IMPACT OF COMPLEMENTARY RELAXATION THERAPY EDUCATION

FOR PALLIATIVE CARE NURSES

by

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DEDICATION

I dedicate this project to my husband and parents for your continued support through my venture to pursue a Doctorate of Nursing Practice degree. I am thankful for all the instructors and guidance from preceptors along my scholarly journal who have impacted my nursing career in a positive manner. I would like to thank my manager Lexie Hoines for helping to facilitate integration of the project on the Oncology unit.

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ABSTRACT

**Background:** CAM interventions can improve symptom management in end of life care. Nursing knowledge and routine integration of CAM in the inpatient setting is lacking in palliative care. Education regarding CAM therapies for health providers could help ameliorate this problem.

**Purpose:** The purpose of this project was to enhance nursing knowledge and comfort with relaxation therapy, and to evaluate of how this knowledge enhancement could impact palliative care patient outcomes.

**Setting/participants:** Setting was an inpatient Oncology unit. This project had two populations; registered nurses (n=13) with primary employment on the oncology unit and palliative care patients (n= 20) with end stage pulmonary disease or pulmonary malignancy.

**Methods:** This quasi-experimental pilot project utilizing before and after comparisons of nursing education and patient symptoms. Three phases were implemented. Phase one included a CAM Health Beliefs Questionnaire distributed to nursing staff. This was followed by an educational intervention for nursing staff regarding relaxation therapy that included instructions on the use of the Emwave Heartmath Biofeedback technology. An instrument (Relaxation Therapy Competency), intended to measure change in nursing knowledge, was developed and utilized in a pre-test/post-test format. Once competence was established, nurses implemented the relaxation therapy for palliative pulmonary patients. Subjective and objective measures were gathered before and after relaxation therapy was initiated on enrolled participants. Data collected included inpatient implementation utilizing Emwave Heartmath Biofeedback technology, pain, anxiety and breathlessness ratings (utilizing Likert scales), and vital sign measurements.

**Results:** Knowledge was improved by an average of 35% for nursing participants through enhancing knowledge with an education session. A reduction in breathlessness, pain, and anxiety resulted for nearly all patient participants utilizing a singular biofeedback session. Physiological coherence achieved through relaxation therapy integration was expressed through significant improvement in blood pressure, respiratory rate, heart rate, and pulse oximetry for the patient population as a whole.

**Conclusion:** The results of this pilot project show that symptom management can be improved for palliative care patients. Nursing knowledge regarding relaxation therapies was greatly improved, and nursing attitudes were positive overall. This safe, effective therapy has the potential to impact palliative care patients’ symptom management and their end of life care.
INTRODUCTION

Palliative care consultation can result in approximately $1700 of reduction in healthcare costs for an admission visit (Center to Advance Palliative Care [CAPC], 2015). Palliative care is intended to optimize the quality of life in individuals living with end of life disease processes. Complementary therapies, such as relaxation therapies, are simple interventions that are cost effective and can be implemented to optimize control of symptoms while creating improved self-care and improved quality of life (Luebbert, Dahme, & Hasenbring, 2001). Cascade County has a limited number of palliative care providers. Expanding a patient’s self care ability through provider education about relaxation therapies can positively impact overall quality of life for palliative patients.

Background and Significance

Integrative health care involves bringing conventional, western medicine and complementary, non mainstream health practices together. These two forms of health care can be implemented congruently to improve patient outcomes (National Center for Complementary and Integrative Health, 2015). Alternative or complementary medicine is referred to as non-mainstream health practices that are used in place of conventional or orthodox medicine (National Center for Complementary and Integrative Health, 2015). These therapies are often referred to as CAM. Interventions that integrate both kinds of practice (conventional and complementary) are especially useful for individuals
who are at the end of their lives. The terms palliative care and end of life care will be used synonymously throughout this project.

Palliative care represents one of the most rapidly expanding sectors of health care. Selected complementary therapies offer significant benefits for reducing suffering and improving quality of life in palliative care patients; however, there currently are no systematic educational offerings on the evidence-based application of such therapies in the palliative care setting. (U.S. National Institutes of Health, 2015)

The primary delivery of knowledge related to CAM occurs in Integrative Healthcare settings, such as universities (U.S. National Institutes of Health, 2015). By developing a local educational intervention, increased competency and comfort with relaxation therapies can hopefully be achieved for palliative providers.

The rates of CAM usage for all patients, specifically those who are considered palliative, are increasing worldwide. It is estimated that approximately 40% of the American adult population are currently using some form of CAM (National Center for Complementary and Integrative health, 2017). This requires providers to have adequate understanding of the complexities that CAM treatment can entail in combination with traditional medicine (World Health Organization [WHO], 2004). When utilized in the right context, CAM treatments can help alleviate unwanted symptoms, enhance health, and contribute to overall improvement of quality of life (WHO, 2017). Many patients seek out CAM or relaxation therapies because they are unsatisfied with conventional therapies in efforts to optimize symptom control (Tsai, Chen, Lai, Lee, & Lin, 2007). Relaxation techniques are the second most frequently used of all CAM modalities in the United States adult population (Tsai et al, 2007). Enhancing the relaxation response is
beneficial in various chronic disease states as part of symptom management (Tsai et al, 2007).

**Types of CAM**

Many forms of CAM treatments are now being supported by quality empirical evidence from and will be reviewed through the next portion of this paper. Relaxation therapies include a variety of methods including; biofeedback, hypnosis, yoga, guided imagery, meditation, breathing techniques, aromatherapy massage, relaxation music, and other methods of stress management (Wolsko, Eisenberg, Davis, & Phillips, 2004). Relaxation therapy is designed to facilitate the mind and body’s capacity to affect health and involves self care based implementation (Wolsko et al., 2004). The forms of relaxation therapy that were implemented in this project were the use of biofeedback, guided imagery, relaxation music, and relaxation breathing.

**Biofeedback.** Biofeedback is a complementary therapy that enables an individual to change physiological activity by utilizing relaxation techniques to decrease their heart rate and respiratory rate, creating a sense of calm and reduction of unwanted symptoms such as anxiety (McKee, 2008). This is accomplished by measuring physiological activity through heart rate, breathing, skin temperature, brain waves via EEG, and muscle activity to provide feedback to the user (Lee et al., 2014). Various technologies exist to provide these measurements. The technology utilized in this
project was Emwave biofeedback technology by HeartMath. This program utilized a pulse oximeter to measure heart rate variability.

Heart rate variability is the beat changes in the overall heart rate and is linked to the parasympathetic branch of the autonomic nervous system [ANS]. As excitation occurs, the heart rate variability increases and is a dynamic example of the functioning and balance of the ANS (HeartMath Inc., 2017). Biofeedback aims to provide patient control of the ANS excitation, while reducing the fight or flight response they experience with adverse pulmonary symptoms. Heart rate variability is important to this project as it is an indicator of overall health, physiological resilience, and physiological flexibility (HeartMath Inc., 2017).

Having physiological resilience is indicative of an individual’s ability to manage and adapt to external and internal stressors. By maintaining neurological homeostasis through biofeedback, patients benefit from the ability to enter restorative stages. Enhanced restoration can decrease the overall burden and mortality associated with hypervigilance in chronic disease states (HeartMath Inc., 2017). The intuitive technology developed by Heartmath provides a guide to simple integration of physiological coherence. As the client begins to implement the Emwave biofeedback, the program provides visual feedback as the patient achieves physiological coherence and relaxation (HeartMath Inc., 2017). For the purpose of this project, the terms relaxation therapy and biofeedback will be utilized synonymously.
Guided Imagery. Guided imagery is a structured visual method to induce relaxation. The goal of guided imagery is to create a state of harmony between the mind and body (Cleveland Clinic, 2017). This state of harmony is achieved by utilizing visual presentation of images that an individual will focus on. Guided imagery helped to direct the participants to a state of calm. Guided imagery has the ability to enhance coping skills by reducing blood pressure, heart rate, and pain ratings. Heart Math Biofeedback technology incorporates guided imagery as a feedback method to direct patients through their journey of relaxation (HeartMath Inc., 2017).

Relaxation Breathing. Relaxation breathing in conjunction with biofeedback has been found by Tsai et al. (2007) to induce relaxation, while simultaneously reducing pain and anxiety. Breathlessness is a prominent symptom in end-stage pulmonary diseases. This breathlessness can be reduced by incorporation of relaxation breathing techniques (Tsai et al., 2007). One prominent relaxation technique utilized in this project was pursed lip breathing. Pursed lip breathing helps to overcome chronic airflow limitations that occur in end-stage pulmonary diseases. Pursed lip breathing allows patients to slow their breath and expand lower airways to promote gas exchange while reducing dyspnea (Maddocks, Lovell, Booth, Man, & Higginson, 2017).

CAM Impact

CAM therapies have been found to cause less adverse effects in comparison to traditional medicine, such as pharmacotherapy side effects (WHO, 2004). In palliative
care, the goal of treatment is not curative, but rather supportive while optimizing current health status. CAM is not only a safe option when informed decisions are made, but it is cost effective and is often available throughout many communities (National Center for Complementary & Integrative Health, 2017). Though CAM is available in many communities, it is often underutilized by patients and is poorly integrated by providers (AARP, 2007; National Center for Complementary & Integrative Health, 2017). Collaboration between palliative and primary care providers about utilization of CAM should be communicated to maintain safe effective treatment plans. Through collaboration, transferring of knowledge about CAM can be achieved, impacting the overall usage of CAM to improve patient outcomes (Bann, Sirois, & Walsh, 2010).

A patient-centered approach with integration of CAM can enhance patient outcomes, patient satisfaction, and improve treatment regimen adherence (Bann, Sirois, & Walsh, 2010). Most individuals seek out CAM independently and the initial conversation is patient driven (AARP, 2007). When AARP (2007) surveyed study participants, 42% of clinicians had not addressed utilization of CAM at all and 56% of discussions about CAM were initiated by the patient. With these reported statistics, it appears there is significant room for improvement in education about the benefits of CAM at a provider level. Providers have a responsibility to keep patients informed, including CAM that patients might be interested in integrating into their plan of care. By enhancing providers’ overall knowledge about complementary treatment modalities, comfort levels with integration of CAM therapies should increase. By enhancing comfort
levels with CAM, practitioners can begin to initiate discussions about integrative health care with their clients with greater competence and confidence. With adequate knowledge, providers can guide patients toward appropriate types of integrative treatment while minimizing risk and optimizing health goals in end-of-life care (Snyder & Lindquist, 2001). There is a limited number of palliative providers in Cascade County. Provider education about relaxation therapies in Cascade County has the potential to positively impact overall quality of life for palliative patients.

Purpose of Project

The purpose of this project was to enhance nursing knowledge and comfort with relaxation therapy, and to evaluate of how this knowledge enhancement could impact pulmonary palliative care patient outcomes in north central Montana. To achieve this goal, the project was divided into three phases. The first phase evaluated the baseline CAM beliefs and knowledge of a group of palliative oncology nurses in north central Montana. In the second phase, an educational intervention on relaxation therapies and Emwave Biofeedback technology was provided to the same group of nurses. The third phase evaluated the effectiveness of the implementation of the educational program, specifically the impact of relaxation therapy for pulmonary care patients with end-stage lung disease or lung malignancy who have experienced adverse symptoms.
A review of evidence was conducted to examine the current literature for impact of relaxation therapy integration for palliative patients. In addition, the literature was explored for studies which evaluated the impact of educating palliative care providers, and how this effected the care provided to palliative care patients. Literature review was assisted by the MSU librarian Sheila Bonnand in Bozeman, Montana. The databases searched included; CINAHL, Medline, Cochrane database, Pubmed, Joanna Briggs, and Google Scholar. Key search terms included; biofeedback, relaxation therapy, palliative care, provider education, CAM, complementary therapy, quality of life, patient centered care, breathlessness, pain, anxiety, end of life care, and comfort. The review of literature included studies conducted within the last fifteen years and included; systematic review, meta-analysis, randomized control studies, and qualitative cohort studies. The evidence table is included in appendix H for viewing.

Only one study was discovered that directly evaluated the provision of an education intervention to enhance provider utilization of CAM (Ben-Arye, Frenkel, & Hemoni, 2006). The lack of studies regarding provider based CAM education strengthens the need to fill a gap in the current literature. Furthermore, there are very few studies that evaluating the impact of biofeedback for end-stage pulmonary disease treatment. The evidence gathered and evaluated in the literature evaluation table all support the importance of CAM integration and the positive effects it can have for symptom management and improved quality of life. During the literature review, extensive focus
was included on patient centered care and how provider approach and CAM treatment modalities can impact a palliative patient’s quality of life.

**Patient Impact**

The focus of this synthesis of literature included complementary relaxation therapies that impact quality of life for palliative care clients. Best outcomes occur when providers can give evidence based individualized treatment approaches with effective patient centered communication and education (Faith, Thorburn, & Tippens, 2015). Another component discussed in the literature and is applied through the phases of this project was consideration of patient preferences and values, while attempting to foresee how these values may impact CAM integration. Many patient outcomes were evaluated and included; self-care, pain, quality of life, fatigue, breathlessness, functional status, sleep quality, psychological health, stress reduction, and frequency of CAM use. Each outcome contributes to the supporting evidence of positive effects of integrating relaxation therapies into treatment regimens in end of life care (Weeks et al, 2014; Ducloux, Guisado, & Pautex, 2013; Lee, Crawford & Hickey, 2014).

Patient interests in CAM therapies are increasing, along with the desire to incorporate CAM therapies into their plan of care (Ben-Arye et al., 2006; Clarke et al., 2015). Incorporation of relaxation therapies provides palliative care patients enhanced self-care and self-management of their symptoms at home while maintaining an individualized approach to their healthcare (Ducloux, Guisado, & Pautex, 2013; Faith et
end-of-life care are often scarce, and implementing complementary therapies, such as relaxation therapies, are non invasive techniques that can be readily learned and implemented in varying settings. CAM therapies can be less expensive than traditional medical care when self-administered, helping to decrease their sense of medical financial burden (Luebbert et al. 2001). Enhancing the capability of the patient to provide self-care for symptom management allows patients and their families to gain a sense of control during a season of vulnerability and fragility, where their disease state is time limiting (The Association for Applied Psychophysiology and Biofeedback Inc., 2011). Empowering patient’s to have self control of their symptoms through biofeedback can help to diminish other adverse effect of their disease process (Faith et al., 2015)

**Pain**

Pain is a primary fear and complaint of many palliative patients. Poorly controlled pain can hinder an individual’s sense of well-being and overall quality of life (Hennegahn & Schnyer, 2015; Downey et al., 2009; Singh & Chaturvedi, 2015). Inadequate pain management is often a reason for incorporation of relaxation therapies and other CAM modalities (Tsai et al., 2007). Incorporation of relaxation therapies can have a sustained effect on reduction of average pain scores for up to 2.5 hours post treatment (Jane, Wilkie, Gallucci, Beaton & Huang, 2009).
Biofeedback is shown to have significant analgesic effects with moderate impact on functional status (Babu, Mathew, Danda, & Prankash, 2007). Optimizing pain control can lead to enhanced function and improved coping. Varying applications of relaxation therapies for pain control are dependent on patient preferences, but can be applied throughout the disease process to optimize comfort and enhanced sense of control over one’s care at end-of-life (Lee et al., 2014). Relaxation therapies take a non-invasive approach to optimizing care while minimizing potential side effects that may exacerbate pain. Chronic pain can also impact patient’s level of energy and overall quality of life (Singh & Chaturvedi, 2015).

Fatigue

Fatigue is defined by Maddocks et al. (2017) as, “a profound feeling of physical and psychological weariness that is not relieved by sleep or rest” (p. 993). Fatigue can be a limiting factor to quality of life for palliative care patients. Terminal diseases can culminate in profound fatigue or fatigue can be transient throughout a course of illness (Singh & Chaturvedi, 2015). Relaxation techniques such as yoga and reflexology have been proven to decrease fatigue (Wilkinson, Lockhart, Gambles, & Storey, 2008). Maddocks et al. (2017) states, “Providing education to support self-management, improving the patient’s psychological resilience, and addressing depression are key to improving fatigue” (p. 993). The goal of relaxation therapies is to increase self-management and psychophysiological coherence. By achieving a state of relaxation
patient’s can impact their overall sleep quality and overall burden of fatigue (Reig-Ferrer et al., 2014).

Sleep

Sleep impairment is multifactorial and can compound fatigue and disease burden (Luebbert et al, 2001). Fatigue also is linked to sleep quality. Many relaxation techniques target enhancing sleep quality and stress reduction to improve overall perceptions of restfulness and inner peace (Reig-Ferrer et al., 2014; Jane et al., 2009; Serfaty, Wilkinson, Freeman, Mannix & King, 2010). Early evaluation of sleep quality in palliative care patients can highlight the need for integration of relaxation therapies to enhance sleep quality (Ducloux et al., 2013). Both short-term and long-term benefits have been noted for insomnia in varying palliative populations (Wang, Tao, Zhao, Zhou, & Jiang, 2014). Relaxation treatment implemented twice daily can help decrease sleep latency, increase total sleep time, and decrease the utilization of pharmacological sleep aids, diminishing the effects of polypharmacy related side effects (Wang et al, 2014; Ducloux et al, 2013). Patients who reported better sleep quality had fewer reports of other adverse symptoms including reduction in stress and anxiety (Wang et al., 2014).

Psychosocial

Many relaxation therapies such as yoga, guided imagery, aromatherapy massage, and biofeedback allow improved functional status and mental health by reducing stress and anxiety, while promoting regulated sleep wake cycles (Ducloux et
Relaxation therapies enhance coping mechanisms and relieve physiological tension and pain associated with terminal disease states in end of life (Luebbert et al., 2001). A study by Luebbert, Dahme, & Hasenbring (2001) implemented relaxation training and found participants reported fewer symptoms of depression, anxiety, and emotional lability following treatment delivery. Relaxation therapy empowered patients to have more control of adverse symptoms and a reduction in overall stress. This result is supported by relaxation techniques implemented within a nursing home, which found reduction in psychological distress, negative affect, enhanced adverse symptom control, and improved health-related quality of life ratings following relaxation therapy implementation (Reig-Ferrer et al., 2014).

Through the incorporation of biofeedback, patients can achieve a psychophysiological coherence. Physiological coherence, a stable state where both physical and psychological balance is achieved leading to enhanced emotional stability, increased mental clarity, and improved cognitive function can be achieved through biofeedback (HeartMath Inc., 2017). Anxiety and depression can lead to enhanced reports of breathlessness. Increased adverse symptoms can lead pulmonary palliative patients towards life stricken with disability causing isolation and loneliness (Maddocks, Lovell, Booth, Man, & Higginson, 2017).

By enhancing symptom control through relaxation therapies, patients at end-of-life are able to enhance their functional status and enjoy improved psychological wellbeing and quality of life. Patients with advanced pulmonary disease have been
found to appreciate acquiring a sense of control, strength of interpersonal relationships, maintaining a sense of dignity, and achieving spiritual peace during their illness (Maddocks et al., 2017). Relaxation therapy integration takes a multidimensional complementary approach to provide patients with a strong sense of self, a sense of autonomy, and control of their disease (HeartMath, 2017).

**Breathlessness**

Breathlessness in patients with lung disease can be a major stressor and can impact quality of life on a daily basis. Breathlessness can impair the ability to perform activities of daily living and can contribute to anxiety and overall emotional wellbeing (Corner, Plante, A’Hern, & Bailey, 1996). COPD is a leading cause of death in the United States with over 235,000 mortalities annually (National Heart, Lung and Blood Institute, 2012). Lung cancer is the second most common malignancy for both men and women in the United States leading to over 220,000 deaths annually (American Cancer Society, 2016). Both of these chronic disease states experience significant disease burden from dyspnea directly impacting quality of life (Maddocks et al., 2017).

Corner et al. (1996) found that breathlessness was alleviated by breath training, and relaxation techniques diminishing psychological and physiological distress with a 53% reduction overall. Maddocks et al. (2017) found that, “non-pharmacological interventions take priority in the mobile patient and can also be helpful in advanced disease. Supporting patients to self-manage can increase the individual’s self-efficacy and reduce feelings of helplessness” (p. 990). By reducing acute instances of
breathlessness in palliative pulmonary patients, hospital admission rates can be reduced, thus decreasing cost burden for these patients (Maddocks et al., 2017).

Ritz, Von Leupoldt, & Dahme (2006) found that biofeedback technology has the ability to decrease heart rate and overall dyspnea by altering the respiratory pattern and reducing generalized muscular tension in healthy participants. Giardino, Chan, and Borson (2004) conducted a cohort study that found six sessions of biofeedback focused on ambulation and heart rate variability to enhanced patient self-care, improved quality of life, and reduced dyspnea distress in a small pilot population. The results reviewed here support the need for randomized studies to evaluate the use of biofeedback in advanced pulmonary disease patients. A standardized approach to patient care helps provide consistency, advocates for best practice, and can improve patient outcomes (Mazrou, 2013). This can be achieved through utilization of clinical practice guidelines for palliative care patients.

**Clinical Practice Guideline**

The clinical guideline evaluated for this project is titled Palliative Care for Adults from Agency for Health Care Research and Quality [AHRQ] (2013). After searching multiple guideline electronic platforms regarding complementary therapies, none directly evaluated application of relaxation therapies to end-of-life care or how education impacts provider’s utilization of this modality. The literature review has
yielded a need for further research in the effects of provider education and comfort with utilizing relaxation therapies.

The topics discussed in the adult palliative care guideline ranged from initiating delicate conversations about end of life, cultural, social, psychological, physical, ethical, and spiritual aspects of care (National Guidelines Clearinghouse, 2013). The guideline serves to help clinicians understand the philosophy of palliative care and identify appropriate patients for referral. Other items addressed are proper assessment of patients palliative needs, ongoing reassessment, and discussing advanced directives (National Guidelines Clearinghouse, 2013). Development of care plan goals are also a big emphasis of the guideline with parameters to deliver bereavement support in an end-of-life transition period. Most items within the guideline were rated 5 or above, those that were not were typically omitted items or lacking detailed explanation. Five is the highest rating attainment.

Each recommendation within the AHRQ guideline is graded and referenced. It is recommended that providers emphasize the need for early palliative care initiation and referral when applicable (National Guidelines Clearinghouse, 2013). Patients' goals of care and advanced directives should be evaluated early for palliative care referral, treatment modalities alignment, and open communication between providers, patients and families. The guideline also includes care algorithms that are user friendly along with succinct information for practice application (National Guidelines Clearinghouse, 2013). A pneumonic for treatment is included in ABCDE format standing for advanced
preparedness, building a therapeutic relationship, communicating well, dealing with reactions, and encouraging and validating emotions (National Guidelines Clearinghouse, 2013). The Adult Palliative Care Guideline does not directly address relaxation therapies for symptom relief. This is a gap in clinical practice that could be addressed in the future practice guidelines to enhance symptom management, while emphasizing patient centered care in end-of-life.

**Patient Preferences/Clinical Expertise**

Provider patient relationship quality is a predictor of CAM utilization (Bishop, Yardley, & Lewith, 2007). By establishing a base of communication and valuing patient preferences, patients are more likely to disclose CAM use and treatment preferences in discussion (Faith et al., 2015). Incorporation of CAM therapies should be integrated with focus on scientific inquiry, medical judgment, and collective decision making with the patient and provider (Bishop, Yardley, & Lewith, 2007). When surveyed, less than 50% of conversations about CAM are initiated by providers, but rather come from patient inquiry (AARP, 2007). Adding CAM therapy education allows providers to have basic competence to recommend treatment modalities to patients and increased skills for referral to ancillary resources. By enhancing competence, an increase in provider to patient communication can occur regarding complementary therapies (Ben-Arye & Frenkel, 2006).
Those individuals who have experienced positive effects from CAM therapies are more likely to seek this form of treatment in the future (Faith et al., 2015). Empowering providers to recommend relaxation therapies as an adjuvant treatment modality will improve patients’ quality of life perceptions in varying measures, from improved symptom management, better sleep quality, improved pain, and decreased anxiety (Luebbert et al., 2001). Patients who utilize CAM tend to seek more control of their care and feel a sense of empowerment through their use of CAM to better control their disease symptoms in conjunction with conventional pharmacological treatment (Bishop et al., 2007).

CAM integration focuses on a holistic approach. Discovering new methodologies for treatment helps providers to implement patient centered care that addresses barriers and strengths to the treatment plan, while focusing on optimizing end-of-life care. Current practices on the Oncology unit has very minimal utilization of CAM therapies. The lack of CAM integration has been attributed to lack of training in CAM and comfort with broaching CAM discussions with patients. Through direct palliative care observations, CAM conversations often do not take precedence for providers in end-of-life care. With enhanced knowledge regarding relaxation therapies and methods to implement a palliative care consult, enhanced utilization of these services could occur. Interdisciplinary collaboration between providers and incorporation of patient preferences with inclusion of relaxation therapies to the care plan, can enhance overall patient and family satisfaction with delivered care (Bishop et al., 2007). A method to
direct providers in palliative care and CAM discussions is the utilization of a nursing theory to guide care.

**Nursing Theory**

The theory selected to guide the scholarly project was Jean Watson’s Philosophy and Theory of Transpersonal Caring (2002). Jean Watson’s Theory (2002) provides support for enhancing palliative care nurses comfort and knowledge of relaxation therapies. The Theory of Transpersonal Caring is a middle range theory and philosophy (Sourial, 1996). Watson’s Theory of Transpersonal Caring transcends beyond that of medical care and focuses on existential, phenomenological, and spiritual factors (Watson, 2002).

Jean Watson’s Theory of Transpersonal Caring originated in 1996 emphasizing that the goals of nursing were to, “facilitate individuals in gaining a higher degree of harmony within the mind-body-spirit; such harmony generates self-knowledge, self-reverence, self-healing, and self-care processes through human-to human caring process and caring transactions” (Masters, 2015, p. 50). Watson places a large emphasis on the art of caring for patients and developed ten carative factors (Masters, 2015). Later Watson developed the ten caritas that relate to the ten carative factors. These carative factors and caritas expand on spirituality as well as the caring and healing relationship that occurs between client and nurse (Masters, 2015). The ten caritas were revered by Watson to be the core of nursing practice (Masters, 2015). The caritas
highlights the sacred spiritual dimension of caring from one human to another through expression of love (Alligood & Jesse, 2014).

Watson’s Theory of Transpersonal Caring gives a humanized approach to the profession of nursing that often becomes task focused, while providing a validation of the nursing process in patient centered care delivery and defining nursing as a specialized profession (Wehr, n.d.). Caring is defined as, “the ethical and moral ideal of nursing with interpersonal and humanistic qualities,” (Alligood & Jesse, 2014, p. 96). The concept of health places emphasis on a trifecta of mind, body, and soul existing in a state of unity and harmony. When illness is prevalent a disruption in the harmony occurs (Masters, 2015). Through utilizing the caritas and practice of transpersonal caring nurses are able to focus on the lived experience of an illness, and not just the disease process (Masters, 2015). Watson’s Philosophy and Theory encourages nursing incorporates holism, empathy, competence, interpersonal skills, and the hierarchy of patient needs (Alligood & Jesse, 2014).

Rationale for Selection of Theory

Individuals living with a chronic illness face daily challenges that impact their connectivity to their surroundings and intrapersonal values. Incorporation of CAM into palliative treatment shifts the focus to optimizing quality of life, while having an emphasis of caring for the individual as a whole being instead of a disease process. The ten carative factors and ten caritas align with the purpose of enhancing nursing knowledge and communication about the positive effects CAM can have for palliative
patients. By working within a holistic theory and philosophy, nurses are able to evaluate where nursing intersects with intentional transpersonal approach to caring for humanity with compassion and reverence (Watson, 2002). Application of Watson’s theory can provide nursing the ability to create connections to their own beliefs, patients, and peers while empowering others to make a difference through education and incorporation of new care methods (Foster, 2006).

How Theory Guided the Project

Watson’s Philosophy and Theory of Transpersonal Caring (2002) guided the review of all quantitative, qualitative research, and grey literature focusing on the impact of providing education to enhance the comfort and competence of CAM integration within the caring context. Reviewing literature from the lens of transpersonal caring narrowed the literature review and highlighted the pertinent literature that illustrated caring holistic practices that are central to CAM therapy delivery and palliative care models.

The Philosophy and Theory of Transpersonal Caring (2002) helps one to understand why palliative care patients seek CAM treatments as an additional modality to optimize quality of life and control extraneous symptoms. Incorporation of Watson’s Theory (2002) also exemplified the caring relationship and how this could be enhanced through CAM integration and holistic healing. This caring process keeps care delivery patient centered and reflective. Incorporation of Watson’s Philosophy and Theory of Transpersonal Caring (2002) enabled evaluation of the root of the relationships
developed through relaxation CAM treatments and how this impacts current health status and future health treatment goals in end-of-life care.

Through incorporation of Watson’s Philosophy and Theory of Transpersonal Caring (2002) into this scholarly project a succinct focus on patient and client needs was maintained. Healing presence and therapeutic communication are actions that do not require any external factors or supplies other than oneself. Caring is the purest method of care delivery and is the motivation for creating positive change in the palliative care population through enhanced CAM modality education with Watson’s theory as a guide (Current Nursing, 2012b). This theory application allowed for a focus on the motivation behind care delivery, giving this project a professional validated structure. Watson’s Theory application allowed a better understanding of palliative and CAM treatment modalities and how to incorporate them in a holistic, reflective, worldly manner, creating an enhanced tool kit for nursing to deliver high quality care within the nursing scope (Frisch, 2001).
METHODS

Populations

This pre-test, post-test project focused on two populations. The first population was inpatient Oncology nurses. This unit included twenty registered nurses with experience ranging from less than a year to greater than thirty years experience. After IRB approval, registered nurses were voluntarily recruited from the Oncology unit by signage and word of mouth, over a one-month period. Nurses were able to volunteer to participate until the educational session began.

The second population included palliative care inpatients on the Oncology unit in north central Montana. These patients had end-stage chronic lung disease and/or lung malignancy and were experiencing adverse effects from their disease processes. The maximum inpatient volume on the Oncology unit is twenty patients with an average daily census of seventeen patients. The primary population served annually is greater than fifty-five years of age. Approximately 25% of the total oncology unit annual volume is palliative care patients, leading to selection of the Oncology unit for project implementation (Hoines, 2016).
Inclusion Criteria

Inclusion criteria for the nursing staff required employment as a registered nurse on the Oncology unit (n=13), and the ability to speak and understand English. Nurses who did not wish to participate were not included in the educational sessions. Those nurses who were interested in participating were required to attend the educational session to explain the project. They could decline participation at anytime during the project.

CAM Beliefs

The first phase included evaluation of nurses CAM beliefs and examination of CAM knowledge. Evaluation of baseline knowledge and perceptions of relaxation therapies served to develop a starting point for knowledge enhancement. Enhanced knowledge encompasses greater provider promotion of CAM therapies and encourages initial conversations between patient and provider to occur, while cultivating a holistic patient centered care model (Faith et al., 2015; Bishop et al., 2007). Demographic nursing data was collected to evaluate the background of the nursing sample population and their nursing experience.

Once consent and demographic data was obtained, a CAM Health Beliefs Questionnaire was completed by all nursing participants. Throughout the extensive literature review, no validated instrument was found to evaluate relaxation therapy
provider perceptions, so a CAM Beliefs Questionnaire was created for this project. The questionnaire was developed to evaluate CAM beliefs, with relaxation therapy and palliative care practices in mind. This questionnaire was used as a method to evaluate subjective data addressing nursing’s perceptions about CAM relaxation therapies and their applicability to current practice. This questionnaire provided a means of evaluating gaps in CAM integration into nursing practice in the inpatient hospital setting in north central Montana. This subjective data will be discussed further. The second phase of this project included educating nursing participants about relaxation therapies.

**Education Intervention**

A Relaxation Therapy Competency (Appendix B) was developed during the extensive literature review. This competency incorporated integrative health topics of; relaxation therapies, guided imagery, relaxation breathing, application of CAM therapies, and Emwave Biofeedback technology. This questionnaire was completed by nurse participants immediately before and after the education intervention to enhance response rates. The pre-test post-test design was implemented to evaluate the effectiveness of the education intervention. This project looked for an overall change in provider knowledge of relaxation therapies.

The nursing education intervention was delivered at a monthly Oncology Shared Governance meeting. All registered nurses were present for a mandatory staff meeting. The initial unit agenda was completed, and then the education session was offered for nurses wishing to participate. The forty-five-minute interactive education session
included a powerpoint presentation covering; Emwave Biofeedback technology, relaxation breathing, guided imagery, relaxation therapy application, and general CAM benefits. Each nurse was instructed on the Emwave Biofeedback technology and completed a session of biofeedback during the education session.

Nurses were educated on the implementation process by way of a relaxation therapy guideline. This included patient inclusion criteria, consenting process, and stepwise process for intervention delivery. Developing a guideline for relaxation therapy implementation ensured consistent application of the guideline by all nurse participants. This guideline (Appendix D) took into consideration patients’ preferences for CAM treatment by allowing a choice of guided imagery medium and relaxation music incorporation (Ben-Ayre et al., 2006; Faith et al., 2015).

Nurses were provided measurement tools in the form of Likert scales for pain, breathlessness, and anxiety ratings. These visual Likert scales were presented to each patient to identify their level of comfort. These three ratings represent the subjective measurements in this project. Each nurse was provided with an educational handout of the powerpoint presentation regarding relaxation therapy application and an additional handout was available for patients to reference. This handout included general information regarding guided imagery, relaxation breathing, and biofeedback. Following completion of the education sessions, the nurse participants implemented relaxation therapy on the Oncology unit for palliative care pulmonary patients.
Additional subjective data was gathered through focus groups. The focus groups occurred at shared governance meetings and at oncology unit shift huddles. Nurses answered open ended questions and were asked to describe their experience with implementing relaxation therapy for palliative care patients. Nursing participants were also surveyed on their experience with the education session through open dialogue. This discussion also included evaluation of barriers and patient impact encountered through relaxation therapy implementation.

A refresher course was offered to all nursing participants during a four-month technology delay, which ensured nursing staff were competent and comfortable with implementing relaxation therapy for the third phase of project integration. During the refresher course time period, an additional education session was conducted for four new nursing participants. These four participants were recruited to increase sample size following nursing participant withdrawal and to ensure adequate power was achieved.

Patient Implementation

Inclusion Criteria

Patients were selected according to the inclusion and exclusion criteria. Palliative care patients who were admitted to the Oncology floor at the health system in north central Montana with the presence of life limiting pulmonary disease were available for participation. Examples of inclusion diagnoses included; lung malignancy, lung metastasis, pulmonary fibrosis, cystic fibrosis, pulmonary hypertension, cor pulmonale,
and chronic obstructive lung disease. These participants had no specified age parameters and were experiencing adverse symptoms related to their disease process prior to relaxation therapy implementation. Patients were required to be alert and able to consent to participation, as well as read English at an eighth grade level in order to understand simple implementation instructions.

The relaxation therapy intervention was delivered between hours four to twenty-four of admission following completion of necessary medical care that typically occurs within the initial admission hours. This time period was selected to address the patients when they were most symptomatic and would most likely to benefit from relaxation therapy integration. Care was taken to avoid implementation in the first four hours of admission to allow for necessary medical care to be provided and to avoid coercion of patients. IRB approved consents were obtained prior to implementation of relaxation therapy. All patient consent forms were kept locked up on the oncology unit in a designated area to protect participant privacy.

Exclusion Criteria

Those excluded from this project included patients who did not speak or read English, due to lack of consistent access to interpreters at the selected health system. Patients who had impaired mentation were excluded. Lastly, patients who were deemed by the RN to be medically unstable or had an immediate need for medical interventions were excluded. Examples of excluded patients were those requiring high levels of oxygen via, bipap, O2 delivered via a high flow cannula or non-rebreather mask, those
who were lethargic, or clients who were hemodynamically unstable. Following these criteria, nurses were able to implement relaxation therapies and evaluate their effectiveness on symptom control.

Impact of Relaxation Therapies

During project development, a literature review was conducted to evaluate the importance of biofeedback instruction from a health care provider and the frequency needed to be effective. It was found by Johnson et al. (2015) that one episode of biofeedback training in comparison to three was found to have no differences in patient outcomes. This study guided the formatting of intervention delivery. For this project, the nurse facilitated relaxation therapy intervention included one relaxation therapy intervention for each palliative participant. This included nurse driven data collection and instruction to patients on breathing techniques and the benefits of relaxation therapy integration. A pre-test post-test design was implemented to evaluate effectiveness of the therapy intervention for objective and subjective measures. A worksheet for documentation and data analysis for relaxation therapy incorporation was completed by nursing staff which included:

- Ten point Likert pain rating
- Ten point Likert anxiety rating
- Breathlessness rating (Borg Scale)
- Vital signs and
• Other treatments required (oxygen titration, pain medications, and breathing treatments)

These measurements were obtained immediately before implementation of biofeedback and immediately following. Patient age, gender, and primary diagnosis were also included with a numerical identifier placed on their consent form and documentation worksheet to maintain participant confidentiality. Relaxation therapy was implemented for patients experiencing adverse symptoms related to their respiratory disease to include:

• Biofeedback utilizing a portable computer with Emwave technology
• Relaxation breathing techniques (i.e. abdominal breathing and pursed lip breathing)
• Guided imagery via the Emwave technology
• Relaxation music via the Care Channel

Patient’s completed one nurse led episode of biofeedback. This intervention delivery with data collection took approximately fifteen minutes per patient. If patient symptoms warranted other medical interventions, these were completed following the session of biofeedback. Patient participants were asked through open ended questions about their experience with relaxation therapy at the conclusion of the nurse led session. This data is discussed further in the results.
Data Analysis

Data collection occurred over a four-month period. The preliminary participation goal was ten to fifteen nurses and a goal of twenty patients for this project. Nursing demographic data was evaluated in addition to CAM health beliefs prior to education delivery. Demographic data is included in the results section of this paper. The nursing competency was evaluated utilizing a paired sample T test to evaluate the differences in knowledge changes. Throughout the project implementation, small focus group sessions were offered for nurses at Oncology Unit Shared Governance Meetings and in unit huddles. The focus groups addressed nursing perceptions of relaxation therapy integration, patient benefits from utilization, barriers to CAM utilization, and any other further concerns expressed through open dialogue.

A paired two sample T test was conducted to evaluate changes in; anxiety, pain, breathlessness, heart rate, blood pressure, respiratory rate, and pulse oximetry. The paired T test allowed for evaluation of change in each subjective and objective measurement following relaxation therapy integration. The statistical significance was set as a=0.05 for all measures. The MSU statistics department was consulted for analysis and sample population recommendations.
RESULTS

Demographics

Demographic data was collected in the first portion of the education session. This information is valuable for evaluating feasibility of future expansion of relaxation therapy application, as well as establishing who was a part of the skilled nursing population. The nurses ranged from twenty-four to fifty-nine years of age, with a mean age of 38. The areas of employment during their nursing careers ranged from oncology, medical, surgical, rehab, service response, and management specialties. The primary location of employment and area of expertise for all participants was oncology. The demographic data of nursing participants is included in the Table 1 below.

Table 1. Nursing Participant Demographics

<table>
<thead>
<tr>
<th>Participant</th>
<th>Age</th>
<th>Years as a RN</th>
<th>Years in Oncology</th>
<th>Areas employed during your career</th>
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<tr>
<td>1</td>
<td>28</td>
<td>2</td>
<td>2</td>
<td>oncology</td>
</tr>
<tr>
<td>2</td>
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<td>3</td>
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<tr>
<td>4</td>
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<td>27</td>
<td>oncology, medical</td>
</tr>
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</tr>
<tr>
<td>7</td>
<td>31</td>
<td>5</td>
<td>5</td>
<td>oncology, service response, rehab</td>
</tr>
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<td>0.5</td>
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</tr>
<tr>
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<td>27</td>
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</tr>
<tr>
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<td>2</td>
<td>2</td>
<td>oncology</td>
</tr>
<tr>
<td>12</td>
<td>59</td>
<td>35</td>
<td>5</td>
<td>medical, oncology, surgical, ortho, management</td>
</tr>
<tr>
<td>13</td>
<td>56</td>
<td>33</td>
<td>33</td>
<td>oncology</td>
</tr>
<tr>
<td>Mean</td>
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<td>13.76923077</td>
<td>11.69230769</td>
<td></td>
</tr>
</tbody>
</table>
Four participants did withdraw from the project prior to the third phase. An additional four participants were recruited and educated during the four-month implementation delay to enhance nursing sample size. The participants who withdrew are excluded from statistical analysis. Nursing participants were added to achieve a statistically significant sample size to provide more significant statistical results.

**CAM Health Beliefs**

Following collection of demographic data, each nurse participant completed a CAM Beliefs Questionnaire (Appendix A). There was a variance in the amount of exposure each nurse had to complementary therapies in their career. The majority of nursing participants reported that they had not experienced significant exposure to CAM in their career. This data increases the importance of the education intervention delivered in this project. All nurse participants felt that CAM therapies could have a positive impact for palliative patients’ health outcomes, as well as increasing the patients’ ability to provide self care.

When surveyed, nurses did not have a general consensus on their observations of routine nurse driven CAM integration in their profession. This highlights the inconsistency of the nursing profession’s exposure to CAM in practice. Nurses reported not having a competent level of knowledge to discuss relaxation therapies with clients. They also reported lack comfort with implementation of CAM therapies for patients with their current knowledge level. This result warrants further discovery in the
discussion portion of this paper. Nursing participants also did not agree that palliative patients regularly had relaxation therapies integrated into their plan of care. In comparison, almost all nurse participants felt patients were interested in some degree of CAM integration into their treatment plans. These results highlight the capacity for growth in CAM integration for palliative care patients, especially those who are having poor symptom management.

Through the survey, nurses were open to integration of relaxation therapies and felt that these integrative health therapies have value with traditional medicine practices. All nurses reported being interested in learning more about relaxation therapies, supporting the validity of this project. By providing education to staff in the palliative environment, nurses have the potential to be more comfortable initiating conversations regarding CAM. Results showed before the education session nurses only felt somewhat comfortable initiating CAM conversations. The questionnaire results also highlight that nursing had room for growth in nurse driven communication about CAM, and this communication was not routinely being implemented in daily practice. When surveyed, nurses identified that resources including knowledge and tools were currently lacking to implement relaxation therapies effectively in their current practice setting. This lack of CAM resources was addressed by providing nursing participants with education and instruction on Emwave Biofeedback technology for integration into the Oncology unit practices.
In order to establish a baseline level of knowledge, each nursing participant completed an author developed Relaxation Therapy Competency, included in appendix B. The questionnaire consisted of true/false and multiple choice questions and covered relaxation therapies including; biofeedback, guided imagery, relaxation breathing, mechanisms of action, and benefits of relaxation therapies. The mean score for the pre-test among thirteen participants was 56%. Education was provided immediately following the pre-test. This education was delivered with a powerpoint presentation, return demonstration, and application of biofeedback with Emwave technology. Nursing repeated the same competency post education. There was considerable improvement in the post-test scores from all participants with a post-test mean of 92%. This equated to 36% change in knowledge with a t (12)= 11.5, p=4.78, t critical two tail=2.17.

This large t value is attributed to a large distribution of scores with unequal variance. This makes the results appear random and a different statistical analysis may have yielded a different p value for this measure. Nursing knowledge did have a small Pearson Correlation of 0.07 showing no linear relationship between variables. The t critical value of 2.17 was then examined in relation to the t value, allowing the null hypothesis to be rejected and conclude that the change in nursing knowledge was not by chance. The relaxation therapy competency data is included in Table 2 below.
Table 2. Relaxation Therapy Competency

<table>
<thead>
<tr>
<th>Participant</th>
<th>Pretest Score</th>
<th>Post test Score</th>
<th>Difference</th>
</tr>
</thead>
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<tr>
<td>11</td>
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<td>93</td>
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<tr>
<td>12</td>
<td>66</td>
<td>100</td>
<td>34</td>
</tr>
<tr>
<td>13</td>
<td>60</td>
<td>80</td>
<td>20</td>
</tr>
<tr>
<td>Mean</td>
<td>56.15384615</td>
<td>92.07692308</td>
<td>35.92307692</td>
</tr>
</tbody>
</table>

Post-test scores amongst the nurses improved greatly. This change in knowledge ranged from a 20% improvement to 53% improvement. This t critical value exemplifies that nurses gained a statistically significant change in knowledge through the education session. Many nursing participants expressed minimal prior knowledge and exposure to relaxation therapies in their CAM Health Beliefs Questionnaire. This lack of pre-intervention knowledge was reflected in their pre-test scores. Additional statistical data regarding the t test for knowledge change is included in Appendix C. An overall positive change in nursing CAM knowledge was assessed after the education session.

Many nurses had difficulty identifying benefits for relaxation breathing in question eleven, which can be referenced in Appendix B. This theme was common throughout the competencies among participants in both the pre and post-test
competency, so additional emphasis was provided through handouts and discussion for during the refresher session regarding relaxation breathing techniques and benefits. There was a variance of knowledge amongst nursing participants and the questions in which they answered correctly, showing a difference in baseline and post-test comprehension.

Twelve participants were unable to define what Biofeedback was in question one during the pre-test. This knowledge gap was ameliorated through education with 100% of post-test answers being correct. All participants answered question four incorrectly, which asked what objective measure the Emwave Biofeedback technology measured. The correct answer was measurement of heart rate variability. Heart rate variability was emphasized greatly through the education session and all participants answered this correctly in their post examination. Most participants had trouble selecting all correct answers in the multiple choice select all that apply questions. Most nurses had a grasp on biofeedback uses, components, and general health benefits of biofeedback described in questions six through eight. Overall comprehension in the nurse group was significant with a large post-test change in knowledge. The education filled a gap in participant’s CAM knowledge and created a platform for nursing to translate the new knowledge in practice to benefit palliative care pulmonary patients.
Patient Implementation

Once nurses completed the education session and became familiar with the relaxation therapy technology, the final phase was implementation of biofeedback for palliative patients. In order to measure the positive patient impact of relaxation therapies, subjective and objective data were collected. Each participant had their vital signs measured prior to initiating therapy in conjunction with measurement of anxiety, breathlessness rating, and pain rating on ten point Likert scales. This data provided a comparison for post implementation evaluation. Each of these objective and subjective measures were repeated following relaxation therapy completion to evaluate the impact made on patient’s physiological and psychological symptoms.

Nursing allowed for patients to describe their CAM experience at completion of relaxation therapy integration through open dialogue. Following each intervention, patient participants were asked how they felt. Overall patients perceived the relaxation therapy session positively. One female participant expressed, “I feel like this will help me relax at home when I’m feeling winded.” Another stated, “My anxiety level feels the same, but I feel less short of breath.” Another male participant expressed, “I feel like I gained control quicker,” in reference to his breathlessness and sense of panic. Many patients simply stated, “I feel more relaxed.” A few participants were not immediately aware of the therapy benefits at fruition, but their vital signs greatly improved showing a state of physiological improvement. No patient participants expressed negative feedback on the relaxation therapy implementation. An overall sense of increased
comfort was achieved for all participants, this is further supported through patient Likert ratings and vital sign measures.

**Patient Results**

The primary goal of relaxation therapy integration was to enhance symptom control and to enhance quality of life in palliative care pulmonary patients. Each patient participant rated their anxiety level on a ten point Likert scale before implementation. Some patients were actively experiencing anxiety at time of biofeedback implementation, where others were not. The pre intervention anxiety rating was compared to a post intervention anxiety rating. The mean pre intervention anxiety rating was 6.4. and the mean post intervention anxiety score was 3.3. This resulted in a mean change of 3.1 Likert scale points with, $t(19)= 5.93$, $p=1.04$. Though this $P$ value is not statistically significant, an overall reduction in anxiety did occur for nineteen patients. This reduction is anxiety is still important and the null hypothesis is rejected due to the critical two-tail $t$ value= 2.09. Reduction in anxiety was aimed at providing patient’s a sense of control over their symptoms through relaxation therapy.

Pain related to the patient participant’s disease processes was variable. Twelve patients did report having pain prior to biofeedback. The pre intervention mean pain rating was 3.75. The post intervention pain mean rating resulted was 2.65, which indicates a mild reduction in pain through relaxation therapy with, $t(19)= 3.31$, $p=0.002$, proving statistically significant. This subjective measurement appeared less noticeable for most patients as their breathlessness and anxiety symptoms were more
predominant on the Likert scales.

The third subjective measurement was breathlessness rating using the Borg Scale. The patients all had advanced pulmonary disease, so breathlessness was a prominent symptom. Many patients described their breathlessness as “debilitating and their greatest symptom burden”. The mean pre intervention breathlessness rating via the Borg Scale was 6.95, post breathlessness rating mean was 3.75. This indicates moderate improvement in overall breathlessness symptomology with t (19)=7.75, p=2.8, t critical two tail= 2.09. Surprisingly the p=2.8 showed no statistical improvement in breathlessness, but the mean improvement of 3.2 Likert points does appear considerable in the overall symptom reduction schema in addition to the t value exceeding the t critical value. This allows the null hypothesis to be reject and exemplified a change in breathlessness through relaxation therapy intervention.

Breathlessness and anxiety often occurred synonymously in the pulmonary patient population. By reducing both of these symptoms, patients were able to gain a sense of control of their symptoms while aiding in activity recovery and providing a state of relaxation.

Objective metric data was collected with implementation of relaxation therapy intervention. Pre intervention vital signs were compared to post intervention vital signs to evaluate a change in overall physiological response to the intervention. Both systolic and diastolic blood pressure were analyzed in this project. The mean reduction in systolic blood pressure was 6.15 mmHg (p=0.01), and a mean diastolic blood pressure
reduction was 2.6 mmHg (p=0.42). There was significant reduction in heart rate as well. The pre intervention heart rate mean was 91.5 beats per minute and the post intervention heart rate mean was 84.5 beats per minute with, $t(19)=4.11$, $p=0.0006$. This is a statistically significant change with treatment. Reduction in heart rate helped patients to enhance their autonomic nervous system control reducing the sensation of fight or flight (Heartmath Inc., 2017).

There was an overall improvement of pulse oximetry post intervention with a pre mean of 91.9% and a post mean of 95.65%; average 3.7% improvement with, $t(19)=4.96$, $p=0.0001$. Respiratory rate was moderately impacted with a pre intervention respiratory rate mean of 21.1 breaths per minute and a post respiratory rate mean of 18 breaths per minute, which is a 3 breath per minute reduction, $t(19)=5.89$, $p=0.12$, $t$ critical two tail=2.09. Comparing the $t$ stat to the critical $t$ value again showed improvement in patient respirations following relaxation therapy. These respiratory rate results were similar to breathlessness ratings before and after treatment (Appendix E-G). Confounding results were found in all areas of patient data. Some variables were more impactful than others, but a general improvement in patient symptomology was achieved through nurse led relaxation therapy for palliative care patients.

Variables without a statistically significant change were evaluated looking at the Pearson Correlation and the critical $t$ value. When the Pearson Correlation value was small, it shows that there is a large distribution and lack of a linear relationship amongst
the variables. These patient measures were evaluated for a t critical value that was smaller than the t stat, which allowed the investigator rejection of the null hypothesis and proved that there was a significant change in patient measurements following relaxation therapy incorporation. The lack of statistical significance amongst some patient variables may also be due to type one error. A larger sample size could have limited the probability of type one error within this project.
DISCUSSION

Key Findings for Nurses

Nursing CAM Beliefs

All nurse participants saw value in offering complementary therapies for palliative care patients in the inpatient setting. The majority of nurses expressed a lack of education regarding these therapies prior to this project, which negatively impacted their recommendation of CAM to clients and resulted in a reduced initiation of conversations about CAM therapies. Nurses expressed their yearning for additional CAM knowledge, to be able to comfortably integrate new treatments into their daily practice. Ben-Ayre, Frenkel, and Hermoni (2006) found that by enhancing provider knowledge, CAM utilization rates and initiation of CAM discussions can occur more fluently and without hesitancy for patients. This study found that providers also sought out additional CAM evidence once they began having open discussions with their clients about CAM, increasing the overall knowledge (Ben-Ayre, Frenkel, & Hermoni, 2006). This DNP project expanded nurses’ awareness of their personal and professional CAM health beliefs through conducting a CAM Beliefs Questionnaire, open dialogue, and providing relaxation therapy education. Nursing perceptions of new patient care processes is important for seamless integration and sustainability of an intervention.
Nurses Focus Groups

The education sessions were successful and allowed for each nurse to participate in a biofeedback session as well as expand their general relaxation therapy knowledge. Positive feedback was received at the conclusion of each education session and participants acknowledge an enhanced comfort with relaxation therapy and patient application principles. One participant stated, “I have never heard of biofeedback before, as an initial exposure this was very beneficial.” Another participant expressed, “This seems like a great adjunctive treatment for our patients to be independent in symptom management.” Both of these statements strengthen the value of providing education for providers, especially in the content area of CAM and relaxation therapies. Nurse participants were excited to incorporate these therapies into practice.

Nurses did report some difficulty incorporating a new process into their daily routine. Factors they reported that impacted the ability to incorporate CAM into their routine nursing care included being short staffed, work flow, and patient availability. The most feasible hours for implementation of biofeedback was in the evenings, as less patient care tasks are completed at this time. Nurses recommended including a wider variance of palliative care patients. One nurse stated, “I wished we could use this for all of our oncology and palliative patients, not just pulmonary patients.” Widening the sample population for future implementation is discussed further. Another nurse stated, “It would be great to have alternative practices available for all of our inpatients.” Overall nursing reported that this implementation was valuable for patients as a whole
and has the ability to be sustainable in the future.

**Key Findings for Patients**

**Patient Preference**

Often patients report a “lack of control” during an acute admission to the hospital. By providing a relaxation therapy intervention, nurses can empower patients to manage their self care and better control their adverse symptoms independently (Maddocks et al., 2017). While individual participants found different value in the relaxation therapy integration, all patients experienced symptom improvement including a reduction in pain, improved anxiety, decreased breathlessness, and improvement in vital signs. The positive effect of relaxation therapy integration in this project lends support to a holistic plan of care that takes into account patient preference is important in achieving comfort and enhanced health goals for patients.

Watson’s Theory of Transpersonal Caring emphasizes the integration of patient centered care focusing on the whole individual (Watson, 2002). By honoring the patient centered caritas through project implementation, patient participants were offered guided imagery and relaxation music options with the readily available resources and technology. Some patients opted to have relaxing music integrated simultaneously, while other participants preferred quietness during their relaxation therapy. These choices allowed for additional individualization of the relaxation therapy delivery,
providing patients with the greatest option to optimize their symptom control (Bishop, Yardley, & Lewith, 2007).

Nursing participants reported that timing of therapy intervention appeared to be a key factor in patient outcomes as well. Patients with acute presence of adverse symptoms were provided a tool to become more comfortable through biofeedback. Those participants who had high breathlessness and anxiety ratings at therapy integration were reported by nursing to have the greatest benefit from relaxation therapy application (Appendices E-G).

**Symptom Management**

Patient data displayed an overall reduction in blood pressure, heart rate, and respiratory rate. These physiological measurements exemplify the patients’ control in their heart rate variability and the overall benefit of the relaxation therapy integration (HeartMath Inc., 2016). All participants had a positive improvement in their pulse oximetry. In addition to providing a glimpse into the efficacy of a patient’s gas exchange capacity, pulse oximetry shows overall hemoglobin carrying capacity in circulation (American Thoracic Society, 2011). This improvement in pulse oximetry occurred when patients were able to consciously control their respiratory rate and heart rate variability through biofeedback application (Appendices E-G).

also found biofeedback integration to reduce overall dyspnea and improved heart rate variability. Reducing dyspnea can have profound effects on patient morale and quality of life in chronic pulmonary illness. Maddocks et al. (2017) states, “supporting patients to self-manage can increase the individual’s self efficacy and reduce feelings of helplessness in both patient and caregiver,” (p. 990). This reduction in breathlessness can help patients to improve activity, increase socialization, decrease anxiety, and improve depression associated with their chronic disease (Maddocks et al., 2017).

Almost all patients in this project had a reduction of their breathless rating. Those who did not improve their breathlessness, maintained their Likert level of dyspnea. This consistent improvement in symptom management is a significant. A few patients required additional treatments in conjunction with the relaxation therapy integration. These interventions included nebulized breathing treatments, anxiety medication, oxygen titration, and pain medication. When patients were experiencing dyspnea, associated anxiety and pain were often present for eighteen participants.

Breathlessness can lead many patients to feel helpless and anxious (Maddocks et al., 2017). Relaxation therapy had an overall positive impact in reduction of dyspnea, anxiety and pain through this project.

**Anxiety.** Anxiety negatively impacts quality of life for patients with chronic diseases. Chronic states of anxiety can impair healing, increase pain perceptions, impair sleep, and diminish overall quality of life (Wang et al., 2014; Lee Crawford, & Hickey, 2014; Reig-Ferrer et al., 2014). By providing patients a means to reduce their anxiety,
participants were empowered to self-manage their symptoms through relaxation techniques. Luebbert, Dahme, & Hasenbring (2001) implemented relaxation training and found participants to have fewer symptoms of depression, anxiety, and emotional lability following treatment delivery. These results were comparable to a more recent study by Tsai et al. (2007), who evaluated biofeedback in palliative care patients with malignancy and found benefit from pain, anxiety, and breathlessness reduction in this population. Relaxation therapy empowered patients to have more control of adverse symptoms in their everyday life. Those patients who had anxiety were able to gain physiological control through biofeedback (Heartmath Inc., 2017).

Cardiovascular. Blood pressure reduction was present in nearly all participants with a statistically significant improvement in systolic blood pressure measurements. This improvement exemplified the ability of patient to attain a state of physiological coherence and conscious relaxation through biofeedback (Heartmath Inc., 2017). No current research studies directly evaluated the impact of blood pressure reduction in overall quality of life. This finding also warrants further exploration to see if it is a reproducible result. Most patients also had improvement in heart rate exemplifying the autonomic nervous system control achieved through physiological coherence.

Pain. Pain can impair sleep, daily functioning, impact psychological well being, and can decrease overall quality of life (Tsai et al., 2007). Not all palliative pulmonary patients have pain directly related to their chronic disease process, but pain is often a
comorbidity (Ducloux, Guisado, Pautex, 2013). Sixty percent of patients in this project experienced pain reduction through relaxation therapy integration at a statistically significant level, while the remaining forty percent had no pain. Pain reduction at a statistically significant level was a surprising result in this project that deserves further exploration in the future in a wider range of patient population.

Quality of Life

Many patients who have end-stage pulmonary disease have three or more comorbid conditions. Multi-morbidity increases symptom burden and overall quality of life (Maddocks et al., 2017). Reig-Ferrer et al. (2014) also found reduction in psychological distress, negative effect, enhanced adverse symptom control, and improved health related quality of life ratings following relaxation therapy implementation in nursing home patients. Each patient participant in this project was encouraged to implement the learned relaxation therapy in further episodes of adverse symptoms, whether present as an impatient or in their daily lives. By providing the participants with the tools to decrease adverse symptoms of their disease, they were empowered to achieve a sense of control of their chronic disease state (Weeks et al., 2014). Whitney (2014) found that by empowering patients to self-manage their symptoms through biofeedback integration, an improvement in overall quality of life was achieved. CAM decision making can be a complex decision making process during end-of-life care. Early access to integrative therapies in has the ability to positively impact chronic disease management (Weeks et al., 2014).
Patient Impact

Maddocks et al. (2017) states, “Going beyond physical symptoms and treating the whole person is important, as patients living with advanced disease place high value on achieving sense of control, strengthening relationships with loved ones, maintaining dignity, and coming to peace spiritually” (p. 994). This project aimed to improve nursing knowledge and in response impact patient symptom management and quality of life through a holistic relaxation intervention. The results of this project, in addition to the current literature, highlight the importance of integrating of complementary relaxation therapies into the care of palliative care pulmonary patients. This noninvasive method of treatment allows patients to self-manage care and impact their health with minimal cost and inconvenience. The impact assessed through this project could transcend to many other palliative care patients to promote quality of life improvement in end-of-life care.

Limitations

Some limitations have been identified in the implementation of this project. The initial barrier encountered was a time delay in approval of the Emwave technology utilization through Information Technology and Biomedical Services departments at the health system. This led to a three-month delay between the nursing education implementation and patient participation. Because of this delay, a refresher course was
provided to the nursing participants once the Emwave technology was installed on the Oncology unit.

Four nursing participants did withdraw from the project during the delay and four new nursing participants were recruited at the time of the refresher course allowing for a nursing sample of thirteen participants. Previous participant data was not included in the final analysis, and these additional participants were included to enhance power of the statistical analysis. The intervention delivery period for patients was constraining. The narrow period for relaxation therapy delivery to patients resulted in the elimination of some potential participants that were interested in relaxation therapy incorporation. Many of these excluded participants were transferred from the intensive care unit outside of the twenty-four hour admission period. Additionally, elderly respiratory patients with altered mental status were unable to consent to participate in the relaxation therapy. Other patients were excluded due to pulmonary acuity. Some of the patient variables measured were not shown to be statistically significant. The lack of statistical significance amongst some patient variables may also be due to presence of a type one error. A larger sample size could have limited the probability of type one error within this project.
Lessons Learned

Many lessons have been learned as a result of development and implementation of this project. This project explored the process of translation of evidence into bedside nursing practices, while impacting both nursing knowledge and patient care outcomes in a positive manner. This project brought to the forefront the amount of organization and facilitation an evidence based project requires to be successfully implemented in an acute care setting. There were many variables that were out of the primary investigator’s and nurse participant’s control. Being adaptive and flexible throughout the project was imperative. Facilitation of the project phases required consistent emphasis to bring the project to fruition. Nurses required some prompting to complete the relaxation therapy intervention for patients, and ultimately the participatory patient goal was met. By maintaining open and consistent communication, the project was able to gain momentum and come to fruition. Translating research into practice is multifaceted and occurs on a continuum of practice improvement. This implementation has the potential to expand to a wider population and a variety of settings of palliative care patients.

Future Implementation

To facilitate a cohesive implementation in the future, the tools and technology needed for implementation should be functional prior to implementation. This would include ensuring all approval for project implementation is completed at an institutional
level. By ensuring all tools are fully operational a seamless implementation through all phases of the project can occur without delays. In future projects, having all technology and coordination of project components before implementation begins would help facilitate fluidity of the overall process. Also, a time lapse between education and patient implementation can deter momentum and knowledge and would be addressed in future projects.

Looking retrospectively, a broader patient inclusion criterion could have allowed for a potentially greater impact of the project. The narrow time window established from four hours following admission to twenty-four hours did exclude some palliative pulmonary patients who could have benefitted from the relaxation therapy. A broader implementation period for patients in the future could allow access to biofeedback at any time during their acute care stay. This broader inclusion criteria, could also capture pulmonary patients who had symptom decline in their acute care stay and who could benefit from relaxation therapy education and integration at a different time interval than this implementation allowed.

In the future, more stringent nursing participant inclusion criterion would help facilitate project implementation. This change could help eliminate withdrawal of participant partially through the experience. By creating more stringent nursing inclusion criteria, established consistency could be established between phases of project integration. While subjective data gathered from Oncology Shared Governance meetings and shift huddles provided an informal basis of overall nursing perceptions
with relaxation therapy, interviewing nurses at the conclusion of the project regarding their experiences could have provided another valuable perspective.

Relaxation therapy could be expanded on a wider scale through the local community in both an inpatient and outpatient setting to help patients better manage their chronic disease. The positive patient impact discovered in this project could be evaluated further to provide insight into the overall benefit on quality of life outcomes in end-of-life care. The positive benefits of symptom management through relaxation therapies could be expanded to many other patient populations in addition to expanding knowledge for providers that serve individuals with chronic respiratory ailments locally. Further education for providers and nurses in Montana is needed to allow for routine implementation of complementary therapies such as relaxation therapies explored by this project.

The implementation of relaxation therapies and education for nursing staff was an initial exposure to organized CAM patient application. The sample sizes for the project were small, and to make statistically significant recommendations a large sample population and a control group would help increase reliability and validity of the results. Both populations of nurses and patients were collected from one facility. Further implementation in varying of settings could also enhance the applicability of the intervention integrations to a wider palliative nursing and patient population. Evaluation of physiological coherence data in the future within the Emwave technology would also
help discover patient level of performance. This data would be valuable to see length and quality of physiological coherence that was achieved in a singular session.

Dissemination of the results of the project at an organizational level will help to advance relaxation therapy availability to many more palliative care patients. In order to disseminate the project results and establish sustainability, a presentation of project results could occur at the hospital wide Nurse Practice Council meeting. Future dissemination could include developing a formal nursing protocol to be implemented into palliative patient standards of care in the health system in north central Montana. This policy would first be presented to the Nurse Practice Council and the Medical Executive Committee for final approval. If organizational approval is acquired inpatient nurses could be educated through semiannual skills day sessions. Palliative care is currently gaining acknowledgement of value within the institution and nationally. This project implementation comes at an exciting time where a focus on patient care preferences in chronic care management and quality of life outcomes are being emphasized for palliative care patients.
Current literature supports an increase of CAM integration into mainstream health practices, particularly palliative care. Educating nurses about CAM allowed for translation of the benefits of relaxation therapies into patient care practices. Relaxation therapy integration can have profound impacts including; fatigue reduction, improved sleep quality, pain reduction, improved functional status, improved psychological health, and improved overall perceptions of quality of life (Wang et al., 2014; Lee Crawford, & Hickey, 2014). Creating an interdisciplinary team approach with incorporation of CAM therapies could help optimize quality of life through anticipating, treating, and preventing suffering in end-of-life care decreasing overall burden to patients and families, while maintaining a patient centered approach (National Consensus Project, 2013). This project successfully completed nursing CAM education and allowed for translation of that new knowledge into patient care at the bedside.

The purpose of this project was to enhance nursing knowledge and comfort with relaxation therapy, and to evaluate of how this knowledge enhancement could impact pulmonary palliative care patient outcomes in north central Montana. This purpose was achieved through providing nursing education, collecting nursing knowledge data through a competency, and finally applying the learned relaxation therapy on an inpatient oncology unit for palliative care pulmonary patients. Subjective and objective measurements were collected before and after the relaxation therapy intervention delivery and evaluated for change through paired sample t test. Palliative care
pulmonary patients had positive psychological and physiological responses to relaxation therapy with improvement in breathlessness, anxiety, pain, and all vital signs measurements. By eliminating adverse symptoms in a non invasive manner, patients will be able to self-manage at home while integrating relaxation therapy techniques in varying settings. An expansion in nursing knowledge of relaxation therapies, created an increase in comfort and enhanced direct utilization of these therapies. This project had a positive impact on patient quality of life outcomes for palliative care pulmonary patients in the inpatient setting.
REFERENCES CITED


Hoinès, L. (October, 2016). Personal interview.


APPENDICES
APPENDIX A

CAM HEALTH BELIEFS QUESTIONNAIRE
CAM Health Beliefs Questionnaire
Below is a list of questions related to relaxation therapies. Please respond to each question by placing an X in the corresponding column of your most appropriate answer.

<table>
<thead>
<tr>
<th>Question</th>
<th>Agree strongly</th>
<th>Agree Somewhat</th>
<th>Disagree Somewhat</th>
<th>Disagree Strongly</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) I have had significant exposure to complementary therapies in my profession</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2) Relaxation therapies can have an impact on palliative patient quality of life outcomes</td>
<td>10</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3) Relaxation therapies have the ability to enhance patient self care</td>
<td>8</td>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4) Relaxation therapies are routinely incorporated into your nursing practice currently</td>
<td>1</td>
<td>6</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>5) I have the knowledge and comfort level with relaxation therapies to discuss therapies with patients and implement them into practice</td>
<td>0</td>
<td>5</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>6) Palliative clients are interested in relaxation therapies as part of their treatment course</td>
<td>1</td>
<td>10</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>7) I am interested in learning more about relaxation therapies</td>
<td>9</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>8) Inpatient palliative clients routinely have complementary therapies incorporated in their standard treatment</td>
<td>0</td>
<td>4</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>9) I have the tools and knowledge to incorporate relaxation therapies into my current practice</td>
<td>0</td>
<td>7</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>10) Relaxation therapies have value in conjunction to traditional medicine practices</td>
<td>10</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>11) I initiate conversations with my clients about complementary therapies</td>
<td>2</td>
<td>7</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>12) Patients initiate conversations about complementary therapies</td>
<td>0</td>
<td>9</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

Years as a nurse__________  Areas employed in career____________________
Age____________________  How many years in Oncology__________________
APPENDIX B

RELAXATION THERAPY COMPETENCY
1. Biofeedback is:
   a. A method of measuring physiological coherence
   b. A method of measuring psychological coherence
   c. A method of measuring cortical inhibition and cortical facilitation
   d. All of the above

2. True or False. Coherence is a connectedness and synchronization between all aspects of our mind and body
   T or F

3. Biofeedback can be used for treatment of
   a. Headaches, stress, insomnia, anxiety, chronic pain
   b. Bowel incontinence, urinary incontinence, Tourettes
   c. ADHD, depression, somatization, emotional dysregulation
   d. All of the above

4. Biofeedback with the Emwave technology measures
   a. Respiratory rate and pulse oximetry
   b. Heart rate variability
   c. EMG wave variability

5. True or False. Biofeedback has the ability to impact psychological coherence through impacting physiological mechanism controlled by the client through harmonious synchronization of cognition and emotions
   T or F

6. Biofeedback includes which key components:
   a. Relaxation breathing and respiratory variability
   b. Relaxation breathing, guided imagery, and heart rate variability
   c. Guided imagery, cognitive variability, and relaxation music
   d. Psychological variability and mind body awareness

7. Biofeedback can help you to control all except:
   a. Self care deficits
   b. Insomnia
   c. Heart Failure
   d. Anxiety

8. Which method of Biofeedback is least invasive
   a. EMG
   b. EEG
   c. EDG
   d. Pulse oximetry/ECG

9. True or False. The sympathetic and parasympathetic branches of the autonomic nervous system continually interact to maintain cardiovascular activity in its optimal range and to permit appropriate reactions to changing external and not internal conditions.
   T or F
10. Guided imagery benefits include all of the following except:
   a. Lowered immune function
   b. Blood pressure reduction
   c. Enhanced sleep
   d. Metabolic modulation

11. Relaxation breathing assists in (choose all that apply)
   a. Modulating heart rhythms
   b. Gas exchange
   c. Reduction in anxiety
   d. Reduction in blood pressure
   e. Changes in metabolic function
   f. Inhibition of the sympathetic nervous system

12. When utilizing the Emwave technology you are seeing your:
   a. Respiratory rhythm in real time
   b. Heart rhythm in real time
   c. Neurological brainwaves in real time

13. Enhanced relaxation following Biofeedback can be expected to be seen:
   a. Immediately
   b. After twelve hours
   c. After twenty four hours

14. Relaxation therapy incorporation to palliative care can assist with (select all that apply)
   a. Improved treatment adherence
   b. Enhanced patient satisfaction
   c. Emotional balance
   d. Coping with end of life decisions
   e. Appetite
   f. Pain control

15. True or False. Biofeedback is not a readily available treatment that can be incorporated into daily life in a cost effective manner while making great impacts on patient outcomes.
    T  or  F
APPENDIX C

NURSING COMPETENCY STATISTICS
Table 2. Nursing Competency Statistics

<table>
<thead>
<tr>
<th>t-Test: Paired Two Sample for Means</th>
<th>Post test Score</th>
<th>Pretest Score</th>
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<tr>
<td>Mean</td>
<td>92.07692308</td>
<td>56.15384615</td>
</tr>
<tr>
<td>Variance</td>
<td>43.57692308</td>
<td>79.30769231</td>
</tr>
<tr>
<td>Observations</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Pearson Correlation</td>
<td>-0.075347268</td>
<td></td>
</tr>
<tr>
<td>Hypothesized Mean Difference</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>df</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>t Stat</td>
<td>11.2844516</td>
<td></td>
</tr>
<tr>
<td>P(T&lt;=t) one-tail</td>
<td>4.782E-08</td>
<td></td>
</tr>
<tr>
<td>t Critical one-tail</td>
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<td></td>
</tr>
<tr>
<td>P(T&lt;=t) two-tail</td>
<td>9.56399E-08</td>
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<td>t Critical two-tail</td>
<td>2.17881283</td>
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APPENDIX D

BIOFEEDBACK GUIDELINE
Biofeedback Guideline

1. Nursing will evaluate the client for appropriateness of Biofeedback application as a nursing intervention following the criteria:
   a. Palliative patient with a chronic lung disease and/or lung malignancy (i.e. COPD, cystic fibrosis, emphysema, lung mets, CHF w/ pulmonary HTN)
   b. Admitted within the last 24 hours to the Oncology Unit
   c. Present on the unit in between hours 4 and 24.
   d. Experiencing adverse symptoms (i.e. breathlessness, anxiety, pain)
   e. Medically able to consent with intact mentation
   f. English Speaking

2. Patient’s who are applicable will be consented between hours zero and twenty four.

3. The patient will be educated with a standardized education handout about the benefits and purpose of relaxation therapies.

4. Vital signs will be obtained prior to Biofeedback and documented on the flowsheet.

5. Pain rating, breathlessness rating, and anxiety ratings will be gathered prior to implementation and documented on the flowsheet.

6. The ear will be assessed for proper skin integrity for placement of the sensor on either ear lobe.

7. The Biofeedback program will be initiated by the nurse and the designated length and type of guided imagery and length of session can be chosen by the client from several options in the Emwave technology.

8. The nurse will assist in directing the patient how to utilize the Biofeedback with relaxation breathing and guided imagery.

9. Once the Biofeedback treatment is completed, nursing will reassess vital signs, pain rating, anxiety rating, and breathlessness rating and document appropriately on the flowsheet. Other necessary treatments can be documented as well (to include pain meds, breathing treatments, anxiety medications etc.).

10. Allow the patient to express how they feel following treatment completion.

11. Review the Biofeedback session with the patient with the results provided in the Emwave program if the patient desires.
APPENDIX E

PATIENT MEASUREMENTS
<table>
<thead>
<tr>
<th>Participant</th>
<th>Age</th>
<th>Gender</th>
<th>Diagnosis</th>
<th>Pain Rating Pre</th>
<th>Pain Rating Post</th>
<th>Pain Reduction</th>
<th>Anxiety Rating Pre</th>
<th>Anxiety Rating Post</th>
<th>Anxiety Reduction</th>
<th>Breathlessness Rating Pre</th>
<th>Breathlessness Rating Post</th>
<th>Breathlessness Reduction</th>
<th>Other Treatments</th>
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<tr>
<td>1</td>
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<td>F</td>
<td>COPD</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>6</td>
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<td>6</td>
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<td>0</td>
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<tr>
<td>2</td>
<td>70</td>
<td>F</td>
<td>Metastatic Breast Cancer w/ lung mets and pulmonary embolism</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>4</td>
<td>2L NC O2</td>
</tr>
<tr>
<td>3</td>
<td>71</td>
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<td>End stage COPD &amp; Chronic respiratory failure</td>
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<td>0</td>
<td>0</td>
<td>5</td>
<td>1</td>
<td>4</td>
<td>5</td>
<td>0</td>
<td>5</td>
<td>4L NC O2 &amp; added a fan to room</td>
</tr>
<tr>
<td>4</td>
<td>80</td>
<td>M</td>
<td>COPD exacerbation, failure to thrive, Decondi oning</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>5</td>
<td>38</td>
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<td>COPD, anxiety</td>
<td>7</td>
<td>6</td>
<td>1</td>
<td>8</td>
<td>7</td>
<td>1</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>2L NC O2, Atarax</td>
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<td>M</td>
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<td>1</td>
<td>9</td>
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<td>0</td>
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<td>2</td>
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<td>10</td>
<td>71</td>
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<td>8</td>
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<td>9</td>
<td>6</td>
<td>3</td>
<td>3L NC O2, norco</td>
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<td>Score 2</td>
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<td>Score 4</td>
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<td>3</td>
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<td>9</td>
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|   |   |   | Mean                             | 3.75    | 2.65    | 1.1     | 6.4     | 3.3     | 3.1     | 6.95    | 3.75    | 3.25    |         |         |         |         |         |         |         |         |         |         |         |

APPENDIX F

CARDIAC MEASUREMENTS
Table 4. Cardiac Measurements

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<th>Difference Reduction</th>
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Mean: 130.15 123.5 6.15 73.5 71.3 2.6 91.95 84.5 7.4

\[ T \text{ value} \]
\[ t=2.79 \quad t=0.82 \quad t=4.11 \]

\[ P \text{ value} \]
\[ p=0.01 \quad p=0.42 \quad p=0.0006 \]
APPENDIX G

PULMONARY MEASUREMENTS
Table 5. Pulmonary Measurements

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</table>

| Mean        | 21.1   | 18.05   | 3.05               | 91.9   | 95.65   | 3.7                    |
| T value     |        | t= 5.86 |                    |        | t= 4.87 |                        |
| P value     |        | p= 1.21 |                    |        | p=0.0001 |                      |
APPENDIX H

IRB FORM
MEMORANDUM

TO: Alice Running and Whitney McKinley

FROM: Mark Quinn
Chair, Institutional Review Board for the Protection of Human Subjects

DATE: April 20, 2017

SUBJECT: "The Impact of CAM Relaxation Therapy Education for Palliative Care Nurses" [ARQ40417]

The above proposal was reviewed by expedited review by the Institutional Review Board. This proposal is now approved for a period of one year.

Please keep track of the number of subjects who participate in the study and of any unexpected or adverse consequences of the research. If there are any adverse consequences, please report them to the committee as soon as possible. If there are serious adverse consequences, please suspend the research until the situation has been reviewed by the Institutional Review Board.

Any changes in the human subjects' aspects of the research should be approved by the committee before they are implemented.

It is the investigator's responsibility to inform subjects about the risks and benefits of the research. Although the subject's signing of the consent form, documents this process, you, as the investigator should be sure that the subject understands it. Please remember that subjects should receive a copy of the consent form and that you should keep a signed copy for your records.

In one year, you will be sent a questionnaire asking for information about the progress of the research. The information that you provide will be used to determine whether the committee will give continuing approval for another year. If the research is still in progress in 5 years, a complete new application will be required.
Subject Consent form for participation in human research at Montana State University
Evaluation of the Impact of Complementary Relaxation Therapy
Education for Palliative Care Providers
Nursing Consent Form

Investigators:
Whitney McKinley RN, DNP-FNP

Name: Student Dept: Oncology Phone: 455-5600

Introduction
- You are being asked to be in a research study to evaluate the impact of complementary therapy education and enhance provider comfort with utilization and recommending complementary relaxation therapies to palliative patients in the Great Falls community.
- Complementary and Alternative Medicine or CAM is defined as, “health and wellness therapies that have typically not been part of conventional Western medicine. Complementary means treatments that used along with conventional medicine,” (Mayo Clinic, 2016).
- CAM relaxation therapies are referring to additional health therapies that are not typically integrated into standard medical treatment of inpatients. This project includes the CAM therapies of relaxation breathing, biofeedback, guided imagery, and relaxation music.
- The aim is to enhance knowledge, enhancing utilization of relaxation CAM services, and implementation of relaxation therapies for clientele whom are interested in an inpatient setting.
- You were selected as a possible participant because you are a registered nurse on the Oncology unit who actively take care of palliative care patients in Benefis Health System. Those excluded are individuals who are not currently employed as a registered nurse on the inpatient Oncology Unit and those who wish not to participate. We ask that you read this form and ask any questions that you may have before agreeing to be in the study.

Purpose of Study
- The purpose of the study is to evaluate baseline assessments of nurses complementary therapy beliefs and knowledge, to provide education about relaxation therapies, and the application to the palliative care population. The goal is enhancing provider comfort, knowledge, and utilization of relaxation therapies in practice.
- Ultimately, this research may be presented as a Doctoral of Nursing Practice Project in a presentation, paper, and published in a palliative nursing journal.

Description of the Study Procedures
- If you agree to be in this study, you will be asked to do the following things:
  - Complete a CAM relaxation therapy beliefs questionnaire.
  - Complete a pretest and posttest regarding relaxation therapies and Biofeedback.
  - Engage in an education presentation and application of Emwave Biofeedback technology, breath training, and guided imagery.

Approved MSU IRB 04/08/2017 Date approved
• Deliver and instruct designated patients on Biofeedback utilizing Emwave technology.
• Collect objective patient data prior to Biofeedback and following completion with the provided data collection tool.
• Data will be collected over a two month period and a mandatory volume of data collection is not required though more than one episode of Biofeedback delivery per participant is preferred if possible to enhance comfort with intervention delivery.
• Small focus group discussions will occur to discuss and evaluate the impact of the intervention and allow for constructive feedback of the intervention delivery and barriers that may be encountered throughout the study.
• Each episode of relaxation therapy incorporation will take approximately twenty to thirty minutes in addition to current patient care responsibilities.

Risks/Discomforts of Being in this Study
• There are no reasonable foreseeable (or expected) risks. There may be unknown risks involved in this study.

Benefits of Being in the Study
• The benefits of participation are potential enhanced knowledge regarding relaxation therapies and Biofeedback technology application for palliative care patients and enhanced awareness as the pilot unit for a proposed system wide policy incorporation into daily practice.

Confidentiality
• This study is anonymous. We will not be collecting or retaining any information about your identity. Demographic data will be collected from study participants to enhance study results without attached identifiers.

Payments
• No payments are involved in the participation of this study. There is no cost to you as a participant.

Right to Refuse or Withdraw
• The decision to participate in this study is entirely up to you. You may refuse to take part in the study at any time without affecting your relationship with the investigator of this study or Montana State University. Your decision will not result in any loss or benefits to which you are otherwise entitled. You have the right not to answer any single question, as well as to withdraw completely from the interview at any point during the process; additionally, you have the right to request that the interviewer not use any of your interview material.

Right to Ask Questions and Report Concerns
• You have the right to ask questions about this research study and to have those questions answered by me before, during or after the research. If you have any further questions about the study, at any time feel free to contact me, Whitney McKinley at whitneybarnekoff@yahoo.com or by telephone at 4069452045. If you like, a summary of the results of the study will be sent to you. If you have any other concerns about your rights as a research participant that have not been answered by the investigators, you may Montana State University Institutional Review Board via telephone 4069946793 or mquinn@montana.edu.
Consent

- Your signature below indicates that you have decided to volunteer as a research participant for this study, and that you have read and understood the information provided above. You will be given a signed and dated copy of this form to keep, along with any other printed materials deemed necessary by the study investigators.

Subject's Name (print): __________________________

Subject's Signature: ___________________________ Date: _____________

Investigator's Signature: ___________________________ Date: _____________

APPROVED MSU IRB
04/20/2014 Date approved

3
Subject Consent form for participation in human research at Montana State University
Evaluation of the Impact of Complementary Relaxation Therapy
Education for Palliative Care Providers
Patient Consent Form

Investigators:
Whitney McKinley RN, DNP-FNP

Introduction
- Complementary and Alternative Medicine also known as CAM is a holistic approach to incorporating health and wellness treatment into your traditional medical care.
- The goal of CAM is to enhance your management of your symptoms in addition to your current medical treatment.
- You are being asked to be in a research study to evaluate the impact of complementary therapy education and enhance provider comfort with utilization and recommending complementary relaxation therapies to palliative patients in the Great Falls community.
- The aim is to increase knowledge, increase utilization of CAM services, and for nurses to implement relaxation therapies for hospital patients who are interested.
- You were selected as a possible participant because you are a patient on the Oncology unit who has chronic lung disease and/or a lung malignancy and have experienced adverse symptoms as part of your disease process. Those excluded are individuals who do not have a lung disorder, are not a patient on the inpatient Oncology Unit, who are medically unstable, unable to consent, and those who wish not to participate.
- We ask that you read this form and ask any questions that you may have before agreeing to be in the study.

Purpose of Study
- The purpose of the study is to look at nurse’s complementary therapy beliefs and knowledge, to provide education about relaxation therapies to nurses, and to implement relaxation therapies for palliative care patients.
- The goal is of this study is increase provider comfort, knowledge, and use of relaxation therapies in patient care practice.
- This study aims to incorporate relaxation therapies into the traditional medical care you receive in the hospital, while trying to improve your comfort and quality of life.
- The study results will be presented as a Doctoral of Nursing Practice Project in a presentation, paper, and published in a nursing journal.

Description of the Study Procedures
- Biofeedback is a method of training your body to relax and improve symptom control through relaxation breathing, guided imagery, and relaxation music.
- If you agree to be in this study, you will be asked to do the following things:
  - Participate in relaxation therapy delivery with Enwave technology Biofeedback. This technology is simple to use and does not require any other attachments except a small clip.
The nurse will place a small pulse oximetry clip on your ear to measure your heart rate and respiratory rate. This connects to a computer where the Emwave technology will guide you through relaxing images with relaxation music to help manage uncomfortable symptoms while in your hospital room.

Your nurse will start up the computer technology and instruct you how to utilize it and can answer your questions about the relaxation therapies.

Your nurse will also provide you with a handout explaining each of the relaxation therapies included in the Biofeedback program.

Your nurse will ask you to rate your pain, anxiety, shortness of breath, and will measure your vital signs before and after Biofeedback.

The length of the relaxation therapy will be approximately twenty to thirty minutes.

Risks/Discomforts of Being in this Study
- There are no foreseeable (or expected) risks in this study. There may be unknown risks involved in this study.

Benefits of Being in the Study
- The benefits of participation include reduced shortness of breath, pain, anxiety, and restlessness. These benefits are not guaranteed in every individual.
- You can request to participate in the relaxation therapy as often as you wish after the initial demonstration of the technology, though measurements will only be obtained once.

Payments
- No payments are involved in the participation of this study.

Right to Refuse or Withdraw
- The decision to participate in this study is entirely voluntary. You may refuse to take part in the study at any time without affecting your relationship with the investigator of this study, your nurse, or Montana State University.
- Your decision will not result in any loss or benefits to which you are otherwise entitled. You have the right not to answer any questions, as well as to withdraw completely from the interview/intervention at any point during the process; additionally, you have the right to request that the interviewer or nurse not use any of your interview material.
- If you decline participation this will have no effect on the standard medical care you would otherwise receive as an inpatient on the Oncology unit.

Right to Ask Questions and Report Concerns
- You have the right to ask questions about this research study and to have those questions answered by me before, during or after the research. If you have any further questions about the study, at any time feel free to contact me, Whitney McKinley at whitneybarneckoff@yahoo.com or by telephone at 4064555600. If you like, a summary of the results of the study will be sent to you. If you have any other concerns about your rights as a research participant that have not been answered by the investigators, you may Montana State University Institutional Review Board via telephone 4069946783 or mquinn@montana.edu.

APPROVED
MSU IRB
6/10/2019
Date approved
Confidentiality

- Your investigator and nurse will treat your identity and health information with professional standards of confidentiality and HIPPA guidelines. Your identity will only be present on your consent form and for other documentation of data you will be identified with a numerical identifier.
- The information gathered in this study will be published in a nursing journal, but your identity will not be revealed.
- The individuals involved in this study who will have access to your information will include your nurse taking direct care of you as well as the primary study investigator.
- This study is anonymous. We will not be retaining any information about your identity. Demographic data (i.e. diagnosis, age, gender) will be collected from study participants to enhance study results without personal identifiers, you will remain anonymous.
- This consent form will be stored in a locked area and only accessible to the study primary investigator.

Consent

- Your signature below indicates that you have decided to volunteer as a research participant for this study, and that you have read and understood the information provided above. You will be given a signed and dated copy of this form to keep, along with any other printed materials deemed necessary by the study investigators.
- I have read the above and understand the discomforts, inconvenience and risk of this study. I, _______________________ (name of subject), agree to participate in this research. I also agree that my health information can be collected and used by the researchers and staff for the research study described in this consent form. I understand that I may later refuse to participate and that I may withdraw from the study at any time.

D# ______________

NUMBER ______________________

Subject’s Name (print):

________________________________________

Subject’s Signature: ___________________________ Date: ___________________________

Investigator’s Signature: ___________________________ Date: ___________________________
Authorization to Share Personal Health Information in Research

We are asking you to take part in the research described in the attached consent form. To do this research, we need to collect health information that identifies you. We may collect the results of tests, questionnaires and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. This information is described in the attached consent form. For you to be in this research, we need your permission to collect and share this information.

We will share your health information with people at the hospital who help with the research. We may share your information with other researchers outside of the hospital. We may also share your information with people outside of the hospital who are in charge of the research, pay for or work with us on the research. Some of these people make sure we do the research properly. The "confidentiality" section of the consent form says who these people are. Some of these people may share your health information with someone else. If they do, the same laws that the hospital must obey may not protect your health information.

If you sign this form, we will collect your health information until the end of the research. We may collect some information from your medical records even after your direct participation in the research project ends. We will keep all the information for at least six years, in case we need to look at it again. We will protect the information and keep it confidential.

Your information may also be useful for other studies. We can only use your information again if the Institutional Review Board gives us permission. This committee may ask us to talk to you again before doing the research. But the committee may also let us do the research without talking to you again if we keep your health information private.

If you sign this form, you are giving us permission to collect, use and share your health information. You do not need to sign this form. If you decide not to sign this form, you cannot be in the research study. You need to sign this form and the attached consent form if you want to be in the research study. We cannot do the research if we cannot collect, use and share your health information.

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to the researcher listed on the attached consent form. The letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.
<table>
<thead>
<tr>
<th>Citation</th>
<th>Design/Method</th>
<th>Sample Setting</th>
<th>Data Analysis</th>
<th>Variables studied &amp; Definitions</th>
<th>Measurement of variables</th>
<th>Strength of evidence</th>
<th>Study findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Henneghan &amp; Schnyer, R.N. (2015)</td>
<td>Systematic Review Evaluating effects of biofield therapies on symptom management and relaxation at end of life in palliative and hospice patients.</td>
<td>N=30 publications Meta-1 Systematic Rev-11 RCT-10 Cohort/Case Clinical studies-7-Mixed samples across studies Setting: Outpatient palliative care</td>
<td>Descriptive statistics</td>
<td>Biofield therapies: Therapeutic touch(TT) Healing Touch (HT) &amp; Reiki</td>
<td>- VAS pain scale - VAS Anxiety - Fatigue - Well being feelings - Relaxation - POMS depression</td>
<td>Level 1: Mod Limitations: Limited evidence, small sample size, multiple research methods. Not specific to only palliative/ Hospice patients Strengths: - no harm noted &amp; good safety record - adequate synthesis of evidence across studies provided - application or recommendation to pt for implementation on individual basis and is applicable to wide age span of patients</td>
<td>Reiki, TT, HT decreased amount of narcotics used and improved pain relief, 1.24 pt pain rating reduction, decreased anxiety, improved emotional well being as adjuncts to standard tx - TT/HT mod reduction pain - Reiki greatest pain reduction - Reiki- improved anxiety from baseline &amp; raised level of comfort, relaxation, &amp; wellbeing post tx, improved QOL, fatigue reduction - HT decreased indicators of depressed mood, chronic/intrac table pain benefit, improved relaxation - TT-effective adjunct pain remedy, restlessness/stress reduction</td>
</tr>
<tr>
<td>Wilkinson, Lockhart, Gamble, &amp; Storey, 2008.</td>
<td>Systematic Review Examining evidence surrounding reflexology for symptom relief and QOL in individuals with cancer</td>
<td>N=5 studies</td>
<td>Descriptive statistics</td>
<td>Control group Reflexology vs placebo group Sham &amp; Authentic Reflexology</td>
<td>Patient reported levels for -VAS Pain ratings -Breathing -POMS Fatigue -VAS Anxiety</td>
<td>Limitations: Small sample size for review, lack of side effects studied, duration of effect not measured in all studies, no specifics about areas utilized with reflexology, not all studies included same variables studied for comparison -no harm noted</td>
<td>Results across studies: -Pain p&lt;0.004 -Breathing p=0.026 -Fatigue p=0.006- sig &amp; P=0.002 -Anxiety p&lt;0.001 -Varied results of symptom reduction due to differing applications of reflexology -Sham reflexology had better improvement in sx than authentic reflexology</td>
</tr>
</tbody>
</table>

Application: Biofield therapies have impact in reducing pain, anxiety and improving relaxation, and overall QOL ratings.
**Singh & Chaturvedi, 2015**

Complementary and alternative medicine in cancer pain management: A systematic review

<table>
<thead>
<tr>
<th>Singh &amp; Chaturvedi, 2015</th>
<th>Systematic Review</th>
<th>Qualitative (Ethnography &amp; phenomenology) &amp; quantitative data includes RCT, case studies, SR, &amp; cohort studies</th>
<th>Summary of evidence</th>
<th>Descriptive statistics</th>
<th>Cancer pain</th>
<th>Acupuncture</th>
<th>Massage</th>
<th>Reflexology</th>
<th>Yoga</th>
<th>Tai Chi</th>
<th>Hypnotherapy</th>
<th>Aromatherapy</th>
<th>TENS</th>
<th>CBT</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Needs further eval for side effects and applicability <strong>Strengths:</strong> Generalized reports of reflexology effects in oncologic population showing sig reduction in pain, fatigue &amp; anxiety</td>
<td></td>
<td>-VAS pain</td>
<td>-Stress levels</td>
<td>-Anxiety VAS</td>
<td>-Well being</td>
<td>-Depression</td>
<td>-N/V</td>
<td>-Sleep</td>
<td>-Mobility</td>
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<td>Application: Reflexology may be utilized in the palliative population as a means to reduce fatigue, anxiety and pain. Sham reflexology may be of greater benefit to palliative patients.</td>
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<td>-Comparison of foot massage to reflexology resulted in similar reduction in symptoms to include pain, breathlessness, fatigue and anxiety.</td>
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</table>

**Level I:** low

**Limitations:** not all areas included in depth systematic review of data but more summary of treatment and some control study results. Provides basic information in each area

**Strength:** qualitative study quotes included -baseline applicable for provider/patient education and individualized pt recommendations -no risk of harm listed

- Massage stress/anxiety reduction, increased well being and pain control
- Reflexology, pain reduction and tx side effect management
- Yoga, effects on physical health/pain unclear, may help improve mobility, sleep, anxiety, fatigue, & stress.
- Taichi, not significantly effective in reduction of symptoms, some increased sense of well being
- Hypnotherapy, pain reduction in
| Babu, A., Mathew, E., Danda, D., Prakash, H. 2007 |
| Management of patients with fibromyalgia using biofeedback: A randomized control trial |
| RCT - double blind w/ placebo group |
| Evaluating Biofeedback effects in pain reduction |
| N=30 |
| Setting: India outpatient department, 6-day treatment span |
| Evaluate efficacy of EMG Biofeedback to reduce pain in fibromyalgia patients |
| - T test & ANOVA between groups assessment - P<0.001 for pain and tender pt reduction - VAS ordinal rating reduction for pain and tender pts - ANOVA analysis shows sig decrease in VAS F=12.23 P=0.002, FIQ, tender points w/in |
| Control group received sham Biofeedback Experiment al group EMG biofeedback |
| - VAS pain scale - Fibromyalgia impact questionnaire (FIQ) to assess function, - Six-minute walk test (SMWT) to assess aerobic fitness - Number of tender points |
| Level II: Mod Limitations: - Significant decrease in pain and number of tender points in biofeedback group p=0.001 - No sig difference between FIQ and SMWT scores. - Biofeedback had sig analgesic effects - FIQ scores decreased by 22% in experimental group and combo w/ CBT and meds, decreased anticipatory N/V - Aromatherapy, best in short term relieving anxiety, pain, depression, improve well being & sleep - TENS, chronic pain relief in limited population - CBT, pain reduction, improved coping methods |
| Application: Many modalities of CAM can be utilized for further symptom management, relaxation and improving QOL. Individualized treatment approach is best in facilitating these treatment modalities. |
| - Evaluating Biofeedback effects in pain reduction |
| N=30 |
| Setting: India outpatient department, 6-day treatment span |
| Evaluate efficacy of EMG Biofeedback to reduce pain in fibromyalgia patients |
| - T test & ANOVA between groups assessment - P<0.001 for pain and tender pt reduction - VAS ordinal rating reduction for pain and tender pts - ANOVA analysis shows sig decrease in VAS F=12.23 P=0.002, FIQ, tender points w/in |
| Control group received sham Biofeedback Experiment al group EMG biofeedback |
| - VAS pain scale - Fibromyalgia impact questionnaire (FIQ) to assess function, - Six-minute walk test (SMWT) to assess aerobic fitness - Number of tender points |
| Level II: Mod Limitations: - Significant decrease in pain and number of tender points in biofeedback group p=0.001 - No sig difference between FIQ and SMWT scores. - Biofeedback had sig analgesic effects - FIQ scores decreased by 22% in experimental group and combo w/ CBT and meds, decreased anticipatory N/V - Aromatherapy, best in short term relieving anxiety, pain, depression, improve well being & sleep - TENS, chronic pain relief in limited population - CBT, pain reduction, improved coping methods |
| Application: Many modalities of CAM can be utilized for further symptom management, relaxation and improving QOL. Individualized treatment approach is best in facilitating these treatment modalities. |
| Faith, J., Thorburn & Tippens, 2015 | Cross sectional survey Evaluates the association between perceived patient centered communication and provider avoidance regarding CAM use | Sample N= 6746 Setting: U.S. survey of patient CAM use and communication disclosure by random phone and mail sampling | Bivariate regression -51% of CAM users had discussed CAM use with provider -Higher levels of patient centered communication were assoc w/ lower odds of provider avoidance AOR=0.63 95% CI | Patient provider relationship Patient provider communication barriers in relation to patient CAM use CAM use disclosure and discussion avoidance - Telephone interviews and mail interviews questionnaires -HINTS survey | Level IV: High Limitations: Not all CAM therapies were listed as choices in the survey which may have skewed results -limited reporting of stats, more narrative focused -Strengths: Explores a topic that is often not reported and enhances the need for provider recognition of CAM and why patients seek this form of tx and motives behind CAM use reporting. -no harm noted -12% in control group Application: Patient education about biofeedback enhances self care and home relaxation implementation is effective to maintain lower VAS, less tender points, and higher functional ratings in chronic illness management. | -Provider patient communication can impact the type of treatment modalities patient seek -Patients with reported poor quality relationships with PCP seek out CAM -Patients who avoid healthcare are more likely to utilize CAM. -CAM use associated with having experienced discrimination from traditional health care -Patients with high quality provider patient relationships more likely to report CAM use to PCP -24% reported use of CAM -51% of CAM users discussed with...
| Lee, Crawford, & Hickey, 2014 | Systematic Review-Review of 146 RCT's for studies Evaluating CAM mind body therapy application for reduction of chronic pain symptoms Integrates education for self care for some interventions | N= 146 Okinawa Japan & Samueli Institute, USA. | Inferential stats P values reported for studies. Most intervention with positive pain reduction p<0.05 Those w/ p>0.05 denied pain reduction and low efficacy intervention implementation | Meditation- training the mind to induce a state of awareness of emotional, sensory, & cognitive events Mindfulness - Awareness of one's bodily functions, feelings, perception Relaxation therapy-Biofeedback - cultivate mind body, gain control of HR and RR and acquire stress reduction Applied Relaxation-reduction in physical tension to refocus mind Guided imagery- mental imagery suggestions | -VAS pain ratings - SF-MPQ pain -SF-36 pain -BPI-pain -NRS pain - 5 & 6 pt Likert scale - pain diary -headache diary | Level I: Mod Strength: Good summary of mind body therapies and their application to wide variety of diseases w/ pain applicable to palliative care Limitations: noted lower strength studies for mind body therapy application, needs further research to enhance application to practice, good status for Biofeedback application for pain reduction -Biofeedback with low risk some dizziness noted. -Other modalities lacking safety profile | PCP use of CAM Application: Communication is key to assessing utilization of CAM. Barriers to CAM utilization should be addressed when attempting to incorporation CAM tx and education. Initial perceptions of tx are important | Meditation usage increasing, easily self administered, mild pain reduction -Mindfulness-helps prioritize feelings away from destructive and towards purposeful, alleviates pain and improves emotional well being -Applied relaxation education with limited pain reduction results -Biofeedback effective in tx chronic low back pain, migraines, decreased muscle contractions. Shown more effective than PT tx for chronic pain. CBT & topical lidocaine equal ratings |
| Luebbert, Dahme, & Hasenbring, 2001 | Systematic Review-Meta Analytical review: Effects of Relaxation on emotional adjustment & relaxation training for adverse symptom reduction in cancer patients | N= 15 studies University Hospital and University settings in Germany | Effect size: Descriptive stats - Chi-square - Level of sig for all studies set at p<0.05 | V= Tx-related symptoms-nausea, pain, BP, HR Emotional adjustment = anxiety, depression, anger, tension, vigor, & fatigue | -VAS scales -VAS pain -VS monitor records -Multiple Affect Adjective Check list -Profile of Mood States | Level I: Mod Limitations: Small number of studies for Meta analysis Strengths: standardized approach to assessment of statistical data using the studies w/ similar measurement of variables -application pertinent to palliative oncological patients and transcends to symptom management of other populations | Groups in the study all utilized relaxation as a psychological intervention, some guided imagery, autogenic training, and deep breathing. - relaxation has a sig effect on tx related symptoms for nausea and pain. Reduction in BP & HR and muscles -relaxation training had a sig effect on reduction of anxiety, mood disturbances, and hostility while improving depression rates -no effect on vigor, fatigue, and confusion -Relaxation therapy enhances self control of adverse symptoms -when combined w/ other | w/ audio to stimulate healing, decrease pain & increase relaxation | in pain reduction -Guided Imagery-not found effective in pain reduction Application: Education about modalities enhanced pain reduction for Biofeedback and guided imagery |
Ducloux, Guisado, & Pautex, 2013
Promoting sleep for hospitalized patients with advanced cancer with relaxation therapy: Experience of a randomized study

| RCT- pilot study | N= 20 (large % withdrawal) Inpatient palliative care unit Two groups: Immediate Intervention group (IIG) & Delayed Intervention Group (DIG) | Non paired t test between tx groups IIG & DIG Pained t test Sleep satisfaction D2 p<0.05 D5 p>0.05 | IIG- intervention delivered from day 3-6 w/ 1 hr. training session D3 DIG intervention day 6-9 w/ 1 hr. training session @ D6 Training entailed deep breathing exercise & somatic tension release | -NRS sleep scale -Daily sleep diary -NRS pain rating -NRS dyspnea rating -Hospital anxiety & depression scale | Level II: mod Limitations: large withdrawal rate limiting validity of study -possible placebo effect increased withdrawal rate -depression & chronic insomnia occurred in half of participants further impacting results Strengths: randomized study w/ good baseline assessments for sleep quality and comorbidities impacting rest -no harm noted in study -Sleep disorders enhance further burden and distress to palliative patients and impair QOL - Improved sleep satisfaction by D2 in both groups -No significant prolonged effects of relaxation therapy on sleep by D5 - No assoc of sleep quality w/ number of hours slept, more perception related - Early evaluation of sleep quality in palliative care patients could highlight implications for relaxation therapy -Further studies are needed to validate relaxation therapy prolonged modalities such as meds or education effects of relaxation training may be positively potentiated * Relaxation therapy training can enhance symptom management in multiple health dimensions in palliative patients

- Non paired t test
- Paired t test
- N= 20
- Immediate Intervention group (IIG)
- Delayed Intervention Group (DIG)
- NRS sleep scale
- Daily sleep diary
- NRS pain rating
- NRS dyspnea rating
- Hospital anxiety & depression scale
- Level II: mod Limitations
- Large withdrawal rate limiting validity of study
- Possible placebo effect increased withdrawal rate
- Depression & chronic insomnia occurred in half of participants further impacting results
- Strengths: randomized study w/ good baseline assessments for sleep quality and comorbidities impacting rest
- No harm noted in study

- Early evaluation of sleep quality in palliative care patients could highlight implications for relaxation therapy
- Further studies are needed to validate relaxation therapy prolonged
Bishop, Yardley, & Lewith, 2007
A systematic review of beliefs involved in the use of complementary and alternative medicine

SR Lit Review of qualitative studies for beliefs involved with use of CAM

N=94 articles
Qualitative studies
Setting not specified

Qualitative design with narrative reporting

-Control & participatio
- Illness perceptions
- Holism & Natural Tx
- Spirituality
- Treatment beliefs

-COPE scale
- QOL ratings
- % ratings for beliefs

Level V: Mod Limitations:
Subjective content w/ qualitative studies
Strengths:
Covered subjected matters of CAM use succinctly w/ good recommenda
tions for rationale behind CAM use that are not easily portrayed in a quantitative study
-applicable to provider recognition of qualitative aspects of CAM utilization
-no harm in study

-Those who use CAM are more likely to believe in personal control and patient centered of health vs provider control
-CAM users felt empowermen
-Active coping & expression of emotions r/t CAM use
-Beliefs about disease can impact CAM use rates and seeking out stress reduction through CAM
-Holism and non toxic nature of CAM is valued by CAM users
-Cultural and Spiritual beliefs predict CAM use

Application:
-Incorporation of CAM modalities by patient preference and establishing baseline beliefs will help palliative providers better connect and make appropriate effects on sleep

* Application: addressing relaxation practices can enhance QOL and sleep hygiene for palliative patients
<table>
<thead>
<tr>
<th>Source</th>
<th>Study Design</th>
<th>Sample</th>
<th>Intervention Details</th>
<th>Outcome Measures</th>
<th>Analysis</th>
<th>Limitations</th>
<th>Findings</th>
<th>Application</th>
<th>Conclusion</th>
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<tbody>
<tr>
<td>Reig-Ferrer, Ferrer-Cascales, Santos-Ruiz, Campos-Ferrer, Prieto-Seva, Velasco-Ruiz, Fernandez-Pascual, &amp; Albaladejo-Blazquez, 2014</td>
<td>RCT</td>
<td>N=30</td>
<td>Educated elderly patient's about relaxation techniques to enhance psychological well being &amp; enhance immune response</td>
<td>Mann-Whitney U test, SWLS, ABS, NHP, Satisfaction with Life Scale</td>
<td>P values in study findings for accuracy</td>
<td>Mann-Whitney U test</td>
<td>Level II: Moderate</td>
<td>Optimization of immune function through relaxation optimizes QOL through disease reduction and reduction in stress</td>
<td>Optimization of immune function through relaxation optimizes QOL through disease reduction and reduction in stress</td>
</tr>
</tbody>
</table>
### Wang, Tao, Zhao, Zhou, & Jiang, 2014

**Optimal timing for initiation of biofeedback-assisted relaxation training in hospitalized coronary heart disease patients with sleep disturbances**

**RCT Study to examine optimal timing for biofeedback relaxation therapy to assist in sleep**

- **N=128**
- Pretest post test design to compare effectiveness of nurse led biofeedback
- **China Inpatient Cardiac unit**
- 4 groups: 36 morning group, 34 night group, 33 morning-night, 39 control group

- Chi square test to analyze variance between group factors, time factors, and effective of nurse led Biofeedback
- Sig differences between 3 IV groups
- P<0.05 indicating improved sleep after intervention
- Night and morning-night group improved the most F values in study
- PSQI intervention groups 10.15 decreased to 7.42 post

- Sleep measures recorded each day and implementation of biofeedback
- D4 -PSQI & SAS measured D4-D9
- 3 timed groups received Biofeedback relaxation training at varying times of the day focused on controlling sympathetic tone and muscle relaxation
- Skin temp monitoring

- Measurement Pittsburgh sleep quality index (PSQI)
- 4 pt Likert scale
- Zung Self Rating Anxiety Scale (SAS)
- SOL extended time from retiring to falling asleep
- TST -amount of time spent asleep
- SE -amount of time spent in bed

- **Level II: mod**

- **Limitations:**
  - smaller study in one hospital
- **Strengths:**
  - Well designed controlled trial w/ consistent expected outcomes
  - provides insight to biofeedback impact in improving sleep quality in hospitalized individuals who have chronic illness and may be palliative
  - no harm noted in study

- **All 4 groups received standard sleep care:**
  - sleep hygiene, temp control, noise & light control
  - Effectiveness of relaxation training was related to timing of intervention
  - night and morning-night groups had greatest improvement
  - TST, PSQI & SAS improved after biofeedback
  - Intervention groups showed decreased sleep latency, less times awakened, and increased TST

- **Application:**
  - timing of relaxation therapy is optimized in am and BID for best sleep quality outcomes
Matching to circadian rhythms with intervention timing acquires best outcomes and decreases need for medication assist for insomnia.

| Downey, Diehr, Standish, Patrick, Kozak, Fisher, Congdon, & Lafferty, 2009. Might massage or guided meditation provide means to a better end? Primary outcomes from an efficacy trial with patients at the end of life. | RCT Evaluating patient QOL outcomes when guided meditation or massage are delivered 2 times weekly vs regular friendly visits at same frequency | Linear regression model 
- stats reporting limited due to decreased sample volume at end of study. | -QOL rating 
- Memorial Symptom Assessment Scale: Pain distress 0-5 
- study partner reports of QOL experiences following expiration 
- Follow up interviews for QOL rating 
- Pain distress rating at end of two treatments and repeated this measure for both QOL & pain distress | Level II: low Strengths: 
- Variance in care delivery site, possibly skewing data 
- No significant effects were noted between massage or meditation group when compared to friendly visits. 
- Very few studies have evaluated CAM integration this close to end of life. Application: Any increased interaction between care personnel and implementation of CAM modalities such as massage or guided imagery can have a positive impact in QOL ratings by enhancing patient and family support in end of life. This study highlights that not all trials... |

- Overall QOL ratings declined over ten-week analysis. 
- The massage group had the highest QOL ratings but had higher baseline ratings as well

N=167 randomized patients 
- University of Washington study 
- Baseline data on CAM use and perceptions of QOL gathered prior to intervention.
Weeks, 2014
Balneaves, Paterson, & Verhoef,
Decision-making about complementary and alternative medicine by cancer patients: integrative literature review

<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th>Setting</th>
<th>Sample Size</th>
<th>Measures</th>
<th>Limitations</th>
<th>Strengths</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Integrative literature review</td>
<td>Evaluates decision support strategies for oncologic palliative patients making informed decisions about CAM</td>
<td>N= 35 articles Mostly descriptive studies Setting not specified</td>
<td>Decision making phases - information seeking -decision making roles -beliefs -contextual factors -decision making outcomes - relationship between CAM and conventional medicine</td>
<td>Level V: moderate</td>
<td>-CAM decision making is a complex non-linear process split into three phases early-characterized w/ loss, fear, and loss of control. mid-maintenance of well being &amp; managing side effects late-overcoming sense of loss, prolonging life, or coming to terms with death -Phase of access describes aim of treatment goals -type of evidence individuals seek depends on underlying beliefs and values and experiences w/ CAM. - Active decision makers embrace a large variety of CAM - Demographic, cultural norms, and disease related factors such as...</td>
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</tbody>
</table>
as age and income affect patient’s CAM decisions
  - Expected outcomes influence CAM access and rationale for access such as desire for control of care and philosophies of healing
  
**Application:** This evidence leads providers to a better understanding of patient preferences and beliefs and varying stages of their disease and why they may access CAM and relaxation therapies. Author provided a conceptual framework for providers to utilize in CAM decision making with their patients.

| Jane, Wilkie, Gallucci, Beaton, & Huang, 2009. | Quasi Experimental Control Study | Effects of a full-body massage on pain intensity, anxiety, and physiological relaxation in Taiwanese patients with metastatic bone pain: A pilot study | N=30 patients Quasi-Experimental pretest-post test design in 5 Oncology Taiwanese units | Evaluation: T test pre & post, at 9 time intervals from 5 min to 18hrs RANOVA for massage effects | McGill Pain Questionnaire- Pain ratings VAS -Anxiety measures by VAS 6 item self assessment scale -Monomeric measurement of physiologica l relaxation with HR & BP reduction | -Pain VAS -Anxiety VAS -Relaxation by BP & HR measurement | Level III: High Limitations: no blinding, possible response bias -no reported adverse effects -individualized application for safety of massage -best in conjunction w/ pharmacologi c treatment Strengths: First study to evaluate longitudinal effects of -Pain VAS measures at up to 2.5 hours post had sig pain reduction – max pain reduction impact at 20 min post -Anxiety peak reduction at 15 min with sustained effects till 16 hr. post -Relaxation-subjective reports of improvement, HR & MAP no sig changes pre-post |

Effects of a full-body massage on pain intensity, anxiety, and physiological relaxation in Taiwanese patients with metastatic bone pain: A pilot study

| N=30 patients Quasi-Experimental pretest-post test design in 5 Oncology Taiwanese units | Evaluation: T test pre & post, at 9 time intervals from 5 min to 18hrs RANOVA for massage effects | McGill Pain Questionnaire- Pain ratings VAS -Anxiety measures by VAS 6 item self assessment scale -Monomeric measurement of physiologica l relaxation with HR & BP reduction | -Pain VAS -Anxiety VAS -Relaxation by BP & HR measurement | Level III: High Limitations: no blinding, possible response bias -no reported adverse effects -individualized application for safety of massage -best in conjunction w/ pharmacologi c treatment Strengths: First study to evaluate longitudinal effects of -Pain VAS measures at up to 2.5 hours post had sig pain reduction – max pain reduction impact at 20 min post -Anxiety peak reduction at 15 min with sustained effects till 16 hr. post -Relaxation-subjective reports of improvement, HR & MAP no sig changes pre-post |
massage on QOL measures. Prolonged effects in many areas. Applicable to a wide population with chronic diseases - Short term effects for pain and anxiety sig. - Narrative reports of muscle relaxation, reduced stress, improved comfort, circulation, sleep, & feeling secure - Pain VAS: F=24.6, P<0.001 Anxiety VAS: F=10.3, P<0.001

Application: Massage therapy is applicable to palliative patients for reduction in pain and anxiety and further evaluation of time interval testing of the lasting effects of CAM could be explored. Generalized relaxation is noted in all patients. Some report of improved sleep, circulation, reduced distressed noted throughout study.

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Study Design</th>
<th>Patient Information</th>
<th>Massage Effects</th>
<th>Pain VAS</th>
<th>Anxiety VAS</th>
<th>Limitations</th>
</tr>
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<tbody>
<tr>
<td>Serfaty, Wilkinson, Mannix, &amp; King, 2010</td>
<td>RCT Parallel group Single Blind Pilot study comparing effectivene ss of aromatherapy massage vs CBT over ten weeks</td>
<td>N= 39 AM group n=20 CBT n=19 London teaching hospital</td>
<td>Descriptive stats  - Between groups t test &amp; chi square  - Fewer individuals preferred CBT over AM  X2=7.4  p=0.025  - greater num ber of  -POMS- TMS- total mood score, 5 pt Likert scale to assess mood  -POMS depression  -POMS anxiety  -POMS fatigue  -TMS evaluated pre and post treatment at 3 months &amp; at 6 months to evaluate tx effect using</td>
<td>Pain VAS: F=24.6, P&lt;0.001 Anxiety VAS: F=10.3, P&lt;0.001</td>
<td>Level II: mod Limitations: treatment as usual can have variance between patients impacting overall TMS changes - small sample size</td>
<td>TMS decreased in both groups following therapy &amp; persisted in the AM group - Preference noted for AM and resistance and anxiety w/ initiation of CBT</td>
</tr>
</tbody>
</table>
examine the clinical effectiveness of aromatherapy massage vs cognitive behavior therapy for emotional distress in patients in cancer/palliative care

| AM sessions provided compared to CBT t=2.03 p=0.05 SD reported for each intervention at baseline, 3 mo., & 6 mo. | -POMS-confusion activity -Psyclops 5 pt Likert scale to assess level of distress -EuroQol-health related quality of life measures |
| **Ben-Ayre, Frenkel, & Hermoni, 2006, An approach to teaching primary care physicians how to integrate complementary medicine in their daily practices: A pilot study** |
| Pilot Study Small study group each developed integrative treatment program with CAM modalities N=12 family practice residents and specialists 12 weekly meeting from 2002-2003 | -Mean CAM score assessment for treatment programs pre and post -Two year follow up evaluation of CSQ -Appropriate ness and quality of treatment plans |
| -Descriptive statistics -Mean values -Demographi c analysis -Qualitative analysis of treatment plans | -CAM score questionna ire (CSQ), 20 item scale |
| Strengths: Highlights importance of CAM modality AM vs traditional tx of CBT for mood regulation and QOL improvement -No harm noted in study | Level II: Mod No harm noted Strengths: yielded consistent results from each provider -Expanded provider comfort -First study in this area of provider application and increased CAM integration education |

Limitations: -Lacked any randomization -Small sample size -CSQ not verified as reliable prior to use -More qualitative approach | -Enhanced provider’s ability to provide educated advice to patients about CAM integration two years post intervention -MD’s able to formulate integrative treatment plans w/ high quality, cost benefit analysis, and patient safety in mind -Takes into consideration patient preferences for CAM integration -Multiple resources are available to guide treatment |

<table>
<thead>
<tr>
<th>RCT</th>
<th>6 EMG sessions pretest posttest design</th>
<th>N= 24 Taiwan inpatient palliative care unit w/ individuals who had end stage cancer with chronic pain &gt;1 wk with pharmacological therapy in place</th>
<th>Exp group n=12 Control n=12</th>
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<tbody>
<tr>
<td></td>
<td>- Mann Whitney U test -Effects of EMG biofeedback on pain and frontalis EMG changes -Spearmann rank correlation for relation between level of pain and muscle tension -ANOVA to eval effects of biofeedback of muscle relaxation</td>
<td>- Brief Symptom Rating scale (BSRS-5) -Karanofsky Performance Status Scale (KPS) -Brief Pain Inventory (BPI)</td>
<td>Level II: Mod No harm noted</td>
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<tr>
<td></td>
<td>- Psychologic al morbidity -Activity and care requirement s -Pain intensity</td>
<td>-Brief Pain Inventory (BPI)</td>
<td>Strengths: -Implements non invasive teaching methods and timed interval testing to eval pain control and quality of life measures with biofeedback application</td>
</tr>
</tbody>
</table>

**Limitations:**
- Small sample size
- No blinding
- Conventional treatment in control group may vary
- No significant changes occurred between control and experimental group for BSRS-5 and KPS
- Post test pain lowered in EXP group p = 0.011 with an average of 2.29 pt reduction in pain ratings
- Pain over time was much better controlled in the exp group F=12.69 and F=22.8
- Post test changes in EMG support decreased pain and increased relaxation
- With training in relaxation breathing and biofeedback significant changes in pain occur from baseline

plan development and CAM integration -Increased comfort with CAM discussion with patients. **Application:** Increased provider awareness and education regarding CAM enables enhanced communication and CAM application to daily practice.
Application: EMG biofeedback training in conjunction with conventional treatment has the potential to greatly increase pain control and improve quality of life in patients with advanced cancer or possibly other end of life diseases.