology Group (ECOG) performance between 0 and 2; (3) and English-speaking. Participants were ineligible if they had non-metastatic cancer, had a primary cancer type other than non-small cell cancer, or were unwilling or incapable of using the application, or had an ECOG performance status > 2.

Ethical Considerations

This DNP project was submitted for review to the institutional cancer center and the Institutional Review Board (IRB). Approval was granted from three cancer center committees, and after feedback was obtained and implemented, the IRB determined that the project was exempt from full IRB approval. Before participating, patients were given written informed consent and had ample opportunity to ask questions. A copy of the signed consent form was provided to all participants. The protocol and informed consent have been provided in Appendices A and B, respectively.

Intervention

An app-based intervention was organized into four weeks of basic meditations followed by four weeks of wellness meditations, using the UCLA Mindful app, which has been made available through the UCLA. Mindful, the mindfulness education center of UCLA Health. Permission was obtained to use the app and has been included in Appendix C. Detailed instructions were provided to the patients in writing. The initial session, lasting approximately fifteen minutes, introduced subjects to mindfulness and instructed them on using the app. Over the eight-week period, patients participated in brief, daily meditations lasting 10-15 minutes each. A meditation schedule is provided in Appendix D. To ensure adherence, patients received weekly reminder emails or phone calls and logged their daily meditation activities via Qualtrics. At the end of eight weeks, participants provided feedback on their experience through a phone call with the project lead (MM).

Instrumentation and Data Collection

Anxiety was assessed using the Generalized Anxiety Disorder (GAD-7) scale (Spitzer et al., 2006) which exhibits a Cronbach alpha reliability coefficient of 0.89. This scale comprises seven items, with scores ranging from 0 to 21, categorizing the intensity of distress as mild (5–9), moderate (10–14), or severe (15–21). A higher score on the scale signifies a greater degree of anxiety (Spitzer et al., 2006). Pfizer owns the GAD-7 copyright, but it is open to public use. The GAD-7 scale has been provided in Appendix E.

Depression was assessed using the 9-item Patient Health Questionnaire (PHQ-9), a well-established and validated measurement tool (Kroenke et al., 2001). The reliability of PHQ-9 has been demonstrated with a Cronbach alpha coefficient of 0.89 (Kroenke et al., 2001). This scale classifies the severity of depression into five categories: minimal (scores 1-4), mild (scores 5-9),

moderate (scores 10-14), moderately severe (scores 15-19), and severe (scores 20-27). Pfizer holds the copyright for PHQ-9, but it is open for public use. The scale has been provided in Appendix F.

QOL was a secondary measure evaluated using the Functional Assessment of Cancer Therapy-Lung (FACT-L) instrument (Butt et al., 2005). Assessment of Cancer Therapy - Lung is a standardized questionnaire designed to assess the QOL and functional well-being of individuals diagnosed with lung cancer. Developed in 1995, it is a reliable scale with a Cronbach alpha of 0.86 (Cella et al., 1995). The FACT-L scale is part of a broader family of FACT questionnaires adapted for various cancer types, helping healthcare providers tailor their care and support to the unique needs of cancer patients. The FACT-L scale has been provided in Appendix G. The authors granted the use of the FACT-L scale (see Appendix H).

Another secondary outcome was feasibility and acceptability, assessed using a daily record documenting patient engagement with the intervention using Qualtrics. This approach yielded insights into the number of patients capable of completing the full 8-week intervention protocol. Furthermore, patients were offered the opportunity to engage in a phone call to give feedback at the end of the 8-week session. Some patients failed to use Qualtrics on each day of meditation, so their self-reports were also considered. All participants who began the intervention elected to participate in the full 8 weeks.

Data Analysis

Data was analyzed using SPSS. Descriptive statistics and paired t-tests were utilized to analyze the results. In addition, Cohen's D (Cohen, 1988) was used to evaluate effect size.

CHAPTER FIVE: RESULTS

Patient Characteristics at the Time of Enrollment

Table 1 reports patient characteristic at the time of enrollment. The sample included three women and one man, ages 43 to 68, with an average age of 52. Time since diagnosis ranged from 3 to 90 months, with an average of 35. One out of four participants was taking a selective serotonin reuptake inhibitor (SSRI) for mental health reasons.

Table 1.

Patient	Sex	Age	Time Since Initial Diagnosis (Months)	Use of Mental Health Medication
1	F	<_50	40	Y
2	F	>_50	90	N
4	F	<_50	6	N
5	M	< 50	3	N

Participation (Feasibility)

Table 2 reports the frequency of participating in the 8-week MBI intervention. 100% of participants completed the full 8-week intervention, participating on average for 32.5 out of 56 days or 58 percent. Notably, three of the four patients meditated more frequently than recorded in Qualtrics, which will be elaborated on in Chapter 6.

Table 2 Participation Outcomes Among Patients Enrolled in an 8-Week MBI Intervention

PATIENT number	**Qualtrics (days)**	**Self-Report Participation (days)**	**Total Participation (days = q + self)**	**Total Percent Participation**
1	40	0	40	71
2	17	7	24	43
4	22	14	36	64
5	20	10	30	54

Primary Outcome: Anxiety and Depression

Participants 1, 2, and 5 were assessed for depression using the PHQ-9 scale, which is categorized as follows: 5-9 (mild depression), 10-14 (moderate), 15-19 (moderately severe), and 20-27 (severe). Participants 2 and 5 showed changes from baseline to post-test scores, while Participant 1's scores remained unchanged. These scores are summarized in Figure 1. Participant 2's scores were in the mild range, decreasing from 8 to 6. Participant 5's score decreased from moderate (10) at baseline to mild (5) post-test. While pre-test to post-test difference in depression was not statistically significant (p=.250), results showed a clinically important improvement in depression with a large effect size (p-=.25, d= .93), with two out of three participants having a decrease in depression (mean score 5.7-8).

Figure 1. Baseline to Follow-Up Depression Outcomes Among Participants Enrolled in an 8-Week MBI Intervention (N=3)

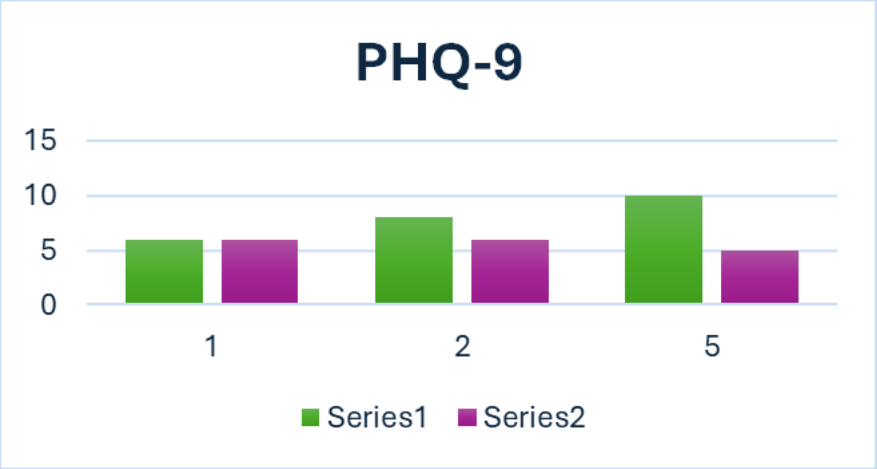
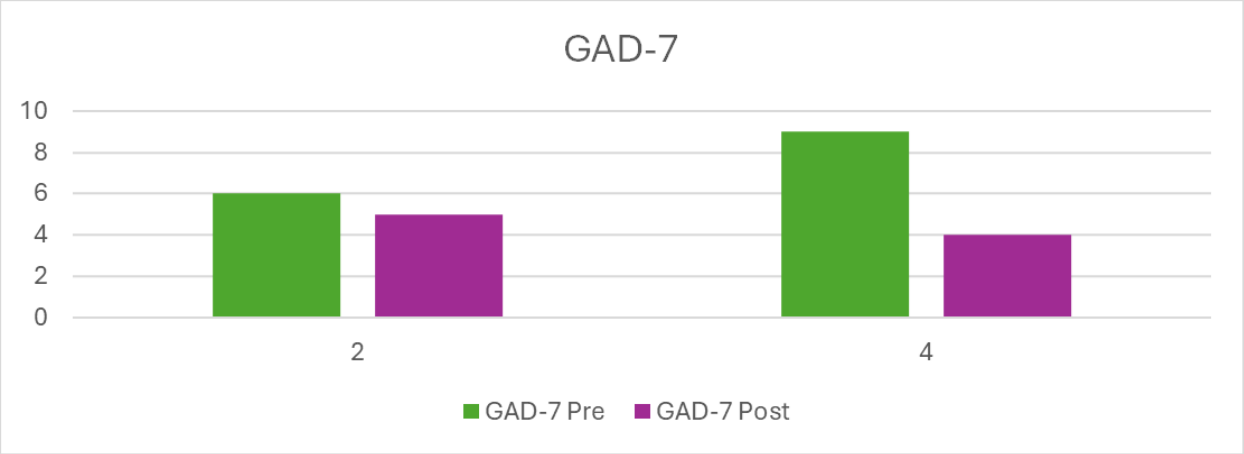


Figure 2 reports the results of pre to post-test anxiety symptom scores among participants enrolled in an eight-week MBI intervention. Participants 2 and 4 were evaluated for anxiety using the GAD-7 scale, which is categorized as follows: 0-4 (none), 5-9 (mild), 10-14 (moderate), and 15-21 (severe). Both participants showed a reduction in their scores from baseline to post-test. While pre-test to post-test difference in anxiety was not statistically

significant, results showed a clinically important improvement in anxiety with a large effect size (*p*=.374, d=1.06) with two out of two patients experiencing decreased anxiety (mean scores 7.5-4.5).

Figure 2. Pre/Posttest Anxiety Symptom Outcomes Among Participants Enrolled in an 8-Week MBI Intervention (N=2)



Secondary Outcome: QOL

Figure 3 reports baseline to follow-up QOL outcomes Among Participants Enrolled in an MBI Intervention. QOL was a secondary outcome for this DNP project, measured using the FACT-L scale. The FACT scale comprises four subscales: physical well-being (PWB), social well-being (SWB), emotional well-being (EWB), and functional well-being (FWB). Additionally, FACT-L includes a lung cancer subscale (LCS). The overall score is calculated by adding the sum of all sub-scales. 100% of participants completed QOL assessments at baseline and post-test. The overall results are highlighted in Figure 3, while the detailed results for the five subscales are presented in Table 3. The results were notable for 75% of participants experiencing improved PWB, SWB, and LSC and 100% of participants had improved EWB. However, the FWB subscale had less improvement with only 50% of patients reporting improvement. While pre-test to post-test difference in overall QOL was not statistically

significant, results showed a clinically important improvement in QOL with a large effect size (p=.125, d=1.06). All participants experienced an improvement in QOL (from mean=84.0 to 105.5).

Table 3. Baseline to Follow-Up QOL Subscale Outcomes Among Participants Enrolled in an Eight-Week MBI Intervention

Patient	PWB-Pre	PWB-Post	SWB-Pre	SWB-Post	EWB-Pre	EWB-Post	FWB-Pre	FWB-Post	LCS-Pre	LCS-Post
1	23	22	19	20	14	19	22	18	25	26
2	20	24	22	20	14	17	21	19	15	19
4	26	27	16	21	12	21	21	24	25	27
5	7	18	10	11	7	15	7	14	10	20

Specific Participant Considerations

Given the small sample size, it is crucial to highlight some participant differences. Patient 1, who showed the least change in scores, was the only participant on medication for depression, possibly explaining the minimal variation. Remarkably, in follow-up, Patient 1 stated, “I can’t believe I have been living with cancer for this long without meditation. It has changed my life.” In contrast, Participant 5 had the most significant impact on the scores, also experiencing notable improvement in disease status during the 8-week intervention, which could have influenced the results. Patients 1, 2, and 4 maintained stable disease throughout the 8 weeks, although Patient 2 was hospitalized for two days just before completing her post-tests.

Participant Comments

Throughout the 8-week project, participants were contacted weekly via email or phone. Early on, 75% of participants identified the Qualtrics survey as a barrier, considering it an unnecessary extra step. One patient said, “I use the app on my phone and then have to log in to my computer to find your Qualtrics link, seems like an unnecessary step.” Despite this, the project lead encouraged them to continue using Qualtrics while also tracking their participation

on their personal calendars. All participants reported enjoying the app and the overall experience. Participants 1 and 4 suggested incorporating more meditation variation into the intervention. All four participants found the intervention beneficial, noted feeling more positive, and expressed their intention to continue meditating regularly.

CHAPTER SIX: DISCUSSION

The purpose of this study was to implement an app-based MBI intervention for patients with metastatic non-small cell lung cancer. While results failed to reach statistical significance, there was improvement in anxiety, depression, and QOL with a large effect size. The app-based intervention was also found to be feasible. These findings are consistent with what has been found in previous literature in cancer patients. For example, Rosen et al. (2018), found that an app-based mindfulness intervention improved quality of life in breast cancer patients, while Vandenbogart et al. (2023) found that an app-based intervention reduced anxiety in heart failure patients. In addition, Mikolasek et al. (2018) found that an app-based mindfulness intervention was feasible for cancer patients, while findings from a previous study by Eyles et al. (2014) suggested that an MBSR intervention was too time intensive for patients experiencing metastatic cancer.

Participation rates, a critical measure of feasibility, showed that patients engaged with the intervention on average for 32.5 out of 56 days, or 58%. This suggests that while some patients found the intervention manageable, others faced barriers to consistent participation. The participant feedback indicated that while the intervention was generally well-received, the Qualtrics survey component was perceived as an unnecessary hurdle, and more variability in the intervention was desired.

In terms of primary outcomes, the project observed reductions in both anxiety and depression scores among participants. Specifically, Participant 2's PHQ-9 scores decreased from 8 to 6, and Participant 5's scores dropped from 10 to 5. Similarly, Participant 4's GAD-7 scores decreased significantly from 9 to 4. These changes, although based on a small sample, suggest that this MBI could positively impact psychological symptoms in this patient group.

QOL measured by the FACT-L scale, indicated improvements in QOL across all participants. Each participant had increased scores in overall QOL, with specific enhancements noted in the physical, social, emotional, and functional well-being subscales. The LCS also showed improvement, highlighting the comprehensive benefits of the intervention.
Overall, the results indicated that such an intervention could be feasible and potentially effective in reducing anxiety and depression. However, the sample size is very limited, and there is no long-term follow-up yet, so it is impossible to draw full conclusions. It does suggest the need for ongoing study.

Limitations

Despite the promising results, several limitations of this study must be acknowledged. Firstly, the small sample size and study design (quasi-experimental, no control) significantly limits the study's validity and the generalizability of the findings. This small cohort also prevented the statistical analysis of the results, reducing the strength of the conclusions that can be drawn. Additionally, one participant did not proceed due to rapid clinical decline, further reducing the sample size and highlighting the challenges of conducting research in a severely ill population.

Another limitation was the self-reported nature of participation, which might not accurately reflect actual engagement with mindfulness practices. The reliance on self-reporting,

combined with issues identified with the Qualtrics survey, suggests that future studies should consider alternative methods for tracking participation to improve accuracy.

Lastly, the intervention period of eight weeks might have been too short to capture the full potential benefits of mindfulness practices, and the lack of long-term follow-up means that the sustainability of the observed benefits remains unclear.

Future Implications/Further Study

Given the results and the limitations identified, several recommendations for future research and practice emerge. First, larger-scale studies with more diverse populations are needed to validate findings and enhance generalizability. This could include increased diversity of race and ethnicity, language, and socioeconomic background. RCTs could be implemented to evaluate the efficacy of app-based MBI interventions more rigorously compared to standard treatments. Extending the duration of studies is essential to assess the long-term effects of mindfulness interventions on psychological well-being, QOL, and survival outcomes. Additionally, incorporating objective measures of engagement and standardized assessment tools will reduce bias and provide more accurate data on intervention effectiveness.

Moreover, developing and testing tailored MBI interventions that consider metastatic lung cancer patients' unique needs and preferences can enhance adherence and effectiveness. Exploring ways to integrate MBI practices into standard oncology care is also crucial, as it can provide a holistic approach to patient management that addresses both physical and psychological health needs. These steps will ensure MBIs are more effective and widely applicable in clinical settings.

CONCLUSION

This DNP project demonstrates the potential benefits of an eight-week app-based MBI intervention for patients with metastatic non-small cell lung cancer, showing improvements in anxiety, depression, and quality of life. Despite the limitations, the findings provide a foundation for future research and suggest practical implications for enhancing cancer care through mindfulness practices. Continued exploration and rigorous evaluation of MBIs are necessary to establish their role in supporting the mental health and overall well-being of cancer patients.

APPENDICES

Appendix A

NON THERAPEUTIC PROTOCOL

University of California, Los Angeles

Melody Mendenhall, NP, UCLA Hematology/Oncology

Research Protocol

The Utility and Feasibility of an App-based Mindfulness Intervention in Anxiety, Depression, and Quality of Life in Patients With Metastatic Non-Small Cell Lung Cancer

Protocol Number:	1
Version Date:	11/26/23
Development Phase:	Student DNP project/Feasibility/Quality Improvement Project
Sponsor:	Melody Mendenhall, RN, MSN, NP-C UCLA Santa Monica Hematology/Oncology 2020 Santa Monica Blvd, Suite 600 Santa Monica, CA 90404
Funding Organization:	Self-Funded
Principal Investigator:	Name: Melody Mendenhall, RN, MSN, NP-C Telephone: 714-422-5804 E-mail: MMendenhall@mednet.ucla.edu

Approval:

Melody Mendenhall, NP — 12/1/2023

PI or Sponsor Signature (Name and Title) — *Date*

1.0 PROTOCOL SUMMARY AND/OR SCHEMA

This DNP project aims to assess the feasibility and utility of a brief, app-based Mindfulness-Based Intervention (MBI) in metastatic lung cancer patients. The project employs pre-test and post-test assessments to examine variations in anxiety and depression levels. As a quality improvement project, it has a limited sample size without a control group, making the pre-test/post-test approach suitable.

Patients will be screened initially for anxiety and depression; those screening positive for either- meeting inclusion/exclusion criteria and willing to use the mindfulness app will be offered an 8-week app-based MBI. The expected sample size is 20 to 30 participants, selected based on diagnosis, willingness to engage with the app, and Eastern Cooperative Oncology Group (ECOG) performance of 2 or greater.

The intervention involves an initial session on mindfulness and app usage, followed by eight weeks of daily 10–15-minute meditations. Participants receive weekly reminders and keep a participation log. After the intervention, they will have the option of providing feedback in a focus group.

Data collection includes preliminary and post-intervention assessments of anxiety, depression, and quality of life (QOL). The Functional Assessment of Cancer Therapy-Lung (FACT-L) scale assesses QOL, while anxiety is measured using the Generalized Anxiety Disorder (GAD-7) scale, and depression levels using the Patient Health Questionnaire (PHQ-9). Feasibility will be assessed using a daily record of patient engagement. Data will be analyzed using SPSS, employing descriptive statistics and repeated-measures ANOVA. The project seeks to determine

if the app-based MBI is a practical and beneficial intervention for metastatic lung cancer patients, potentially improving their QOL and reducing anxiety and depression.

2.0 OBJECTIVES AND SCIENTIFIC AIMS

- Primary objective: Assess the feasibility and efficacy of an eight-week app-based mindfulness intervention in treating anxiety and depression symptoms in patients with metastatic non-small cell lung cancer (NSCLC)
- Secondary Objective: Assess the efficacy of an eight-week app-based mindfulness intervention on quality of life in patients with metastatic NSCLC

3.0 BACKGROUND AND RATIONALE

Lung cancer, a pervasive and life-threatening malignancy worldwide, imposes not only physical but also significant psychological distress on affected individuals. A systematic review and meta-analysis by Yan et al. (2019) underscored the substantial burden of depression in this population. Importantly, these psychological symptoms are not confined to the post-diagnostic phase but often persist throughout the cancer journey.

Anxiety and depression exact a heavy toll on the quality of life of individuals with lung cancer. Brown-Johnson et al. (2014) highlighted the role of lung cancer stigma in intensifying psychological distress, eroding patients' overall well-being. These symptoms are associated with a myriad of challenges, including social isolation, disrupted sleep, reduced physical activity, and difficulties adhering to treatment regimens. Of particular interest is the potential influence of anxiety and depression on disease morbidity and mortality. Andersen et al. (2021) employed a joint model analysis, linking psychological symptom trajectories with the survival of non-small cell lung cancer patients. Their study revealed that patients with persistent high levels of psychological symptoms faced poorer survival rates than those with lower symptom burdens. This suggests a bidirectional relationship between mental health and cancer progression, where psychological distress might contribute to deteriorating physical health. Psychosocial stress, encompassing anxiety and depression, significantly impacts immune responses in cancer patients (Antoni & Dhabhar, 2019). Chronic stress may disrupt the immune system, potentially influencing tumor growth and treatment response. This underscores the importance of holistic care in cancer management, where addressing psychological distress not only enhances patient comfort but also may have implications for disease control. Moreover, Mausbach et al. (2018) discussed the substantial healthcare costs associated with depression in cancer patients, further underscoring the need for comprehensive care that addresses both the physical and psychological aspects of lung cancer. Duan et al. (2022) emphasized that addressing frailty, often associated with psychological distress, can improve outcomes in lung cancer patients undergoing chemotherapy. Additionally, McFarland et al. (2021a, 2021b) reported prognostic implications of depression and inflammation in metastatic lung cancer patients, further supporting the notion that psychological well-being is intertwined with disease progression.

Su et al. (2022) explored the interplay between cancer fear, emotion regulation, and emotional distress in newly diagnosed lung cancer patients. Their findings underscore the importance of addressing fear and providing tools for effective emotion regulation to enhance the psychological well-being of patients.

Talk therapy and medication have demonstrated efficacy in managing cancer patients; however, the accessibility of such interventions may be hindered by financial limitations. The issue of cost-prohibitive care is further exacerbated by an increasing number of psychiatrists and psychologists discontinuing acceptance of insurance coverage (Bishop et al., 2014). Studies examining the efficacy of antidepressant interventions in patients diagnosed with cancer have produced inconclusive outcomes, highlighting the need for a more nuanced and adaptable therapeutic approach (Ostuzzi et al., 2015).

Mindfulness is a deliberate and nonjudgmental practice that centers on the present moment. which involves techniques such as intentional breathing, meditation, and focusing attention on specific areas of the body through body scans (Kabat-Zinn, 2013). The underlying concept of mindfulness shifts an individual's response from being reactive to being reflective when facing stressors or discomfort. By doing so, mindfulness can potentially disrupt negative thoughts, emotions, and sensations, enabling better self-regulation and leading to positive psychological outcomes.

The effectiveness of mindfulness-based stress reduction (MBSR) interventions has been supported by research, building on the pioneering work of Jon Kabat-Zinn (1982). This initial research showcased the efficacy of MBSR in individuals dealing with chronic pain, psoriasis, and immune dysfunction. A literature review by Chayadi et al. (2022) showed that mindfulness-based interventions (MBIs), including MBSR, mindfulness-based cognitive therapy (MBCT), and mindfulness-based cancer recovery (MBCR), can be effective in reducing symptoms of depression, anxiety, and cancer-related fatigue (CRF) in multiple cancer types, with these benefits often lasting beyond the intervention period. Considering these findings, incorporating mindfulness practices could serve as a beneficial approach to managing chronic stress and promoting overall mind-body health for individuals with metastatic cancer.

4.0 OVERVIEW OF STUDY DESIGN/INTERVENTION

4.1 Design

The DNP project aims to assess the feasibility and utility of a brief, app-based MBI in metastatic lung cancer patients. A quasi-experimental design will be utilized, encompassing both pre-test and post-test assessments, to elucidate the variabilities in the dependent constructs of anxiety and depression. Being a quality improvement project, the project will have a relatively constrained sample size with no control group. Consequently, the employment of the pre-test/post-test modality is most fitting.

4.2 Intervention

Subjects will undergo an initial session with an introduction to mindfulness and instruction on utilizing the app, expected to take 30-45 minutes. A screening assessment for QOL will also be done during this session, as this will be a secondary outcome. Over eight weeks, patients will have pre-selected brief, daily meditations lasting 10-15 minutes each. Patients will receive a weekly reminder phone call and will be asked to keep a daily log to document participation via Redcap. Following the 8-week intervention, patients will have the opportunity to participate in a focus group to provide feedback to the team lead.

5.0 CRITERIA FOR SUBJECT ELIGIBILITY

Describe the characteristics of the subject population.

5.1 Subject Inclusion Criteria

- Metastatic NSCLC
- Able to read and understand English or Spanish
- Current patient of UCLA Santa Monica Hematology/Oncology
- Screen positive for, at minimum, mild anxiety or depression
- ECOG performance Status of 2 or less
- Willingness/Ability to engage with a mindfulness app
- Willing to receive weekly phone call reminders

5.2 Subject Exclusion Criteria

- Disease types other than NSCLC
- Non-metastatic NSCLC
- Unable to read/understand English/Spanish
- ECOG Performance status of 3 or greater

6.0 RECRUITMENT PLAN

Participants will be selected through convenience sampling through multiple outpatient oncology clinics at a major Santa Monica, California medical center. Over two months, all willing metastatic lung cancer patients with an appointment during the screening window will be screened for anxiety and depression. Individuals who screen positive for anxiety or depression and meet inclusion/exclusion criteria will be offered an eight-week MBI facilitated via the institution's existing mindfulness app. A sample size of twenty to thirty participants is anticipated.

7.0 ASSESSMENT/EVALUATION PLAN

- Patients will be screened for anxiety and depression at baseline
- Prior to starting the intervention, QOL will also be assessed.
- Participants will be assessed for anxiety, depression, and quality of life immediately following the intervention, and then at 4 week intervals thereafter for a total of one year.
- Feasibility will be assessed by number of participants completing the intervention; participants will be asked to register their participation daily via Redcap.
- Anxiety will be measured using the GAD-7 scale.
- Depression will be measured utilizing the PHQ-9
- QOL will be measured using the FACT-L scale for lung cancer
- Permission was granted to utilize the FACT-L scale and was not required for GAD-7 or PHQ-9

8.0 CRITERIA FOR REMOVAL FROM STUDY

Patients will not be considered in the final results if they cannot complete the 8 week questionnaires within two weeks of completion.

9.0 RESEARCH PARTICIPANT REGISTRATION

- Confirm eligibility as defined in the section entitled Criteria for Patient/Subject Eligibility.
- Obtain informed consent, by following procedures defined in section entitled Informed Consent Procedures.

- During the registration process registering individuals will be required to complete a protocol specific Eligibility Checklist.

10.0 DATA COLLECTION, RETENTION AND MONITORTING

10.1 Data Collection Instruments

The Investigator will prepare and maintain adequate and accurate source documents designed to record all observations and other pertinent data for each subject treated with the study intervention.

Study personnel will enter data from source documents corresponding to a subject's visit into the protocol specific CRF when the information corresponding to that visit is available. Subjects will not be identified by name in the study database or on any case report form to be collected by the project lead, but will be identified by a site number, subject number and initials.

The project lead (PI) will identify potential study patients by accessing medical records. Once a participant has consented to the trial their medical records will be accessed by the PI to collect data on age, gender, medical history, social history, and a medication list.

The Investigator is responsible for all information collected on subjects enrolled in this study. All data collected during the course of this study must be reviewed and verified for completeness and accuracy by the Investigator. A copy of the CRF will remain at the Investigator's site after the study.

10.2 Data Management Procedures

The data will be entered into a database. The study team will be responsible for data processing, in accordance with procedural documentation.

10.3 Data Quality Control and Reporting

After data have been entered into the study database, a system of computerized data validation checks will be implemented and applied to the database on a regular basis. All changes to the study database will be documented.

10.4 Archival of Data

The database is safeguarded against unauthorized access by established security procedures; appropriate backup copies of the database and related software files will be maintained. Databases are backed up by the database administrator in conjunction with any updates or changes to the database.

10.5 Availability and Retention of Investigational Records

The Investigator must make study data accessible to the IRB upon request. A file for each subject must be maintained that includes the signed Informed Consent, HIPAA Authorization, and copies of all source documentation related to that subject. The Investigator must ensure the reliability and availability of source documents.

10.6 Subject Confidentiality

In order to maintain subject confidentiality, only a site number, subject number and subject initials will identify all study subjects on CRFs and other documentation.

11.0 ADMINISTRATIVE, ETHICAL, REGULATORY CONSIDERATIONS

The study will be conducted according to the Declaration of Helsinki, Protection of Human Volunteers (21 CFR 50), Institutional Review Boards (21 CFR 56), and Obligations of Clinical Investigators (21 CFR 312).

To maintain confidentiality, all laboratory specimens, evaluation forms, reports and other records will be identified by a coded number and initials only. All study records will be kept in a locked file cabinet and code sheets linking a patient's name to a patient identification number will be stored separately in another locked file cabinet. Clinical information will not be released without written permission of the subject. The Investigator must also comply with all applicable privacy regulations (e.g., Health Insurance Portability and Accountability Act of 1996, EU Data Protection Directive 95/46/EC).

11.1 Protocol Amendments

Any amendment to the protocol will be written by the principle investigator. Protocol amendments cannot be implemented without prior written IRB/IEC approval

11.2 Institutional Review Boards and Independent Ethics Committees

The protocol and consent form will be reviewed and approved by the IRB/IEC of each participating center prior to study initiation.

Any documents that the IRB/IEC may need to fulfill its responsibilities (such as protocol, protocol amendments, Investigator's Brochure, consent forms, information concerning patient recruitment, payment or compensation procedures, or other pertinent information) will be submitted to the IRB/IEC. The IRB/IECs written unconditional approval of the study protocol and the informed consent form will be in the possession of the Investigator before the study is initiated. This approval must refer to the study by exact protocol title and number and should identify the documents reviewed and the date of review.

Protocol and/or informed consent modifications or changes may not be initiated without prior written IRB/IEC approval.

11.3 Informed Consent Form

Informed consent will be obtained in accordance with the Declaration of Helsinki, ICH GCP, US Code of Federal Regulations for Protection of Human Subjects (21 CFR 50.25[a,b], CFR 50.27, and CFR Part 56, Subpart A), the Health Insurance Portability and Accountability Act (HIPAA, if applicable), and local regulations.

The Investigator will prepare the informed consent form.

A properly executed, written, informed consent will be obtained from each subject prior to entering the subject into the trial. Information should be given in both oral and written form and subjects (or their legal representatives) must be given ample opportunity to inquire about details of the study. If appropriate and required by the local IRB/IEC, consent from the subject will also be obtained. If a subject is unable to sign the informed consent form (ICF) and the HIPAA authorization, a legal representative may sign for the subject. A copy of the signed consent form (and assent) will be given to the subject or legal representative of the subject and the original will be maintained with the subject's records.

12.0 PUBLICATIONS

The preparation and submittal for publication of manuscripts containing the study results shall be in accordance with a process determined by mutual written agreement among the study Sponsor and participating institutions. The publication or presentation of any study results shall comply with all applicable privacy laws, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996.

13.0 INVESTIGATOR RESPONSIBLITIES

By signing the Agreement of Investigator form, the Investigator agrees to:

1. Conduct the study in accordance with the protocol and only make changes after notifying the Sponsor (or designee), except when to protect the safety, rights or welfare of subjects.

2. Personally conduct or supervise the study (or investigation).

3. Ensure that the requirements relating to obtaining informed consent and IRB review and approval meet federal guidelines, as stated in § 21 CFR, parts 50 and 56.

4. Ensure that all associates, colleagues and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.

5. Maintain adequate and accurate records in accordance with §21 CFR 312.62 and to make those records available for inspection with the Sponsor (or designee).

6. Ensure that an IRB that complies with the requirements of §21 CFR part 56 will be responsible for initial and continuing review and approval of the clinical study.

7. Promptly report to the IRB and the Sponsor (or designee) all changes in the research activity and all unanticipated problems involving risks to subjects or others (to include amendments and IND safety reports).

8. Seek IRB approval before any changes are made in the research study, except when necessary to eliminate hazards to the patients/subjects.

9. Comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements listed in § 21 CFR part 312.

Appendix B

University of California, Los Angeles

CONSENT TO PARTICIPATE IN RESEARCH

Feasibility and Efficacy of an App-Based Mindfulness Intervention For Anxiety, Depression, and Quality of Life in Patients with Metastatic Non-Small Cell Lung Cancer.

INTRODUCTION
Melody Mendenhall, RN, MSN, NP from the at the University of California, Los Angeles are conducting a research study. This study is being funded self-sponsored. You were selected as a possible participant in this study because you have lung cancer and have screened positive for anxiety and/or depression. Your participation in this research study is voluntary.

WHAT SHOULD I KNOW ABOUT A RESEARCH STUDY?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

WHY IS THIS RESEARCH BEING DONE?

This research is being done, in order to establish the feasibility and utility of an app-based mindfulness intervention in anxiety, depression, and quality of life for patients with metastatic non small-cell lung cancer.

HOW LONG WILL THE RESEARCH LAST AND WHAT WILL I NEED TO DO?

Participation will take a total of about one year. There will be an 8-week active mindfulness intervention, followed by assessments every four weeks for up to one year.

If you volunteer to participate in this study, the researcher will ask you to do the following:

- Participate in an 8-week app-based mindfulness intervention, with daily tasks lasting 10-15 minutes
- Perform a baseline quality-of-life assessment
- Perform assessments of anxiety and/or depression, as well as quality of life immediately following the intervention, and then every four weeks thereafter for a total duration of one year.
- Receive weekly phone call reminders.
- Participate in a daily survey to keep track of participation
- There will be an option of participating in a focus group to provide feedback to the principal investigator following the 8-week intervention.

ARE THERE ANY RISKS IF I PARTICIPATE?
There have not been any risks identified that are associated with this project.
ARE THERE ANY BENEFITS IF I PARTICIPATE?
You may benefit from the study if you have anxiety and/or depression, along with metastatic non-small cell lung cancer.
The results of the research may add an additional treatment option for lung cancer patients suffering from symptoms of anxiety and/or depression.
What other choices do I have if I choose not to participate?
You can elect to do nothing, or you may elect to utilize existing treatments for anxiety and depression, including medications and talk therapy.
HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?
The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.
Use of personal information that can identify you:
You will be assigned a subject ID. All statistics associated with the study will only be linked to that subject ID.
How information about you will be stored:
Personal details about you will be kept in a file on a secure desktop computer at UCLA Health.

People and agencies that will have access to your information:
The principal investigator and clinic staff will be the only people who have access to your personal information.
The research team, authorized UCLA personnel, and the principal investigator may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.
Employees of the University may have access to identifiable information as part of routine processing of your information, such as lab work or processing payment. However, University employees are bound by strict rules of confidentiality.
How long information from the study will be kept:
Personal information and statistics will be kept in a file on a secure desktop computer, in the office of the principal investigator.
USE OF DATA FOR FUTURE RESEARCH
The data from this project may be used for similar research or for more intensive research.
WILL I BE PAID FOR MY PARTICIPATION?
You will not be paid for your participation in this research study.
WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?
The research team:
If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact: The principal investigator, Melody Mendenhall or research staff-member, Dannyeal Hamilton at 310-829-5471
UCLA Office of the Human Research Protection Program (OHRPP):
If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?
- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

You will be given a copy of this information to keep for your records.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you want to participate in this study you should sign and date below.

SIGNATURE OF THE PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

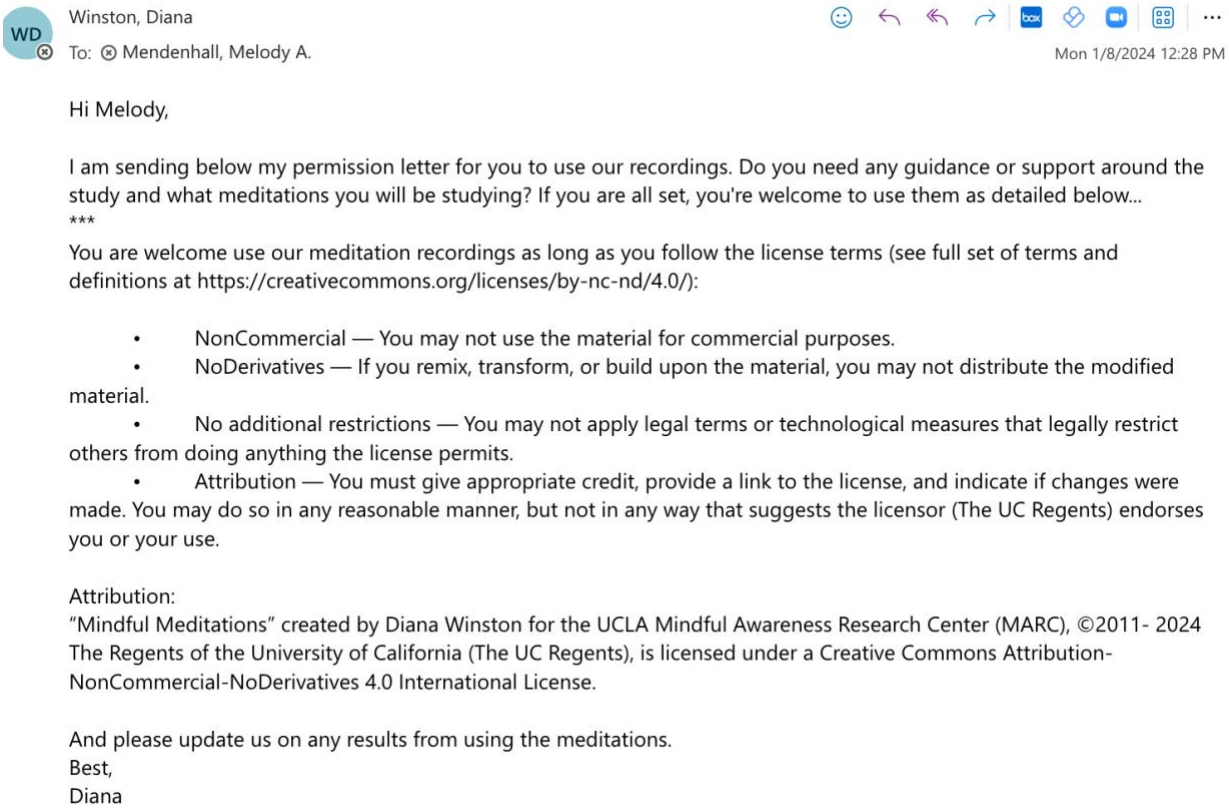
SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person

Appendix C

Permission to Use Mindfulness App



Winston, Diana

To: Mendenhall, Melody A.

Mon 1/8/2024 12:28 PM

Hi Melody,

I am sending below my permission letter for you to use our recordings. Do you need any guidance or support around the study and what meditations you will be studying? If you are all set, you're welcome to use them as detailed below...
***
You are welcome use our meditation recordings as long as you follow the license terms (see full set of terms and definitions at https://creativecommons.org/licenses/by-nc-nd/4.0/):

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And please update us on any results from using the meditations.
Best,
Diana

Appendix D

Meditation Schedule

Meditation Schedule

Thank you for participating in my study! Below is the schedule I would like for you to follow for the 8 weeks.

Week 1:
Day 1: Under getting started- please watch introduction to mindfulness, selecting a meditation posture, and introduction to the science of mindfulness. Then please do the breathing meditation under basic meditations
Day 2-7: Do the breathing meditation once each day

Week 2-4 (Basic Meditations)**:**
Day 1: Meditation for Working with Difficulties
Day 2: Breath Sound Body Meditation
Day 3: Meditation for Working with Difficulties
Day 4: Loving Kindness Meditation
Day 5: Breathing Meditation
Day 6: Body and Sound Meditation
Day 7: Body Scan Meditation

Week 4-8 (Wellness Meditations)
Day 1: Tibetan Singing Bowls
Day 2: Body Awareness, Sound, Breath
Day 3: Body Scan
Day 4: Loving Kindness
Day 5: Working with Difficulties
Day 6: Tibetan Singing Bowls
Day 7: Body Scan
Please do not forget to click on the Qualtrics link to record your attendance!

Appendix E

GAD-7

GAD-7				
Over the last 2 weeks, how often have you been bothered by the following problems? *(Use "✔" to indicate your answer)*	**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

PHQ-9

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

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

FOR OFFICE CODING 0 + _____ + _____ + _____

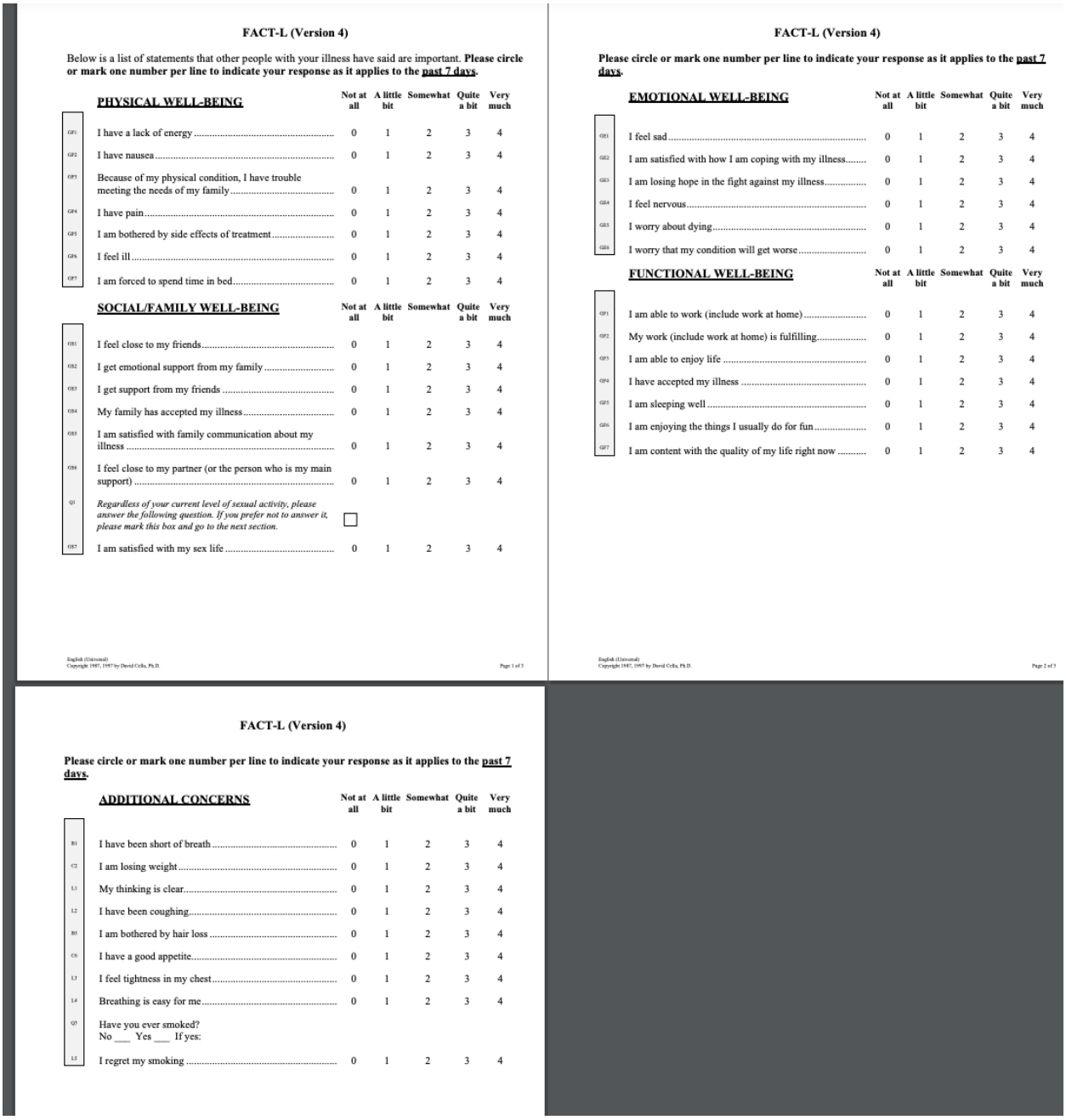
=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

Appendix G

FACT-L Scale



FACT-L (Version 4)

Below is a list of statements that other people with your illness have said are important. **Please circle or mark one number per line to indicate your response as it applies to the past 7 days.**

	PHYSICAL WELL-BEING	Not at all	A little bit	Somewhat	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Somewhat	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box and go to the next section.*	☐				
GS7	I am satisfied with my sex life	0	1	2	3	4

FACT-L (Version 4)

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	EMOTIONAL WELL-BEING	Not at all	A little bit	Somewhat	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	Not at all	A little bit	Somewhat	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

FACT-L (Version 4)

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Somewhat	Quite a bit	Very much
B1	I have been short of breath	0	1	2	3	4
C2	I am losing weight	0	1	2	3	4
L1	My thinking is clear	0	1	2	3	4
L2	I have been coughing	0	1	2	3	4
B5	I am bothered by hair loss	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
L3	I feel tightness in my chest	0	1	2	3	4
L4	Breathing is easy for me	0	1	2	3	4
Q5	Have you ever smoked? No ___ Yes ___ If yes:					
L5	I regret my smoking	0	1	2	3	4

Appendix H

FACT-L licensing

FACIT.org FACIT trans

PROVIDING A VOICE FOR PATIENTS WORLDWIDE

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY (FACIT) LICENSING AGREEMENT

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Name ("Licensee"): Melody Mendenhall, UCLA

Measurement: FACT-L

Language(s): English, Spanish, Korean, Simplified Chinese, Vietnamese, Farsi, French

Study Title ("Study"): Utility of an App-based Mindfulness Intervention on Depression, Anxiety, and Quality of Life in Metastatic Lung Cancer Patients

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Signature: Melody Mendenhall
Melody Mendenhall (Aug 21, 2023 08:20 PDT)

Email: mmendenhall@mednet.ucla.edu

TABLE OF EVIDENCE

Citation	Purpose	Sample and Setting	Methods: Design, Intervention, Measures	Results	Discussion, Interpretation, Limitations
Milbury, K., Li, Y., Durrani, S., Liao, Z., Tsao, A. S., Carmack, C., Cohen, L., & Bruera, E. (2020). A mindfulness-based intervention as a supportive care strategy for patients with metastatic non-small cell lung cancer and their spouses: Results of a three-arm pilot randomized controlled trial. *The Oncologist*, *25*(11), e1794–e1802.	Assess the feasibility and efficacy of couple-based meditation (CBM) compared to supportive-expressive (SE) and usual care (UC) addressing psychospiritual distress	Seventy-five patient-caregiver dyads in metastatic lung cancer. Patients taken from one center. Interventions were delivered via videoconference.	Design: RCT: Patient-caregiver dyads were randomly assigned to CBM, SE, or UC groups. Intervention: Baseline assessments were conducted, followed by four 60-minute sessions delivered through videoconference. Reassessments were performed at 1 and 3 months after the intervention. Measures: Patient and spouse ratings of session benefits, depressive symptoms (CES-D) cancer-related stress- Impact of Event Scale (IES) Psychospiritual distress: Functional Assessment of Cancer Therapy Spiritual Well-being Scale. Feasibility benchmarks, attendance rates, and effect sizes were also measured.	Met feasibility benchmarks both groups: 65% retention. CBM reported greater benefit from sessions than the SE CBM. CBM patients, compared to UC, had significantly lower depressive symptoms(p=0.05, d=0.53) and marginally reduced CRS (p=0.07, d= 0.59) CBM compared to SE group had Medium effect sizes favored CBM over SE for both depression (d=0.59) and CRS (d-0.54) Spouses in the CBM group reported significantly lower depressive symptoms than the UC group (P,0.01, d=0.74)	Intervention was feasible and potentially efficacious for couples coping with metastatic lung cancer. The study highlights the value of mindfulness-based interventions in managing psychological symptoms in the palliative care setting. Limitations: Small sample size, self report, limited to patients with a partner.

Citation	Purpose	Sample and Setting	Methods: Design, Intervention, Measures	Results	Discussion, Interpretation, Limitations
Janusek, L., Tell, D., & Mathews, H. L. (2019). Mindfulness based stress reduction provides psychological benefit and restores immune function of women newly diagnosed with breast cancer: A randomized trial with active control. *Brain, Behavior, and Immunity*, *80*, 358–373.	Determine the effect of MBSR on psychological, behavioral, and immunological function	Sample: Women with resected, lymph node negative breast cancer. N=192 Setting: Breast Cancer centers in west-suburban Chicago	RCT: MBSR vs active control condition (ACC) Intervention: MBCT 8-week program Measures; **Primary Outcomes**: Immmune: NKCA and cytokines **Secondary Outcomes:** Perceived Stress: Perceived Stress Scale (PSS) Depressive symptoms: Center for Epidemiological Studies, Depression (CES-D) Fatigue: Multideimensional Fatigue Scale Inventory (MFSI-SF) Sleep Quality: Pittsburg Sleep Quality Inventory (PSQI) Mindfulness: Five Facet Mindfulness Questionnaire (FFMQ) 5 assessment timepoints: T1= at least 2 weeks following surgery, prior to intervention T2= 4 weeks into intervention T3= Completion of 8 week program T4= 1 month post T5= 6 month post	MBCT group= significant improvements in	Valuable evidence to support the benefits of Mindfulness-Based Stress Reduction (MBSR) for women recently diagnosed with early-stage breast cancer. Limitations: relatively small sample size, The focus on early-stage breast cancer limits generalizability

Citation	Purpose	Sample and Setting	Methods: Design, Intervention, Measures	Results	Discussion, Interpretation, Limitations
Park, S., Sato, Y., Takita, Y., Tamura, N., Ninomiya, A., Kosugi, T., Sado, M., Nakagawa, A., Takahashi, M., Hayashida, T., & Fujisawa, D. (2020). Mindfulness-based cognitive therapy for psychological distress, fear of cancer recurrence, fatigue, spiritual well-being, and quality of life in patients with breast cancer—a randomized controlled trial. *Journal of Pain and Symptom Management*, *60*(2), 381–389.	Determine the effect of MBCT on psychological distress, fatigue, spiritual well-being, fear of cancer recurrence (FOCR), QOL and mindfulness skills	Sample: Women with stage I-III breast cancer N=74 MBCT=38 Control= 36 Setting: Ambulatory affiliates of a tertiary care center in Tokyo.	Design: RCT 1:1, MBCT vs usual care (waitlist control) Primary outcome: Psuchological distress- Hospital Anxiety and Depression Scale (HADS) Secondary Outcomes: Fear of Cancer Recurrence (FOCR Fatigue: Brief Fatigue Inventory Spiritual Well Being Functional Assessment of Chronic Illness Therapy-Spiritual QOL- Functional Assessment of Chronic Illness Therapy-General Data collection: T0: Baseline T1: Week 8 T2: Week 12 (four weeks post-intervention)	MBCT Group had better outcomes with psychological distress (Cohen's d=1.17, p<0.001), spiritual well-being (d=0.98, P<0.001), Fatigue (d=0.66, P<0.01), QOL (d=0.79, P<0.001), FCR (D=0.43, p<0.01) These differences persisted at T2 (four weeks following the intervention).	The improvements in psychological distress and other outcomes were maintained four weeks after the intervention, giving some suggestion of a maintained effect, although future studies could improve on studying the length of follow-up Limitations: Waitlist controlled, small sample size from a single institution.

Citation	Purpose	Sample and Setting	Methods: Design, Intervention, Measures	Results	Discussion, Interpretation, Limitations
Würtzen, H., Dalton, S., Elsass, P., Sumbundu, A. D., Steding-Jensen, M., Karlsen, R., Andersen, K., Flyger, H. L., Pedersen, A. E., & Johansen, C. (2013). Mindfulness significantly reduces self-reported levels of anxiety and depression: Results of a randomised controlled trial among 336 danish women treated for stage i–iii breast cancer. *European Journal of Cancer*, *49*(6), 1365–1373.	Evaluate the effectiveness of MBSR on anxiety and depression in women with breast cancer	Sample 336 women post-surgery for breast cancer, stage 1-III Setting: Breast surgical centers-affiliates of University of Copenhagen	RCT: MBSR vs Usual care Anxiety: Symptom Checklist-90r anxiety subscale Depression: Symptoms Checklist 90r depression subscale, Center for Epidemiological Studies Depression Scale (CES-D) Scales were administered prior to the intervention and immediately, 6, and 12 months following the intervention.	Improvement in anxiety at 12 months ($p=0.00002$). Improvement in Depression at 12 months (SCL-90r, $p<0.00001$; CES-D, $p=0.0367$ Participants with greater anxiety or depression at baseline had greater improvement.	Results were sustained up to 12 months, longer follow-up than most studies.

Citation	Purpose	Sample and Setting	Methods: Design, Intervention, Measures	Results	Discussion, Interpretation, Limitations
Eyles, C., Leydon, G. M., Hoffman, C. J., Copson, E. R., Prescott, P., Chorozoglou, M., & Lewith, G. (2014). Mindfulness for the Self-Management of Fatigue, Anxiety, And Depression. In Women With Metastatic Breast Cancer: A mixed Methods Feasibility Study. *Integrative Cancer Therapies*, *14*(1), 42–56.	Evaluate the acceptability and feasibility of MBSR in women with metastatic breast cancer Anxiety, fatigue, and depression were also measured	19 women with metastatic breast cancer in NHS setting.	Mixed methods convergent design Qualitative Interviews+ Questionnaires at baseline, 4 weeks, 8 weeks (end of intervention, 16 weeks, and 24 weeks. Fatigue: BFI Depression: HADS Depression Anxiety: HADS anxiety Mindfulness: TMS Curiosity and TMS Decentering QOL: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ) Mean attendance was 8 out of 9 sessions	Qualtitative Themes: 1. Barriers to Recruitment: Too Ill or too time consuming, too structured. 2. Acceptability: Additional Band Of Inner Strength- may talked about improved coping and adopting strategies in the rest of life. BFI: Reduction: Mean change 0.91, P=0.062) HADS Depression: Reduction (m= 1.95, p=0.044) HADS Anxiety: Reduction (m=3.63, p<0.001) TMS Curiosity Increase (m=2.68, p=0.087) TMS Decentering: Increase (M=5.53, p=0.002) EORTC QLQ: Significantly beneficial changes in global health scale, physical functioning, cognitive functioning, and insomnia.	MBSR was deemed acceptable to MBC patients, showcasing perceived benefits. However, the study highlighted challenges related to the 8-week time commitment, indicating potential modifications for a less intensive intervention. Limitations: Small sample size- could be the reason for some results not reaching clinical significance.

Citation	Purpose	Sample and Setting	Methods: Design, Intervention, Measures	Results	Discussion, Interpretation, Limitations
Vandenbogaart, E., Gawlinski, A., Grimley, K. A., Lewis, M., & Pavlish, C. (2023). App-based mindfulness intervention to improve psychological outcomes in pretransplant patients with heart failure. *Critical Care Nurse*, *43*(2), 15–25	Evaluate the effect of an app-based MBI on stress, anxiety, and resilience in hospitalized patients awaiting heart transplant.	Sample: 20 hospitalized patients awaiting transplant. Setting: A major medical center in Los Angeles	1 group pre-test/post test design. Daily 12 minute app-based meditation for four weeks. Outcomes: Stress: 10-item Perceived Stress Scale Anxiety: 7-item Generalized Anxiety Disorder Instrument (GAD-7) Resiliance: 10-item Connor-Davidson Resiliance Scale	Significant reduction in stress and anxiety, as well as significant increase in resilience at both 2 and 4 weeks post-intervention (all measures p=0.001)	This study demonstrates feasibility and efficacy of a brief mindfulness intervention reduce stress and anxiety while increasing resilience among patients with advanced HF. Limitations: single-setting, a small convenience sample, and the lack of a control group.

Citation	Purpose	Sample and Setting	Methods: Design, Intervention, Measures	Results	Discussion, Interpretation, Limitations
Mikolasek, M., Witt, C. M., & Barth, J. (2018). Adherence to a mindfulness and relaxation self-care app for cancer patients: Mixed-methods feasibility study. *JMIR mHealth and uHealth*, *6*(12), e11271.	Evaluate feasibility of a mindfulness and relaxation app for cancer patients. Evaluate predictors of adherence	Sample: 100 cancer patients (Various cancer types) Setting: 2 hospitals in Zurich	Design: Prospective observational study, using a mixed methods approach. 10 weeks: Asked that patients utilize the app 5 days per week.	At week 10 62% of females were still using the app, while 31% of males were using it continuously= females had better adherence. Patients who were open to the experience were more likely to continue. Patients with greater resistance to change had lower attrition rates Patients with higher levels of depressive symptoms had lower levels of attrition.	The study demonstrates the feasibility of a mindfulness and relaxation mobile health (mHealth) intervention for cancer patients, with acceptable adherence and positive feedback. The findings align with the potential of mHealth apps to support cancer patients' well-being. Limitations; Small sample size and the absence of a control group.

Citation	Purpose	Sample and Setting	Methods: Design, Intervention, Measures	Results	Discussion, Interpretation, Limitations
Rosen, K. D., Paniagua, S. M., Kazanis, W., Jones, S., & Potter, J. (2018). Quality of life among women diagnosed with breast cancer: A randomized waitlist controlled trial of commercially available mobile app-delivered mindfulness training. *Psycho-Oncology*, *27*(8), 2023–2030.	Evaluate the effect of a mobile app-delivered mindfulness training on QOL in breast cancer patients	Sample: 112 breast cancer patients, mostly stage II, although all stages represented ‘ Setting: Outpatients across the US	RCT: Waitlist controlled vs mobile app-delivered mindfulness training (AMT) Intervention: AMT over 8 weeks. Beginning with a 10-day foundation course, which was followed by daily self-guided training x 8 weeks, and a 4 week post-intervention follow-up. QOL: Functional Assessment of Cancer Therapy Breast version 4 (FACT-B) Secondary Outcome: Mindfulness: Mindful Attention Awareness Scale (MAAS) App-Utilization: Measured through App-log	Participants assigned to AMT reported higher QOL through follow-up (P<0.01) Participants assigned to AMT reported higher mindfulness scores up to 4 weeks of follow-up (P-0.04) Retention: 67% completed all measures.	Discussion: Small participation from stage IV patients. Limitations: Small sample size. Use of single app

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