AURICULAR ACUPRESSURE AS AN ADJUNCT TREATMENT IN CANCER PATIENTS WITH PAIN: A PILOT STUDY

by

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ABSTRACT OF THE DISSERTATION

Auricular Acupressure as an Adjunct Treatment in Cancer Patients with Pain:

A Pilot Study

By EUNHEA YOU

Dissertation Director:

Dr. William L. Holzemer, RN, FAAN

Approximately 50% of cancer patients experience pain even when they take standard pain medications. These pain medications have many side effects, like headache, vomiting, and addiction. Complementary or alternative medicine have become increasingly popular in the US. Complementary or alternative medicine therapies are defined as replacing of or combining with primary care. Complementary or alternative medicine therapies such as auricular acupressure (AA) may decrease medical costs by reducing doctor's visit and usage of pain medication. The ear acupoints may be stimulated by pressure from fingers, hands, or automatically by the seeds themselves. The basic theory behind AA is that the outer ear, brain, and every part of body are connected by nerve system. When a patient stimulates auricular acupoints, the body produces some opioid substances and hormones or increases anti-inflammatory reaction. Auricular acupressure intervention may empower cancer patients to increase their pain self- management because they need to self-administer AA at their home. Cancer patients may well self-administer AA therapy if they get supported by healthcare

providers. There are few studies that have assessed the effect of AA on cancer pain. The purpose of this study is to evaluate the feasibility and effect of AA intervention on cancer patients experiencing pain. One group repeated measure and five visits in time to evaluate retention, adherence, and completion of AA therapy and to assess alleviating cancer pain by an AA intervention. This study was done at Rutgers University and participants' home. The participants were withdrawn at 33% in the study, adhered to this AA intervention at 99.4% and completed the AA intervention at 100%. The pain severity, pain interference, and the neuropathic pain showed a statistically significant decrease throughout the 4-week AA intervention. As pain severity and pain interference improved in this study, body pain and physical component in quality of life had also improved during the AA intervention period. However, the depression score did not show a statistically significant improvement in this study. Further research with AA therapy with bigger sample size and robust research design is required to build on the evidence on the feasibility and the effect of AA intervention.

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I must thank to all who help me to complete my thesis with all my heart and acknowledge their dedication and sacrifice. First and foremost, I thank God for giving me an opportunity to have a higher education and learn to be perseverant in difficult situations and learn to share knowledge and information with others. Secondly, I thank my advisor and committee members for my theses. To Dr. William L. Holzemer, my thesis advisor and mentor, who encouraged me to focus on my research and research progress, I am lucky to have him as an advisor and I cannot thank you enough all that he has done for me. I thank Dr. Zha Peijia whose opinion I respected as an expert statistician. I thank Dr. Judith Barberio for her practical suggestions and expertise of recruitment for my thesis. Third, I thank my husband Patrick, my best friend, for helping out at home, encouraging me, and praying together to finish my thesis during PhD program. I also thank prayers from my parents, my sisters, and my brother whenever I have requested. Fourth, Dissertation Fellowship Grant by Graduate School at Rutgers University supported financially to pay participants and buying all equipment. Thus, I was able to finish my thesis without extra work for myself for my thesis. Last, but not the least, I would like to thank all my participants for my thesis who made this research completed. They encouraged how important this study was and how they thank me to participate in this study. To them, I am forever thankful for them to finish this research.

This research is dedicated to my husband, my family and to all my research team including my committee members, participants who participated in this study.

Hopefully, this research may dedicate to healthcare system and healthcare policy to take better for cancer patients.

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Chapter I

The Problem

Discussion of the Problem

A cancer patient is a person who is invaded by cancer cells in the human body, gets treated with cancer treatments such as chemotherapy and radiotherapy, and very often dies with cancer. There are more than 15.5 million cancer patients in the US in 2015 (National Cancer Institute, 2018). The number will continue to grow to around 20 million by 2020 due to early diagnosis and medical and technology advancement (National Cancer Institute, 2018). Nearly half of cancer patients in the US have reported experiencing pain due to disease, cancer treatments (Mayo Clinic, 2017). Moreover, its prevalence among cancer patients who are receiving cancer treatments such as chemotherapy is around 90% of cancer patients with pain (Glare et al., 2014). About 40% of cancer pain is neuropathic in nature (Loomba, Kaveeshvar, Upadhyay, & Sibai, 2015). Neuropathic pain is defined as somatic pain resulting from damage of central or peripheral nervous system due to a disease or a lesion (Boland, Mulvey, & Bennett, 2015). Although analgesics are the most common treatment for cancer patients with pain, narcotic analgesics in particular have many undesirable side effects, including addiction (National Cancer Institute, 2018). This un-abating cancer pain and side effects of cancer pain management have led to decreased patient's daily physical function, well-being, quality of life, and increased financial, mental, and physical burden for family, healthcare providers, and burdens healthcare systems (Koller, Miaskowski, De Geest, Opitz, & Spichiger, 2012). As a result, many cancer patients are no longer satisfied with traditional drug managements of their pain (American Cancer Society, 2017). Thus, many patients

who experience pain seek non-pharmacologic interventions to manage their pain, including forms of complementary or alternative medicine (CAM) (Yeh et al., 2014). Those CAM therapies have been popular for cancer patients with pain since their introduction in 1800s. Complementary or alternative medicine, has mainly identified seven modalities in the USA, such as acupuncture/acupressure, acupressure, massage, yoga, hypnosis, relaxation/progressive muscle relaxation and guided imagery, biofeedback (Eaton, Brant, Mcleod, & Yeh, 2017). According to a 2012 government survey, 60% of cancer patients used CAM therapies such as auricular acupressure (AA), for pain management (National Institutes of Health, 2016).

Auricular acupressure is a modality of CAM therapy used to treat and control pain as an adjunctive therapy (Mehta, Dhapte, Kadam, & Dhapte, 2016). Auricular acupressure uses seeds which vaccaria plant, metal, or magnet, approximately 2mm in size, that are covered by a piece of tape. The ear acupoints may be stimulated by pressure with fingers, hands, or automatically by the seeds (stimulators) themselves.

The auricular acupoints was originally utilized in China more than 2,000 years ago (You, Kim, Harris, & D'Alonzo, 2018). In Traditional Chinese Medicine theory, Qi is the energy flow for blood circulation and physiology action and process in the body (Rerksuppaphol, 2012). Auricular acupressure is one of modalities to recover and balance Qi flow among patients with various types of diseases (Yeh et al., 2014). Maps of auricular acupoints have been approved by the World Health Organization (WHO) (World Health Organization, 2017). These ear-zone maps have been validated by functional magnetic resonance imaging (fMRI) (Rabischong & Terral, 2014; Romoli et al., 2014). Recommendations for AA have been supported by the National

Comprehensive Cancer Network guidelines, the World Health Organization (WHO), American Pain Society, the National Institutes of Health (NIH), Centers for Disease Control and Prevention, and International Association for the Study of Pain (IASP), the European Society for Medical Oncology, the Southeast Asian Pain Societies, and Canadian Cancer Society.

There are many advantages to using AA. First, AA may reduce levels of pain and pain medication. From a physiological perspective, AA stimulates nerve systems from each ear linked bi-directionally to both the specific parts of the body and the brain to regulate pain (Nogier, 2011). These processes balance opioid peptides (endorphins, enkephalins, morphine, and dynorphin), neurotransmitters (serotonin, norepinephrine, and g-aminobutyric acid), and regulate cytokines in the body (Molina, 2013). Second, AA is safely self-administered by patients after AA training (Yeh et al., 2014). Not all CAM therapies can be self-administered. For instance, acupuncture therapy is required by an acupuncturist or specialist during the entire intervention. However, acupressure therapy is only required by an acupuncturist or specialist at the beginning of an intervention and it is possible to be administered by the patient during the rest of the intervention. Third, AA thearpy may decrease medical costs by reducing visits to physicians and pain treatments (You et al., 2018). Fourth, AA is a non-invasive method, so persons who do not want to use acupuncture with needles can use AA for their pain management (Singh & Chaturvedi, 2015). Thus, AA is less invasive than acupuncture and results in lower chance of infection to a patient. Fifth, patients who use AA experience less interruption in their work or activities due to self-administration (McDonough et al., 2008).

Randomized controlled trials evaluating the effectiveness of AA on pain has been conducted on many kinds of pain, including lower back pain (Yeh, Chien, Liang, & Glick, 2015; Yeh et al., 2013; Yeh, Morone, et al., 2014; Lin et al., 2015; Suen, Wong, Chung, & Yip, 2007), dysmenorrhea (Wang, Hsu, Chien, Kao, & Liu, 2009; Cha & Sok, 2016; Yeh, Hung, Chen, & Wang, 2013), post-operative knee pain (Chang et al., 2012; He, Tong, Li, Jing, & Yao, 2013), post-operative back pain (Chung, Tsou, Chen, Lin, & Yeh, 2014; Yeh, Tsou, Lee, Hsing-Hsia, & Chung, 2010), hip fracture (Barker et al., 2006), acute post-partum perineal pain (Kwan & Li, 2014), and general pain (Rodriguez-Mansilla et al., 2014). Auricular acupressure has been also evaluated for anxiety (Michalek-Sauberer, Gusenleitner, Gleiss, Tepper, & Deusch, 2012), substance abuse (Chen, Berger, Gandhi, Weintraub, & Lejuez, 2013), and obesity (Hsieh, 2010).

One or two decade(s) ago, oncologists had focused on only cancer treatments or acute care related to cancer. This old cancer practice has been changed so that cancer cares should be considered as continuing or long-term cares. Self-management (SM) may play a crucial role in care to control cancer pain since the pain is chronic and cancer patients deal on a more time daily basis (Koller et al., 2012). In order to better self-manage by cancer patients with pain, cancer patients also need a good support by healthcare providers especially. One of the best ways is to improve patient's SM is for healthcare providers to choose self-care interventions for their patients.

There have been many different non-pharmacologic SM interventions available for cancer pain such as CAM therapies and psychoeducational programs (Eaton, Brant, Mcleod, & Yeh, 2017). Most CAM intervention studies among cancer patients have shown within 3 years. On the other hand, the number of educational and/or counseling

intervention studies have decreased since 2013. A systematic review by Eaton et al. (2017) reported that even though psychoeducational interventions tended to decrease cancer pain, they have a short effect and mixed results. The authors said that the main goal of educational or/and counseling intervention is not intended to produce behavior changes. Eaton et al. (2017) emphasized that promoting SM is important in cancer pain management. Interventions are specifically related to decrease cancer pain and increase SM are necessary (Eaton, Brant, Mcleod, & Yeh, 2017).

Auricular acupressure has shown to improve in decreasing pain severity, analgesic consumption, and adverse effects of analgesics. Most of studies also measured physical function, side effect of AA, AA self-efficacy, and satisfaction of AA (Yeh et al., 2015; Yeh, Chien, Lin, Bovbjerg, & Van Londen, 2016). A recently published systematic review by You et al. (2018) reported that 12 auricular therapies decreased pain intensity and the use of pain medications for various types of pain (acute and chronic pain). There are few AA studies among cancer patients with pain compared to other intervention studies (Yeh, Chien, Chiang, Ren, & Suen, 2015; Yeh et al., 2015; Yeh, Chien, Lin, Bovbjerg, & Van Londen, 2016). However, the small number of AA intervention studies in cancer pain are required more to explore the feasibility of AA research protocol regards of retention, adherence, and completion of AA intervention in cancer patient. Even though few studies with AA therapy in cancer pain concluded that AA reduced levels of pain, we need to explore the potential AA analgesic effects for cancer pain.

Study Purpose and Research Question (Problem Statement)

The purpose of this study was to evaluate the feasibility and potential analgesic

effect of an auricular acupressure (AA) intervention on cancer patients experiencing pain. This study was also to evaluate the change of quality of life and depression while the cancer patients conducted AA. Additionally, survey of side effects and satisfaction on AA intervention of this study, and degree of self-confidence on self-administering AA intervention at the end of the study, participant's opinion for recommendation of AA therapy to their friends for improving cancer pain, and any suggestions of future AA intervention study were obtained by participants.

Research Questions

Question 1: To examine attrition, adherence, and completion rates of 4 week- AA therapy in cancer patient with pain.

Question 2: To assess whether AA therapy changes over time potential analgesic pain symptoms, quality of life, and depression in cancer patients.

Definition of Terms

Cancer. Cancer is defined as abnormal and DNA changed cell growth in countless number and attack normal cells in the human body (National Cancer Institute, 2018).

Pain. Pain is defined as an unpleasant and subjective feeling and experience related with nerve and sensory injury, and somatic cause (Haugen, Hjermstad, Hagen, Caraceni, & Kaasa, 2010). Since McCaffery (1968) defined pain as whatever people who experience pain express about pain, the definition of pain has not been changed (Haugen et al., 2010). Most of pain's definition and assessment stresses a person's subjective pain experience. There are so many instruments to measure subjective pain, but no objective

pain tools. In addition, the pain mechanism is not clearly discovered.

Pain can be divided into several definitions depending on duration (chronic vs acute), injury location (sensory, nerve, somatic pain etc.), and transition (transduction, perception, transmission, and modulation) (Garland, 2012). The pain definitions are important for people with pain to enhance pain assessment, management, and control.

Cancer pain. Cancer pain can be caused by tumor itself, infiltration of tumor, progress of cancer (inflammatory or infection), treatments (surgeries, chemotherapy etc.) (National Cancer Institute, 2018). Cancer pain is very complicated and changeable due to cancer related progress and treatment. Not all cancer patients have pain; however, about half of cancer patients experience pain. The severity of cancer pain can be from very mild to life-threatening.

Neuropathic Pain in Cancer Patients. Neuropathic pain (NP) is defined as somatic pain resulting from damage of the central or peripheral nerve system due to a disease or a lesion (Boland, Mulvey, & Bennett, 2015). Neuropathic pain in cancer patients can be caused by cancer itself (because tumors can compress nerves) or by cancer treatments such as surgeries, chemotherapies, radiotherapies and immunotherapies (American Cancer Society, 2017). Neuropathic pain is the most common kind of pain in cancer patients. Neuropathic pain also tends not to respond well to drug therapy. The best treatment of NP is reversing the cause of nerve damage.

Self-Management. Self-management is defined as knowledge, ability, and confidence of patients with any chronic disease or condition to manage their symptoms, treatments, and lifestyle changes in daily life (Improving Chronic Illness Care, 2018).

Self-Management Support. Self-management support means that a health disciplinary

team supports and engages patients with chronic conditions in SM. Self-management support is defined as empowering patients with chronic disease to manage their conditions and daily health decisions to achieve their health goals (Improving Chronic Illness Care, 2018).

Auricular Acupressure. Auricular acupressure is a type of acupressure therapy that is used on the ear. Auricular acupressure uses the same acupoints as acupuncture, but is performed without needle insertion (Mehta et al., 2016).

Delimitations (Sample Inclusion/Exclusion)

The inclusion and exclusion criteria of study participants are:

Inclusion criteria:

1. Are men and women
2. Are greater than 21 years of age.
3. Had been diagnosed with cancer.
4. Had pain by cancer treatment (chemotherapy, radiation, surgeries or immunotherapy etc.) and cancer itself.
5. No current major depression and anxiety treatment.
6. Had confirmed pain intensity of 3 or higher on a 11-point pain scale by a healthcare provider.
7. Able to competently conduct AA therapy and give consent.
8. Able to speak, read, and understand the English language. Rationale: study procedures will be conducted in English.

Exclusion Criteria:

1. Evidence of metastasis in cancer.
2. Inability/unwillingness to undergo questionnaire completion or AA treatment.
3. Medically being treated for major depression and anxiety.
4. Having received any ear acupressure or acupuncture 3 months prior to entry into this study.

Significance

The direct medical costs for cancer in the US in 2014 was $87.7 billion (7% of total health care costs) (American Cancer Society, 2017). Thirty to eighty five percent of cancer patients experience pain; 66% of advanced cancer patients, around 55% of cancer patients with treatment, and 30% of cancer patients with complete cancer treatments suffer pain (Yeh, Suen, Park, Londen, & Bovbjerg, 2017). Cancer pain is caused by the tumor itself, cancer progress, and treatments (surgeries and chemotherapy). About 40% of cancer pain is neuropathic in nature (Loomba, Kaveeshvar, Upadhyay, & Sibai, 2015). Although analgesic use is the most common treatment for cancer patients with pain, narcotic analgesics in particular have many undesirable side effects, including addiction (National Cancer Institute, 2018). As a result, many cancer patients are no longer satisfied with traditional drug managements of their pain (American Cancer Society, 2017). According to a 2012 government survey, 60% of cancer patients spend out-of-pocket more than $2.1 billion dollars each year on CAM therapies such as AA, for pain management (National Institutes of Health, 2016).

Auricular acupressure stimulates afferent nerve systems from each ear connected bi-directionally to both the specific parts of the body and hypothalamus in the brain to

regulate pain. This process releases opioid peptides and catecholamine neurotransmitters such as dopamine and β-endorphin and regulates cytokines.

Auricular acupressure may reduce cancer pain levels and increase physical function, self-control ability, and SM (Yeh et al., 2017). Auricular acupressure is easily taught to patients by healthcare providers and acupuncturists and therefore may be a beneficial SM intervention for pain relief in the cancer population. Nurses are the most available and accessible professional personnel among healthcare providers and as such have a pivotal role in educating cancer patients in SM interventions such as AA. However, some research studies have reported that more than half of patients did not tell their healthcare providers that they were using CAM, due to healthcare providers' lack of knowledge and training and apparent interest in CAM (Wahner-Roedler et al., 2014; Winslow & Shapiro, 2015).

To date, few studies have assessed the effect of AA on cancer pain. This study proposes a pre-posttest evaluation study design to exam feasibility and the potential analgesic effects of AA on cancer pain. The potential findings in this study will inform and guide the future follow-ups in a larger study (larger sample size and longer intervention period) with control group so we can provide a more robust effect of AA with treatment strategies such as dose and specific acupoint. Eventually, future research could lead to guidelines for using acupressure in research and practice for cancer patients with pain.

Chapter II

Theoretical Framework and Review of the Literature

A literature review was extensively presented made up of 4 parts in this chapter. The first part was introducing the main independent and dependent variables for the thesis and theory based on the thesis which is Chronic Care Model (CCM). The independent variable is auricular acupressure (AA) and the dependent variables are cancer pain. The second part was presented as one of my manuscripts which was already published in the Journal of Pain Management in Nursing in 2019. The manuscript was based on my thesis regarding the effect of AA therapy in pain. The third part was also presented as one of my manuscripts which was accepted in Holistic Nursing Practice in 2020. The manuscript was also based on my thesis regarding self-management (SM) in cancer patients. The above two journal associations did not allow to attach figures and tables. Thus, the readers should go to the original manuscripts. The fourth part was presented as the linkage between my manuscripts and the theoretical frame.

Part 1

Cancer Pain

Cancer pain can be divided into 4 different pains; neuropathic pain, sensory pain, somatic pain, and psychological pain (Ilhan, Chee, Hush, & Moloney, 2017). Cancer pain is a kind of physical stress in the line with the model of allostatic load. When early cancer pain activates the HPA axis, the paraventricular nucleus of the hypothalamus is activated to release corticotropin-releasing hormone (CRH). Corticotropin-releasing hormone arouses hypothalamic proopiomelanocortin (POMC) and POMC, which cleaves into

small proteins which are beta-endorphin, alpha-melanocyte stimulating hormone (MSH), and adrenocorticotropic hormone (ACTH) in the anterior pituitary (Przewlocki & Przewlocka, 2005). Additionally, the immune system also manufactures small amount of β-endorphin. Adrenocorticotropic hormone stimulates the adrenal gland to release glucocorticoids. Glucocorticoids impact the metabolism, immune function, hemodynamic function, and central nerve system (Przewlocki & Przewlocka, 2005). This stress process is controlled by negative effects at all systems of central nervous system.

B-endorphins are called morphine-like, as they are endogenous opioid neuropeptides in humans and animals (Stephan & Parsa, 2016). There are three opioid receptors: δ-opioid receptors, κ-opioid receptors, and μ-opioid receptors (Przewlocki & Przewlocka, 2005). The three opioid receptors have very similar structure with G protein coupling receptors. Mu (μ)-opioid receptors are morphine-like receptors (Przewlocki & Przewlocka, 2005). Endogenous opioid peptides do not bind to a specific opioid receptor, but certain types of opioid peptides have a stronger affinity for specific opioid receptors. For example, B-endorpine has a stronger affinity with μ-opioid receptors (Przewlocki & Przewlocka, 2005). This binding occurs on both pre-synaptic and post- synaptic central and peripheral nerve terminals. This binding inhibits the release of gamma aminobutyric acid (GABA) and produces more dopamine (Stephan & Parsa, 2016). NCP may occur due to the impairment of μ-opioid receptor-G protein coupling (Przewlocki & Przewlocka, 2005).

If cancer pain is continued or delayed or prolonged, it promotes maladaptive stress response (Li & Hu, 2016). Glucocorticoid and β-endorphin no longer relieve pain symptoms and signs. The effects of delaying and chronic pain change the function of

HPA axis, and damage negative feedback system, but the relationship is not fully understood. Some studies have explained that if an individual has chronic pain, the level of glucocorticoids is decreased (Li & Hu, 2016). However, other studies on this matter have shown with opposite results. For example, some chronic pains such as fibromyalgia or chronic back pain have presented with more activate the function of HPA axis and over increase glucocorticoids. Recent studies reported that early stage of cancer pain can increase the function of HPA axis and increase level of glucocorticoids (Li & Hu, 2016; Slade et al., 2011). However, the later stage of cancer pain can decrease the function of HPA axis and decrease level of glucocorticoids. Thus, we need additional studies of these conflicting results on the function of HPA axis and the level of glucocorticoids in chronic pain.

Acute cancer pain activates the hypothalamic-pituitary-adrenal (HPA) axis and interacts with immune systems (Li & Hu, 2016). The dysregulation of immune systems and HPA axis pathways is correlated with developing chronic cancer pain (Li & Hu, 2016). In the immune systems, cytokines are mediated by cell death and cell development. Neurons, microglia, and astrocytes all release cytokines. There are two kinds of cytokines, pro-inflammatory (such as IL-1α, IL-2, IL-6, and TNF-α) and anti-inflammatory (IL- 4 and IL-10) (Slade et al., 2011). Changes in pain signaling pathways have been shown to be related in abnormal levels of proinflammatory cytokines (Lin et al., 2015).

Recently scientists have proposed that monoamines, endogenous opioids, inflammatory mediators, and epigenetic mechanisms may have an impact on cancer pain as well (Li & Hu, 2016). For instance, in an animal model, after pups were chronically

received with corticosterone, rats tended to have cold allodynia (high sensitivity to pain) and heal hyperalgesia (need of high dosage of pain medication) in their later life stages. In another instance, women with incidents of sexual abuse had indicated lower pain thresholds, more pain symptoms, psychological problem, and lower cognitive response than women without an incident of sexual abuse. Lastly, patients with multiple sclerosis (a chronic disease) have reported changes in histone acetylation. However, these kinds of studies are in their infancy and are needed to provide more evidence for the future.

Origin and Development of Auricular Acupressure

The use of auricular acupoints originated in China more than 2,000 years ago in Huangdi NEi Jing (Chinese Cannon of Medicine) (Lin & Hsu, 2014). In Traditional Chinese Medicine theory, Qi is the energy flow or blood circulation of the body in living creatures (Rerksuppaphol, 2012). In 1991, Paul Nogier who was a French neurosurgeon theorized that the outer ear corresponds to an inverted fetus when they are in the mothers' womb base on traditional Chinese medicine (Nogier, 2011). Auricular acupressure (AA) uses to treat and manage pain, addicton, and stroke, and it is usually used as an adjunctive therapy (Mehta, Dhapte, Kadam, & Dhapte, 2016). Auricular acupoints correspond to body systems and organs. A detailed map of auricular acupoints has been developed by the World Health Organization (WHO) (World Health Organization, 2017).

Theoretical Frame: The Chronic Care Model (CCM)/Self-Management Support

The research team at the MacColl Center for Health Care Innovation at Group Health Research Institute developed the CCM in the mid-1990s via an extensive literature

collection (Improving Chronic Illness Care, 2018). In 2003, the CCM version was finalized from national experts, including patient safety, cultural competency, care coordination, community policies, and case management (Improving Chronic Illness Care, 2018). The CCM is extensively used and has been studied in many different patients with chronic diseases such as diabetes (Baptista et al., 2016; Vargas et al., 2007), asthma (Greene, Rogers, & Yedidia, 2007; Improving Chronic Illness Care, 2018) cardiovascular disease (Vargas et al., 2007; Improving Chronic Illness Care, 2018), and depression (Garrison, Angstman, O'Connor, Williams, & Lineberry, 2016), but it is used in few studies on cancer patients (Slev et al., 2017). The CCM has included concepts of the community, health system, SM support, delivery management support, delivery system design, and clinical information system (Figure 1). This thesis focused on the concept of the SM support.

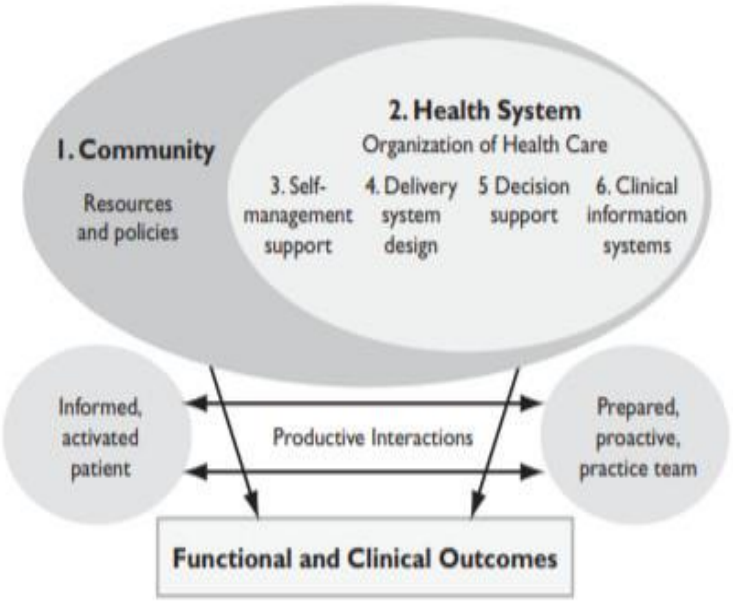

Figure 1. Improving Chronic Illness Care. (2018). The Chronic Care Model

Self-Management Support

Self-management support means that a health disciplinary team supports and engages patients with chronic conditions in SM. Self-management support is defined as empowering patients with chronic disease to manage their conditions and daily health decisions to achieve their health goals (Improving Chronic Illness Care, 2018). For instance, when a multi-disciplinary team implements self-management interventions such as AA therapy to patients, the team needs to then assess patients' confidence in abilities, knowledges, and skills. Evidence suggests that health education alone is insufficient to encourage the patient to engage in health promoting behaviors (Bodenheimer, Wagner, & Grumbach, 2002; Bodenheimer, Lorig, Holman, & Grumbach, 2002; Bodenheimer, Wagner, & Grumbach, 2002a). In order to successfully accomplish self-management support, multidisciplinary teams and patients should actively interact. Additionally, everyone in the team including patients must understand that patients are in charge for their long-term care. Multidisciplinary teams and patients are partners in achieving the patients' health goal.

The model of SM support in the CCM was originally adopted by the 5A's Behavior Change Model (2002). The process of SM support includes ongoing assessment, advice, agreement, assistance, and arrangement in the primary care setting (Figure 2). The main focus in the frame of process of self-management support is the personal action plan. The personal action plan is for patients to make their own health goals and follow-up plans.

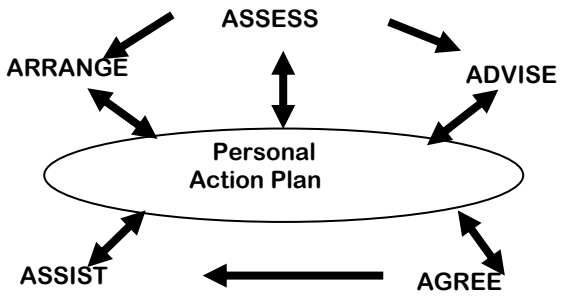

Figure 2. Improving Chronic Illness Care. (2018). The Proces of Self-Management Support

Assessment

In the past, healthcare providers evaluated patients on their knowledge and understanding of their unique chronic diseases when they assessed their patients. Recent evidence has proven that it is important to assess patients' self-management, including skills, confidence, knowledge, supports, belief, barriers, and risk factors (Coleman et al., 2009). After a healthcare team assesses a patient, the team can give advice to the patient or make arrangements for follow-up as a next step. There are useful tools to assess patients for AA SM.

Advice

The stage of advice can occur any time after the assessment of patients. Advice can be given by the disciplinary team or other patients who have similar diseases or symptoms, but the advice should be based on current evidence and knowledge. A healthcare provider discusses the benefits and science behind AA and explain the application of AA intervention.

Agreement

The stage of agreement can occur any time after the assessment of patients. Patients and a healthcare provider may collaboratively finalize health pain goals and plans based on the patient's ability and confidence on AA intervention, in order to improve their pain symptoms and conditions. The goals should include measures that can be reached within 3-6 months.

Assistance

Like the stages of advice and agreement, assistance can occur any time after the assessment of patients. A healthcare provider should help patients to achieve their goals and plans by providing AA skill education, encourage patients, introducing peers who have the same health issues.

Arrangement

Like the stages of advice, agreement, and assistance, this stage can occur any time after the assessment of the patient. A multidisciplinary team can schedule follow-ups or referrals to specialists to continue support for patients and improve patients' AA.

Literature Review

Section 2- Manuscript 1 included

Manuscript Details

Manuscript number PMN_2017_117

Title Effects of Auricular Acupressure on Pain Management: A Systematic Review

Article type Review Article

Abstract

Nearly one-half of hospitalized patients experienced pain in America even though they received pain treatment. Many patients who experience pain look for better pain management with many reasons including side effect of drugs and they try to use complementary or alternative medicine (CAM) such as auricular acupressure (AA). The objective of this study was to conduct for the first time this systematic review to evaluate the effect of AA on pain management. We searched PubMed, CINAHL, Embase, and Wiley for RCTs of AA. The pain outcomes were pain severity and analgesic consumption. Fifteen randomized control trials (RCTs) were included in this analysis. Upon methodological quality being assessed, the selected studies showed medium quality, but there was a lack of high quality. We noticed that there was a need to improve blindness, data analysis, usage of the intentions to treat, pain medication control, and protocols of duration or techniques of AA. Twelve studies among 15 RCTs showed statistically significant pain outcomes of AA treatment as compared to the control groups. Despite promising and useful adjunct AA therapy, we need to be more cautious given the lack of high-quality evidence and data from the included 15 RCT studies. In future research, the physiological biomarkers for AA therapy may be significant to build scientific evidence. The implications based on this review are patient's empowerment, cost effectiveness, educational necessity of AA therapy, healthcare provider' pain management skills, research and initiative to pass a bill regarding the full health insurance coverage of AA therapy. Keywords: Auricular acupressure, Self-Symptom

Management, Pain

Taxonomy Pain Management, Systematic Review, Nursing, Pain Care, Interventional Pain Management, Pain

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Introduction

Pain has long been a major health issue, affecting not only patients' lives but also impacting their families, healthcare providers, and healthcare systems. It is estimated that pain affects more than 100 million Americans, and the total annual healthcare cost due to pain ranged in 2010 from $560 billion to $635 billion (Institution of Medicine, 2016). Nearly one-half of hospitalized patients in the US have reported experiencing pain even while they are undergoing treatment for pain (Institution of Medicine, 2016). Analgesics are the most common type of treatment for pain management.

Pain medications have many serious side effects including drowsiness, bleeding, and addiction (Institution of Medicine, 2016). Thus, many patients who experience pain seek non-pharmacologic interventions to manage their pain, including forms of complementary or alternative medicine (CAM) such as auricular acupressure (Yeh et al., 2014). According to a 2012 government survey, 91.5 million Americans (38% of Americans) spend more than $30.2 billion dollars each year out-of-pocket on CAM

therapies, including those specifically indicated for pain management (National Institutes of Health, 2016). However, most health insurance providers do not pay for the coverage of CAM treatments (Ananth, 2010).

Auricular acupressure (AA) is a type of CAM therapy used to treat and manage pain, and it is usually used as an adjunctive therapy (Mehta, Dhapte, Kadam, & Dhapte, 2016). Auricular acupressure is an acupressure therapy that is used on the ear. Auricular acupressure uses the same acupoints as acupuncture, but without needle insertion (Mehta et al., 2016). Auricular acupressure uses stimulators (seeds) made of botanical, metal, or magnetic seeds, approximately 2mm in size, which are covered by a small piece of waterproof tape. The ear acupoints may be stimulated by pressure from fingers, hands, or automatically by the seeds themselves.

There are many benefits to using AA. First and foremost, AA empowers symptom self-management because patients can be taught to safely self-administer AA (Yeh et al., 2014). This process is in line with the Theory of Symptom Self-Management (TSSM) (Hoffman, 2013). The TSSM proposes that healthcare providers can tailor or enhance interventions for patients experiencing unpleasant symptoms to produce better performance outcomes (Hoffman, 2013). Second, AA may decrease medical costs by reducing visits to physicians and the consumption of pain medications. Third, AA is a non-invasive method, so it can be used by persons who do not want to use acupuncture needles (Singh & Chaturvedi, 2015). Auricular acupressure is safer than traditional acupuncture and results in less chance of infection to the patient. Fourth, patients who use this therapy experience less interruption in their daily life activities due to the ease of AA self-administration (McDonough et al., 2008).

The use of auricular acupoints originated in China more than 2,000 years ago. In Traditional Chinese Medicine theory, Qi is the energy flow or blood circulation of the body in living creatures (Rerksuppaphol, 2012). Auricular acupressure is used to improve Qi flow among patients with various types of illnesses (Yeh et al., 2014). A detailed map of auricular acupoints has been developed by the World Health Organization (WHO) (World Health Organization, 2017). From a physiological perspective, AA is thought to work through the stimulation of nerves in the outer ear, which connect to specific areas of the brain. The nerves in the ear are also connected with specific parts of the body (Nogier, 2011). This process releases opioid peptides (endorphins, enkephalins, morphine, and dynorphin) and neurotransmitters (serotonin, norepinephrine, and g-aminobutyric acid) (Molina, 2013). This ear-zone map has been substantiated by functional magnetic resonance imaging (fMRI) (Rabischong & Terral, 2014; Romoli et al., 2014).

Research testing the effectiveness of AA has been conducted on many kinds of pain, including lower back pain (Yeh, Chien, Liang, & Glick, 2015; Yeh et al., 2013; Yeh, Morone, et al., 2014; Lin et al., 2015; Suen, Wong, Chung, & Yip, 2007), dysmenorrhea (Wang, Hsu, Chien, Kao, & Liu, 2009; Cha & Sok, 2016; Yeh, Hung, Chen, & Wang, 2013), post-operative knee pain (Chang et al., 2012; He, Tong, Li, Jing, & Yao, 2013), post-operative back pain (Chung, Tsou, Chen, Lin, & Yeh, 2014; Yeh, Tsou, Lee, Hsing-Hsia, & Chung, 2010), hip fracture (Barker et al., 2006), acute post-partum perineal pain (Kwan & Li, 2014), and general pain (Rodriguez-Mansilla et al., 2014). Auricular acupressure has been also used as a therapy for anxiety (Michalek-Sauberer, Gusenleitner, Gleiss, Tepper, & Deusch, 2012), substance abuse (Chen, Berger, Gandhi,

Weintraub, & Lejuez, 2013), and obesity (Hsieh, 2010). A recently published meta-analysis by Yeh et al. (2014) focused on pain management with a mix of auricular acupuncture (16 studies) and AA (7 studies). The 7 AA studies included two intervention studies and five randomized control trials (RCTs). To date no systematic review was discovered that addresses the effect of AA on pain management. No CAM was reported prior to 1800s. This is because home remedies were the only care methods available to many at this time (Sherman et al., 2005). This review includes only AA RCTs (n =15) from the 1800s to 2016. Thus, we have conducted the first systematic review to evaluate the effect of AA on pain management comparing the number and selection of AA acupoints, intervention period, intervention frequency, and pain outcome assessments. The pain outcomes were pain severity and analgesic consumption. The data on the efficacy of AA on pain in this systematic review can inform patients, healthcare providers, and policy makers. Eventually, AA may be used as an intervention to promote pain relief and empower patients to self-manage their pain.

Methods

We decided to conduct a systematic review instead of a meta-analysis because there is a lack of statistical power to support a true combined estimate of the effect of AA on pain management. In the 15 included studies, variability in the intervention (selections of AA acupoints and intervention periods), participants (ages and types of pain), and study design (types of comparison group) makes it difficult to combine individual data. Even if we limit the studies to those with the best criteria for a meta-analysis, in order to decrease variability, the lower-back pain studies (n = 2) would be included in the analysis; thus, a

total of five lower-back pain studies could not be included in a meta-analysis, as one study does not have enough data to calculate the effect size, and two studies were underpowered (Cohen's $d < .2$).

Data Sources and Searches

The literature search was developed and executed using PubMed (1809 to July 2016), CINAHL (EBSCO, 1981 to July 2016), Embase (Elsevier, 1947 to July 2016), Scopus (Elsevier, 1823 to July 2016), Google Scholar (1989 to July 2016), and Cochrane Central Register of Controlled Trials (Wiley, 1992 to July 2016). The search terms were 'ear acupressure,' 'auricular acupressure,' 'vestibulocochlear apparatus acupressure,' 'vestibulocochlear system acupressure,' 'pain,' 'pain relief,' and 'pain symptom,' with RCTs in the methodology filters.

Inclusion and Exclusion Criteria

Inclusion criteria for published studies were the following: randomized control trials (RCTs), published in peer reviewed journals, English language, compared auricular acupressure to sham and/or standard medical care, and measured pain outcomes. Exclusion criteria were studies that were not RCTs, did not use auricular acupressure as an intervention, and had no pain outcome. The literature search was conducted independently to assess eligibility criteria by the first and the third authors. Discrepancies and disagreements regarding eligibility were resolved by discussion.

Methodological Quality Assessments

We assessed methodological quality (MQ) for the selected articles. The criteria were based on previous systematic analyses of CAM research (Boutron, Estellat, & Ravaud, 2005). The criteria were divided into 11 categories: [1] adequacy of allocation sequences between intervention group and sham and/or standard medical care group, [2] concealment of treatment allocation, [3] description of the intervention administration, [4] adequacy of AA training for patients by practitioners, [5] comparison at baseline between AA and sham and/or standard medical care groups, [6] adherence of participants, [7] blinding of participants, [8] blinding of interventionists, [9] blinding of data assessors, [10] follow-up schedule, and [11] use of intention-to-treat strategy. The scores ranged from 0 to 11. Higher scores indicate higher MQ.

Results

The two researchers located 2,314 articles using the above search terms. After correction for duplication, 1,819 articles remained. The first author screened only titles and abstracts and excluded 1,720 articles that did not meet the inclusion and exclusion criteria. Next, we reviewed 99 full-text articles and excluded another 84 articles for the following reasons: non-English language (n=26), acupuncture studies (n=26), no pain management outcomes (n=15), not a RCT (n=13), intervention was conducted on body sites other than ears (n=3), and co-intervention (n=1). A total of 15 RCT studies were included for this systematic review.

Characteristics of Included Studies

Seven countries where research was conducted were Taiwan (n=5), the United States (n=4), Hong Kong (n=2), Austria (n=1), South Korea (n=1), China (n=1), and Spain

(n=1). The sample size ranged from 19 to 256 and the median of the sample size was 85. Most individuals in this analysis were female. Type of pain consisted of lower back pain (n=5), dysmenorrhea (n=3), post-operative knee pain (n=2), post-operative lumbar-spine pain (n=2), hip fracture pain (n=1), post-partum pain (n=1), and general pain (n=1). The pain outcomes of 15 studies were evaluated by pain severity (n=15) and analgesic consumption (n=5). Other outcomes including anxiety (n=3), physical function (n=2), depression (n=1), quality of life (n=1), and blood samples (n=1) were also evaluated. There have been 10 instruments for pain measurement used in the 15 studies: Visual Analogue Scale (VAS) (n=7), Short-Form Brief Pain Inventory (SF-BPI) (n=4), Short-Form McGill Pain Questionnaire (SF-MPQ) (n=3), Menstrual /Distress Questionnaire (MDQ) (n=3), Pain and Catastrophizing Scale (n=2), Verbal Rating Scale (VRS) (n=1), American Pain Society Patient Outcome Questionnaire (APSPOQ) (n=1), Medication Quantification Score Version III (MQR III) (n=1), Verbal Descriptive Pain Scale (n=1), and Doloplus Scale (n=1). Seven studies (47%) used more than one pain measurement tool.

The range of the AA intervention period varied from a single instance to 3 months. In 33% of the studies (n=5) participant's follow-up ranged from 2 weeks to 2 months after completing AA treatment. Most treatment sessions lasted 3 minutes per acupoint, at least 3-4 times a day (n=9).

The most common auricular acupoints (n=13) were located on the superior and central to the apex of the triangular fossa (also known as Shenmen acupoint), at auricular acupoints (n=10) that correspond to the location of the individual's pain, on the inside aspect of the antitragus (n=7; also called Nervous Subcortex), and at the lower border of the inferior

antihelix crus (n=4; also known as Kidney acupoint). Most of the studies (n=13) used only one group, those with a comparison group included either a sham group (n=12) or a standard pain treatment group (n=1). Pressure techniques (n=10) included hand- or finger-point pressure to acupoints, and transcutaneous acupoint electric stimulation (n=1), which was added to increase stimulation on the ears.

Nine studies used the sham acupoints from non-AA acupoints for the sham group. Three studies utilized the same ear acupoints in both the AA and sham groups, but for the sham acupoints only a tape without a seed was attached. Ten studies, including a sham group, chose the same number of ears acupoints as the AA group. An electrical point finder in the three RCTs was used to locate the points. In the seven RCTs, both ears were used for the AA intervention and one ear was used for five trials. However, three trials did not specify whether one or two ears were used. Only 21% of studies (n=3) were implemented, as noted in a daily diary; the diary recorded AA self-treatment, including the frequency and duration of each subject's AA practice and any side effects. Most of the studies reported more than a 75% retention rate among their participants (n=13), except two studies which reported a 62% and 68% retention rate, respectively.

Methodological Quality (MQ) assessments

In order to evaluate MQ assessments, the five authors were contacted to verify proper information because the necessary data were not provided in the articles. Of the 15 RCTs, nine studies had MQ assessments that scored greater than 8 out of 11, with a mean score of 7.7. Five studies attained a score between 6 and 7. Only one study had a score less than 5. The general MQ in the 15 RTCs was ranked as medium, and only four studies were

ranked as high. There were four areas of methodological weakness identified among the studies. First, care providers (practitioners) for the participants (n=14) were not adequately blinded as to group assignment: the auricular acupoints were visible whether or not participants belonged to the AA group. However, in one study the interventionists who were not acupuncturists were blinded because they were not informed whether the ear acupoints were AA or sham acupoints. Second, an intention to treat (ITT) analysis for missing data was performed in only four studies. Third, outcome assessors were not adequately blinded in 8 of the 15 studies reported. Lastly, there were not enough details provided to adequately address issues such as generated allocation sequence, concealment of group allocation, administration of the intervention, and credentials and experience of care providers.

The Evaluation of Pain Outcomes of AA

Most studies reported significant reduction in pain intensity. Twelve studies reported statistically significant improvement in the pain outcomes (pain severity and/or analgesic consumption) of AA treatment as compared to the sham or standard care groups. Even though three studies did not report statistically significant results, a positive pain relief trend was found in the AA group more than the comparison group in Yeh et al.'s (2010) and Rodriguez-Mansilla et al.'s (2014) studies. In Kwan and Li's (2014) study the use of pain medication was found to be a confounding factor because it was used for not only postpartum pain but also breast engorgement pain.

Lower Back Pain

Five RCTs utilized an AA treatment for lower back pain. Across the studies, pain severity

in the true AA group was significantly lower than the sham AA or control group. However, there were differences across the studies, including the number (3 to 7 points) and selection of AA acupoints, intervention period (3 to 4 weeks), intervention frequency (no record to at least 3 times a day), daily diary use (n=2), and pain outcome tools (SF-BPI, SF-MPQ, and blood biomarkers). These differences make it hard to compare results of the five studies. For instance, Lin et al.'s (2015) study compared blood bio-markers with the SF-BPI pain assessment. Serum blood samples showed a decrease in pro-inflammatory cytokines (IL-1β, IL-2, IL-6) and calcitonin gene-related peptide (CGRP) and an increase in anti-inflammatory (IL-4) after a 4-week treatment as pain levels decreased. In Suen et al.'s (2007) study, the sham acupoints were chosen by the same acupoints and seeds were also attached with the AA group, but there was no application of massage. Yeh et al. (2013) and Yeh et al. (2015) used a daily diary which was filled out by each participant to record his or her AA practices, analgesic use, and pain intensity for pain measurement. Yeh et al. (2014) chose AA acupoints based on a Chinese Traditional Medicine Theory for individual pain sites, unlike the other studies where the AA points were taken from previous studies.

Dysmenorrhea

Three studies were conducted to test the effectiveness of AA therapy on alleviating dysmenorrhea and menstrual distress in young women. Dysmenorrhea occurs when the uterus experiences an increase in uncontrolled contractions (Yeh et al., 2013). Pain severity in the AA group was significantly lower than the sham AA or control group across the studies. The number of AA acupoints (3 to 6 points), selection of AA acupoints, period of AA treatment (2 to 20 days), intervention frequency (no massage to

15 times), daily diary use (n=1), analgesic control, and pain outcome tools (VAS or MDQ) varied among the studies. These differences make it difficult to compare the three studies. For instance, while Cha & Sok's (2016) and Yeh et al.'s (2013) studies chose AA acupoints from previous studies, Wang et al.'s (2009) study chose AA acupoints based on consultation with 3 physicians and experts. Only Wang et al. (2009) used a daily diary, which was filled out by each participant to record the time of application of acupressure and any possible side-effects.

Post-Operative Knee Pain

Two RCTs using AA therapy for post-operative knee pain are described. Across the studies, pain severity in the true AA group was significantly lower than the sham AA or control group. The number (2 and 4 points) and selection of AA acupoints, intervention period (3 and 7 days), and intervention frequency (3 and 4 times a day) in both studies were different. For example, in Chang et al.'s (2012) study, the sham acupoints were chosen by the same ear acupoints with the AA group, but were only attached tape without a seed, and there was no application of massage. On the other hand, in He et al.'s (2013) study, the four sham acupoints were chosen due to non-meridian points. However, both studies used analgesic patient-controlled analgesia (PCAs) for all participants as a traditional postoperative pain management and PCA medication records were reviewed at the end intervention.

Post-Operative Back Pain

Chung et al. (2014) and Yeh et al. (2010) tested the effect of an AA therapy on post-operative lumbar surgery patients, and the studies yielded conflicting results. The comparison group (use of transcutaneous electric acupoint stimulation, TEAS), number

(5 and 6 acupoints) and selection of AA acupoints, and intervention frequency (10 and 12 times) differed between studies. For example, Chung et al.'s (2014) study examined the effect of AA combined with two uses of TEAS in order to increase impulse on the ear acupoints. However, the period of AA intervention and the usage of analgesic PCAs for all participants as traditional pain management postoperatively in both studies were the same.

Hip Pain, Acute Postpartum Pain, and General Pain

Barker et al. (2006), Kwan & Li (2014), and Rodriguez-Mansilla et al. (2014) conducted an AA therapy for relieving hip pain, acute postpartum pain, and general pain, respectively. AA was statistically effective in relieving hip pain ($p < .01$), but not on acute postpartum ($p > .05$) and general pain ($p > .05$).

Discussion

This systematic review was conducted to evaluate the effects of auricular acupressure (AA) on pain management. Importantly, our review of 15 randomized controlled trials (RCTs) that met the research criteria is the first to focus soley on the effect of AA on pain relief. This systematic review of AA as an adjunctive therapy reveals statistically significant reductions in various pain types such as back pain and dysmenorrhea, as compared to sham or standard care. However, uncertainty remains regarding the strength of the evidence, due to the small number of studies included and lack of high quality and consistent methodologies.

The mean score of methodological quality (MQ) across the studies was 7.7. According to the MQ scoring system, a score between 7 and 8 indicates medium quality. Although the

general MQ of the 15 RTCs was medium, only four studies (36%) were ranked as high. In order to build strong evidence about the effect of AA on pain management, researchers need to improve methodological quality in conducting RCTs. Particular areas of poor methodology included the lack of blinding of interventionists and data assessors, lack of usage of intention to treat methodology, lack of discussion related to details on generation of allocation sequence, lack of concealment of group allocation, and poor description of care provider's credentials.

The selection of auricular acupoints is one of the crucial factors in AA treatment effects (Yu et al., 2015). The selection of AA acupoints for studies and practice has varied (Yu et al., 2015). Across the 15 studies, the selection of AA acupoints was taken from previous studies, authors' decisions, or recommendation of practitioners based on the ear zone system. The auricular acupoints, Shenmen (n=13) (He et al., 2013) and corresponding points of individual pain (n=10), were frequently chosen. Our perspective, based on our review, is that comparative studies of those various AA acupoints' selection will help us elucidate the best AA acupoint selection protocol for pain types and sites.

The use of sham (placebo) auricular acupoints could help measure the true effect of AA. Seventy-nine percent of the selected studies in this systematic review (n=12) utilized sham acupoints to compare with AA acupoints. Most the sham acupoints were outside of AA acupoints (n=9). However, we need to be cautious about the selection of sham acupoints because there have been reports that a sham acupoint may stimulate a true acupoint due to a short distance between AA and sham acupoints (Yeh, Chang, Chu, & Chen, 2009; Yeh, Chung, Chen, & Chen, 2011). Furthermore, only one study recognized that a sham ear acupoint can cause an impulse to AA ear acupoints (Yeh, Hung, et al.,

2013). Thus, this liability needs to be considered and disclosed in reporting of AA studies.

Review and monitoring of pain medications and pain medication adjuvants throughout AA studies are very important in order to eliminate confounding effects. Pain medication records were reviewed in sixty percent of the studies (n=9) at the end of interventions, and only one study monitored the use of pain medications throughout the study (Yeh, Hung, et al., 2013). Therefore, it is important to closely monitor pain medication consumption throughout a study to avoid a confounding effect.

Methods related to acupressure intervention, such as pressure application, duration of session, frequency per day, use of daily diary, and length of intervention may influence the effectiveness of the intervention (Yeh et al., 2014). In this systematic review, the duration of AA treatment for pain was from one time to 3 months. Chronic pain such as lower back pain (3 weeks to 3 months) had a longer AA treatment period than acute pain such as post-operative and hip fracture pain (one time to 7 days). Most studies (n=9) employed 3-minutes on a acupoint during per session with at least 3-4 sessions per day. Thus, there was a lack of clinical protocols on the duration of AA treatment and per session. Future studies should investigate the optimal frequency, duration of treatment, and duration per session of AA, as well as acupressure techniques. Various methods can be used to stimulate the seed, but without further studies we cannot comment on the effectiveness of one over the other. As is true with all self-management techniques, adherence to carrying out the intervention is crucial to success. The use of the patient daily diary can enhance compliance and aid in communication with the healthcare provider (Yeh et al., 2015).

The physiological biomarkers for AA therapy are necessary to build scientific evidence as to effectiveness. Only one RCT measured physiological bio-markers for pain (Lin et al., 2015), linking relief of pain to a reduction in inflammatory markers. Pro-inflammatory cytokines can induce afferent neurons and propel pain messaging to the central nervous system (Molina, 2013), so further investigations of the potential for AA to mitigate the release or action of pro-inflammatory cytokines is warranted.

There are limitations in this systematic review. First, only studies published in English were included in our review. This may have resulted in the exclusion of studies published in other languages. Additionally, negative or non-supportive studies are many times left unpublished, thus skewing our view of the true effectiveness of this intervention. Lastly, methodological variability made cross-study comparison difficult.

Conclusion

In 12 of the 15 studies we reviewed, AA therapy revealed statistically significant improvements in decreasing pain severity, analgesic consumption, and adverse effects of analgesics. As such, and based on our review, we provide preliminary evidence that AA may be a beneficial adjunctive therapy for patients with pain. However, the small number of studies and the lack of consistent rigorous methodology across the studies preclude definitive statements regarding the effectiveness of AA.

This review suggests three nursing implications. First, symptom self-management may improve patients' tolerance of pain. Second, education about AA and CAM therapies for healthcare providers may assist them in providing pain control for their patients. Lastly, additional AA research is required to build on scientific evidence. Positive subjective

patient outcomes, less analgesic use, and the lack of adverse effects associated with this modality, support the use of AA as an adjunct to patient pain self-management. Auricular acupressure education for health professionals can enhance their understanding of the usage and mechanism of action of AA as a pain management tool for patients. Healthcare providers should feel confident considering this self-management modality as an adjunct in their pain management plan. At minimum, they can communicate about AA with their patients who are interested in using it and refer patients to licensed practitioners. However, we need to continue research of the effect of AA on pain management. In order to advance the science of AA, and so we can compare results across studies, future research should include the development of standard protocols for the delivery of the intervention, identify relevant physiological biomarkers, and assure that high-quality methodologies such as RCT are used to establish evidence. It is also important that we extend the research of AA effects to other types of pain such as neuropathic pain in cancer patients because different forms of pain may respond differently to this therapy. Advancing scientific evidence about AA therapy can more effectively inform health policy and clinical practice.

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Section 3- Manuscript 2 included

Holistic Nursing Practice

Non-Traditional and Home-Based Self-Management Interventions in Cancer Patients

with Pain: A Mixed-Method Systematic Review

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Abstract: Background: One or two decades ago, oncologists had focused on only cancer treatments or acute care related to cancer. Since cancer care is considered as long-term cares, cancer patients require self-management (SM) ability or skill to manage their symptoms and daily cares. Objective: This mixed-method review is to evaluate

quantitative and qualitative studies which were conducted using non-traditional SM interventions for cancer pain based on their home. This review will also explore the process of SM in the CCM. Methods: PubMed, CINAHL, Scopus, and Wiley were used from 2011 to 2018. Results: A total of 16 quantitative studies and 2 qualitative studies were included for this review. All interventions are divided into three types which are educational and/or counseling programs, complementary and alternative medicine (CAM) therapy, and exercise. Ten of the included 16 studies were statistically significant on pain management; Three CAM studies (100%), one exercise study (100%), and six of the 12 educational and/or counseling studies (50%). Conclusions: The CAM and exercise was statistically effective in improving cancer pain in the review. However, uncertainty remains regarding the strength of the evidence, due to the small number of studies included and lack of consistent methodologies.

Implications for Practice: The application (5A) of SM support may help for cancer patients to enhance their pain.

Introduction

It is estimated that there were more than 15.5 million U.S. cancer patients in 2016.[1] This number will continue to grow to approximately 23 million by 2026 due to early diagnosis and medical and technology advancement.1 Thirty to 85% of cancer patients experience pain; 66% of advanced cancer patients, 55% of cancer patients undergoing cancer treatment, and 30% of cancer patients who have completed cancer treatments.[2] Approximately 50% of cancer patients who experience pain develop chronic pain even though they received traditional (mainstay of) pain therapies.[3] As a result, many cancer

patients are no longer satisfied with traditional pain managements.[4] Thus, they look for non-traditional interventions to manage their pain.[5]

One or two decades ago, oncologists focused on only cancer treatments or acute care related to cancer.[14] This old practice has been changed now that cancer care should be considered continuing or long-term care. Furthermore, cancer treatment and end-of-life care is increasingly shifted to the outpatient or home settings. These patients deal with pain on a daily basis at home. It is crucial that cancer patients should be equipped with many Self-Management (SM) skills to control their pain.

The concept of SM and SM support is developed from Alberta Bandura's self-efficacy.[6] Self-management is defined as the combine knowledge, ability, and confidence of patients with any chronic disease or condition who manage their symptoms, treatments, and lifestyle changes in daily life.[7] When patients feel confident in their ability to control their health, they tend to have greater success in attaining their health goals. If multi-disciplinary teams support and/or implement SM interventions for patients, these patients can improve their chances of successfully managing their diseases and its symptoms.[8] Evidence suggests that health education alone is an insufficient form of SM support. By itself, health education is not keeping patients engaged in health promoting behaviors.[9-12] However, SM support can be valuable in health-related goal setting, self-assessment, action planning, problem solving, or follow-up. In order to have successful SM support, multidisciplinary teams and patients should actively communicate. Additionally, everyone in the team, including patients, must understand that the patients are in charge of their long-term care. Multidisciplinary teams and patients are partners in achieving these patients' health goals.

Only few non-traditional and home-based SM intervention studies have been conducted based on non-SM theories such as rational emotive behavior theory.[15] Self-management and Self-management intervention application in the Chronic Care Model (CCM) is practically incorporated and has been studied in many different patients with chronic diseases such as diabetes,[16,17] asthma,[7,18] cardiovascular disease,[7] and depression.[19] However, few studies were used for cancer patients.[20] When a multidisciplinary healthcare team proposes to provide SM support, the team may employ the 5A approach (offering Assessment, Advice, Agreement, Assistance, and Arrangement).[13]

This review will evaluate quantitative and qualitative studies to compare the effect of non-traditional SM interventions for cancer pain conducted at home. Among non-traditional SM interventions for cancer pain, education alone is less effective than other non-traditional SM interventions. This review will also explore the application of SM support in the CCM as a future guidance for SM intervention studies and practices since few included studies in this mixed-method systematic review were led by a SM theory. Thus, the results can inform not only healthcare providers and researchers how to empower cancer patients in a collaborative way, but they can guide also healthcare policy makers seeking to enhance patients' outcomes.

Methods

This mixed-method systematic review was updating the previous studies by Hammer et al,[22] Koller, Miaskowski, De Geest, Opitz, & Spichiger,[23] and McCorkle et al.[21] Koller et al.[23]conducted the review of solely SM educational interventions on cancer pain. McCorkle et al[21] and Hammer et al[22] conducted a review of studies on broad

symptoms of cancer patients, including nausea, pain, and vomiting.

PubMed, CINAHL (EBSCO), Scopus (Elsevier), and Cochrane Central Register of Controlled Trials (Wiley) were used to search the literature for the period from January 2011 to May 2018. The search terms used were ‘self-management,’ ‘self-care,’ ‘pain self-management,’ ‘self-management interventions,’ ‘non-traditional self-management interventions,’ home-based self-management interventions,’ ‘cancer,’ ‘oncology,’ ‘pain,’ ‘cancer pain,’ and ‘cancer pain symptom.’

Inclusion and Exclusion Criteria

All selected studies included non-traditional SM interventions targeting cancer patients living with pain. These studies featured SM interventions that were incorporated into home-based activities. Educational, exercise, or CAM therapy interventions can be used as a non-traditional and home-based SM intervention. However, if those interventions are required an interventionist without the self-administrating part during the entire intervention, those interventions are no longer a home-based SM intervention. For instance, Yoga can be a non-traditional and home-based SM intervention. However, if Yoga is required by an instructor during the entire intervention, the Yoga intervention is no longer a home-based SM intervention in the specific situation. All literature were published in peer reviewed journals, written in English, and measured pain outcomes using either quantitative or qualitative methods. Self-management interventions that were not conducted at cancer patients’ homes, that measured the effects of traditional interventions such as pharmacology therapies and surgical and medical procedures, or that had no pain outcomes were excluded.

Results

The author located 510 articles (507 quantitative, 3 qualitative). After correcting for duplication, 395 articles remained (392 quantitative, 3 qualitative). The author screened only titles and abstracts and excluded 327 articles that did not meet inclusion criteria. Another 49 quantitative articles and 1 qualitative article were eliminated after reviewing the full text for the following reasons: they were not home-based SM studies (n=38), no pain outcomes were reported (n=7), and the interventions were conducted on healthcare providers, not on cancer patients (n=5).

A total of 16 quantitative and 2 qualitative non-traditional and home-based SM intervention studies were included in this mixed-method systematic review. All interventions are divided into three types: use of an educational and/or counseling program, use of complementary and alternative medicine (CAM) therapy, and use of exercise. All interventions were required that participants receive a minimum amount of instruction and assessment in order to explain a specific program or intervention.

Quantitative Non-Traditional/ Home-Based Self-Management Intervention Studies

The 16 quantitative studies utilized educational and/or counseling programs (n = 12), CAM therapy (n = 3), and exercise (n = 1). The nine countries in which the research was conducted. The mean age of participants in these studies ranged from 48 to 66 years. A total of 1753 participants took part in the educational and/or counseling program studies, 106 took part in the AA/CAM studies, and 81 took part in the exercise study. More women than men took part in these 16 studies; 62.2% were women, while 37.8% were male. Seven studies that reported white individuals made up the majority of study

participants, ranging from 62% to 93% of the total sample, but 9 studies did not report participant ethnicity. Most studies recruited participants diagnosed with more than one type of cancer: breast cancer (n = 8), lung cancer (n = 4), other (n =3), GI cancer (n =2), urogenital cancer (n =2), head and neck cancer (n =1), lymphoma (n =1). Only four studies reported the cancer stage of study participants. Five studies of the 16 did not report the proportion of participants who dropped-out while 7 studies had less than a 20% drop-out rate (4 studies had more than a 20% drop-out rate). Six studies included patient family members in the intervention process. On a scale of 0-10, most studies (n = 10) included only those who reported that their pain was at level of 3-4 or above. These pain outcomes included pain severity, physical function, pain self-efficacy, pain blood biomarkers, and pain medication usage. There were 14 instruments that have been used to collect data regarding cancer pain across all 16 studies: Brief Pain Inventory (BPI) (n = 7), Pain Self-Efficacy Scale (n = 5), Short Form (SF) Health Survey (n = 3), Numeric Rating Scale (n = 3), Karnofsky Performance Scale (n = 2), Patient Pain Questionnaire (PPQ) (n = 1), MD Anderson Symptom Inventory (MDASI) (n = 1), Pain Management Index (PMI) (n = 1), Visual Analogue Scale (VAS) (n = 1), McGill Pain Questionnaire (MPQ) (n = 1), functional status scale (n = 1), oral morphine equivalent calculation (n = 1), and Medication Quantification Score Version III (MQSV III) (n = 1). More than 80% of these studies used 2 or more pain outcome measurements. All studies used subjective measures and some studies also utilized objective measures (n = 3) or biomarkers (n = 1). The quantitative SM interventions across these 16 studies were employed more often during the survivorship phase (n = 9) than during the treatment phase or at the end of life. All the CAM and exercise intervention studies only appeared during the last 3 years of

the review period and the CAM studies used only auricular acupressure (AA) interventions. However, the number of educational and/or counseling intervention studies have decreased since 2013 in this review and only the educational and/or counseling program studies were guided by a theory.

Educational and/or Counseling programs

Across the 12 quantitative intervention studies, 10 held educational and counseling sessions and 2 held only educational sessions. There was variability among the educational and/or counseling programs presented with differences in type and duration of intervention, and study design: different types of comparison group. Educational and/or counseling programs included psycho-educational programs, PRO-SELF Pain Control Programs (PRO-SELF PCPs), cognitive behavioral programs, rational-emotional therapy programs, and problem-solving training programs.

Telephone counseling was usually used at the end of life in cancer patients because the cancer patients could not go to see their doctor due to their physical limitation.24-27 The pain outcomes of these studies were mixed. Three studies using PRO-SELF PCP as the chosen home-based SM intervention did not report statistically significant results.24-26,28 The key strategies used in PRO-SELF PCP were pain management knowledge provision, skills building, and nursing coaching. All three PRO-SELF PCPs utilized slightly different strategies based on the host countries and populations targeted. All three PRO-SELF PCP studies found that, while knowledge improved, the intervention did not change patients' behaviors regarding pain management. Ohlsson-Nevo, Karlsson, & Nilsson (2016) and Oldenmenger et al. (2011) tested the effect of a Psycho-Educational

Program (PEP) on cancer pain management, and the two studies reported statistically significant on pain severity. Oldenmenger et al. (2011)'s PEP stimulated patient's help-seeking behavior based on WHO pain guideline. Ohlsson-Nevo et al. (2016)'s PEP educated participants regarding general pain management and relaxation techniques. Risendal et al. (2015) tested the effect of a Chronic Disease SM Program (CDSMP) on cancer patients with pain. The CDSMP utilized education intervention aimed at building skills, sharing experiences, and generating support among the participants. The authors reported that pain outcomes were not statistically significant. Kwekkeboom et al. (2012) used an education-based intervention utilizing 12 Cognitive Behavioral (CB) techniques to relieve not only cancer pain but also fatigue and sleep. The 12 CB techniques were divided into four categories: symptom-focused imagery, natural focused imagery, relaxation exercises, and nature sounds. Participants could choose one of 12 CB strategies depending on their preferences for 2 weeks. Behavior pain outcomes were statistically significant ($p = .05$).

Complementary and Alternative Medicine Therapy/Auricular Acupressure

Complementary or Alternative Medicine (CAM) therapies have been utilized to assist cancer patients who were not satisfied with Western approaches to pain management. Guidelines and recommendations for CAM have been supported by the National Comprehensive Cancer Network guidelines, the World Health Organization (WHO), and the National Institutes of Health (NIH). There are seven types of complementary or alternative medicine modality for pain management in the US (acupuncture, acupressure, massage, yoga, hypnosis, relaxation/progressive muscle relaxation and guided imagery, biofeedback). Not all CAM therapies can be incorporated

into an SM component. For instance, acupuncture therapy requires an acupuncturist or specialist during the entire intervention. However, Auricular Acupressure (AA) therapy only requires an acupuncturist or specialist at the beginning of an intervention, because the patient can self-administer the rest of the intervention.

All the three CAM SM intervention studies in this review used only AA therapy during cancer treatment or survivorship. Auricular acupressure uses stimulators (referred to as "seeds") taped onto the ears. Theses stimulators are made of botanical, metal, or magnetic materials: they are used in place of the needles utilized in standard acupuncture.[2] The three studies showed that AA was statistically effective in relieving cancer pain.[2 36 37] However, uncertainty remains regarding the strength of the evidence, due to the small number of studies included and the lack of consistent methodologies employed.

Exercise

Exercise has been used to relieve symptoms such as pain and fatigue and enhance physical function, anxiety, depression, and quality of life on cancer patients. Cantarero-Villanueva et al. (2011) tested the effects of three parts of exercise (warm-up, resistance and aerobic exercise training, and cool-down sessions) on cancer survivors living with pain: the intervention was offered three times per week and each session was offered online and lasted 90 minutes. The authors reported significant interaction effects for pain severity and pain interference.

Qualitative Non-Traditional/Home-Based Self-Management Intervention Studies

Two qualitative studies were included in this review. The studies incorporated only educational and/or counseling programs (n = 2). Both were based in grounded theory

methodology.

Educational and/or Counseling Programs

All qualitative home-based SM intervention studies (n = 2) utilized a combination of education and counseling sessions. The two interventions employed in these qualitative studies utilized PRO-SELF PCP and an educational toolkit (including a motivational video, a cancer symptom SM guide, and a cancer resource directory). Hodge et al. (2012) developed a pain management toolkit specifically for South American Indians. 39 The author reported that cultural considerations such as language differences, illness beliefs, cultural practices, and literacy levels must be incorporated into cancer pain SM. Schumacher et al. (2014) utilized a mix-methods approach.[40] The authors explained that pain medication processes should consider individual contexts, including ways of understanding, organizing, storing, scheduling, remembering, and taking the medications at home.

Application of Self-Management Support (5A)

The application of self-management support was adopted for an intervention by the Behavior Change Model. The Behavior Change Model proposes that an intervention should be orderly, conducted using ongoing assessment, advice, agreement, assistance, and arrangement (the 5A approach) in the primary care setting. The main focus in application of SM support is the personal action plan. The personal action plan is for patients to make their own health goals and follow-up plans.

Assessment

Recent evidence has proven if healthcare providers assess patients' SM skills,

confidence, knowledge, supports, belief, barriers, and risk factors to maintain their health, healthcare providers can provide feedback to their patients and their interdisciplinary team based on their patients' SM so the teams and patients can enact better care plans for patients' chronic illnesses.[41] There are useful tools to assess patients for SM. General patient information, treatment information, pain information, perceive treatment efficacy, and performance status can be used in part or in totality for the initial and ongoing assessment of SM by an interdisciplinary team.

Advice

Advice can be given by the disciplinary team or by other patients who have similar diseases or symptoms, but the advice should be based on current evidence and knowledge.41 Through shared advice, patients can make or revise their health goals and plans. The team can discuss the benefits of SM and explain the application of SM interventions.

Agreement

Agreement can occur any time after the assessment of patients. Patients and multi-disciplinary teams may collaboratively finalize health goals and plans and select treatment based on the patient's preference, ability, and confidence, in order to improve their chronic symptoms and conditions.[41] The goals and plans are not abstract, but they should be small and behavior-specific. The goals should include measures that can be reached within 3-6 months.[41]

Assistance

Assistance can occur any time after the assessment of patients. A healthcare disciplinary team should help patients to achieve their goals and plans by providing

education, encourage patients, and connecting peers who have the same health problems.[41] Open communication between the team and patients, and within the team itself, is crucial.

Arrangement

Arrangement of resources to improve one's health can occur any time after the assessment of the patient. A multidisciplinary team can schedule follow-ups or referrals to specialists to continue support for patients and improve patients' SM.[41]

Discussion

This mixed-method systematic review evaluated 16 quantitative and 2 qualitative studies utilizing non-traditional and home-based SM interventions for cancer pain. Pain outcomes included in these studies were pain severity, physical function, pain self-efficacy, and pain medication usage. All home-based SM interventions in this review were divided into three types: use of educational and/or counseling programs, use of CAM therapy, and use of exercise. The 16 quantitative studies utilized all three types of interventions; however, the 2 qualitative studies used only education and/or counseling programs.

Ten of the included 16 quantitative studies reported statistically significant results with regard to pain outcomes such as pain severity and pain medication usage; three CAM studies (100%), one exercise study (100%), and 6 of the 12 educational and/or counseling studies (50%). Thus, CAM and exercise interventions provide promising avenues for pain management in cancer patients compared to the use of only educational and/or counseling programs. However, little is known about the mechanism by which CAM and exercise

work, and we cannot conclude that CAM and exercise therapies are better than educational and/or counseling programs based on the small number of the studies conducted. We need further studies on pain management in cancer patients utilizing CAM, exercise, and educational and/or counseling interventions.

The quantitative SM interventions included in this review were varied in study design, duration, and methodology, so it is hard to compare them to one another. Future research should include the development of standard protocols for the delivery of the SM interventions in order to establish evidence. The qualitative SM studies reviewed here suggest that pain intervention and management should be tailored to individual culture.

Most of the studies (n = 11) used home-based SM interventions during survivorship than during cancer treatment or at the end of life. Cancer patients live longer now and they need SM skills in their daily lives. However, cancer patients receiving cancer treatment or at the end of life depend on the skills and assistances of healthcare providers. Thus, more non-traditional and home-based SM intervention studies can be conducted during survivorship.

Across the 18 studies, few incorporated theories into their chosen SM intervention. Only one study utilized an intervention based on the CCM, however, the study did not statistically significant behavior pain outcomes, possibly because it used only an educational program. The study did not incorporate the application of SM support. If so, it is likely that this would change their pain behaviors on patients. The application of SM support makes patients to engage more on their own care to change pain outcomes.

Incorporating physiological biomarkers for pain into SM interventions may be one way to build scientific evidence about effectiveness of the interventions. Current

researchers speculate that physiological bio-markers may change depending on the level of pain experience.2 Only one study has measured blood bio-markers such as inflammatory cytokines as pain changes.[2] Pro-inflammatory cytokines can be induced by neuron damage and lead to pain,[42] so further investigation into the use of non-traditional and home-based SM interventions to buffer the release or action of pro-inflammatory cytokines is warranted.

There are limitations to this mixed method systematic review. First, only studies published in English were included. Additionally, the number of CAM therapy and exercise studies were small and the intervention periods of these studies were short, so it was difficult to compare them with educational and/or counseling intervention studies. Lastly, methodological variability made cross-study comparison difficult.

Conclusion and Implication

This mixed-method systematic review informed future implications of SM interventions for better pain management outcomes in cancer patients. The small number of CAM and exercise studies and the lack of protocols and consistent methodologies across the studies preclude that specific interventions can be the best choice among included SM interventions in the review.

This review may inform further research and clinical practice related to cancer pain. First, more studies using the '5A approach' of SM support in the cancer practice would be "useful," and additional quantitative and qualitative non-traditional/home-based SM studies will be needed to achieve better understanding of cancer pain care. Second, more home-based SM intervention studies including cancer caregivers are warranted. We need

to gather evidence about whether it is more effective to include cancer caregivers in a home-based SM intervention in order to enhance care of cancer pain. Third, more research is needed to measure the long-term effects including physiological bio-markers of non-traditional and home-based SM intervention on cancer patients dealing with pain. Lastly, a study utilizing an online, home-based SM intervention for cancer patients is warranted, because the patients may not be able to keep up with their clinical visits due to disease progression and pain.

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Section 4

My research question is "Is the use of auricular acupressure (AA) as an adjunctive care feasible to manage cancer pain at cancer patient's home?" The first manuscript has

shown the feasibility and the possible analgesic effect of AA therapy for patients with pain. More than 80% of studies concluded that AA was effective to control pain such as lower back pain, knee pain, post-operative pain, and general pain. The results were important that AA therapy can be a good modality for possible cancer pain management. The second manuscript has presented why important SM and using SM modalities to control cancer pain. The manuscript also presented the linkage of the theory of the Chronic Care Model (CCM). Cancer patients can be taught to self-administer AA therapy after receiving training by a qualified healthcare provider. Auricular acupressure would empower cancer patients and promote pain symptom SM skills. The process of SM support in the CCM may be useful for healthcare providers to assist their patients who enhance SM skill, knowledge, and confidence.

Hypotheses / Research Question(s)

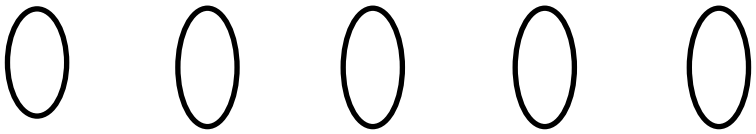
Hypothesis 1: Most of cancer participants in this study can complete more than 80% of AA intervention at their home as an adjunctive therapy for 4 weeks.

Hypothesis 2: AA therapy changes pain severity, pain interference (physical function and sleep etc.), quality of life, and depression in cancer patients with pain.

Chapter III

Methods

A pilot study was conducted to evaluate the feasibility and potential analgesic effects of a 4-week auricular acupressure (AA) therapy on cancer patients with pain. One group repeated measure and five visits in time to evaluate retention, adherence, and completion of AA therapy and to assess alleviating cancer pain by an AA intervention.



Time	Baseline	1 week	2 week	3 week	4 week

Research Setting

Cancer participants (N = minimum 12) were recruited by self-referral from Facebook social media, pain management clinics, local community centers, cancer survivor groups, Rutgers University School of Nursing building in Newark and New Brunswick and from referrals from participants' family members or friends. The cancer participants were treated from the Rutgers School of Nursing. Study duration was total of 4 weeks. Enrollment, adherence, completion, and data collection were occurred over 4 months.

The sample

Participants in this study were adult female and male participants who were diagnosed cancer, treated by cancer treatment, and experienced pain. These participants

were able to complete AA therapy and speak English because study procedures were conducted in English. For a pilot study, Julious (2005) suggests a minimum sample size of 12 subjects.

Recruitment of participant was executed through diverse activities including Facebook commercial advertisement, flyer distribution to local pain management clinics, local community center, and cancer support or survivor groups in local community. First, participants were recruited throughout Facebook social media. The PI advertised flyers for this project through commercial Facebook page. The PI opened a commercial account through Facebook. Many cancer patients or healthcare providers who were possibly interested in cancer research saw the flyer even though they were not the PI Facebook friends. Potential participants would contact the PI through Facebook social media. Second, the flyer was posted at public bulletin boards in local pain management clinics, local community center, and cancer survival associations. The PI searched local pain management clinics and cancer survival associations in New Jersey, The PI called and emailed them to get the permission for the PI to post the flyer on their public bulletin boards. Any organization in NJ allowed the PI to visit them, the PI went and posted the flyer on their bulletin boards. Some participants self-referred to this study after hearing of this study from their friends or family members or have seen the flyer. Approximately 600 flyers were distributed. Recruitment started July 2019 and completed in December 2019. A total of minimum 12 was needed to recruit. For consideration of attrition rate, 30% of the total sample size were added (N = 21). Of the 45 cancer initially approached to participate, 31 cancer patients with pain agreed to participate. The responses of 10 cancer patients were excluded from the analysis due to the delimitations of the study.

Five cancer patients withdrew from the study and the incomplete responses of 2 cancer patients were discarded.

Descriptive data was analyzed with respect to sociodemographic information, performance status, types and characteristics of pain, past health history, and prior cancer therapy to characterize the study sample.

Instruments

Cancer pain was evaluated in this study by pain severity (subjective measure) in the Brief Pain Inventory (BPI) and the Neuropathic Pain Scale (NPS) and the Visual Analogue Scale (VAS) in the daily diary, pain interference (objective measure) in the BPI and medication use in the daily diary. Daily diary was used every week by participants. The BPI and the NPS was given to participants whenever participants weekly visited the research site. Additionally, quality of life and depression evaluated as levels of pain changed. The SF-8 Health Survey for quality of life and the Patient Health Questionnaire (PH)-2 for depression were used for this study.

Instrument	Baseline	1 week	2 week	3 week	4 week
Demographic	x				
Medication History	x				
Neuropathic Pain Screening Tool	x				
Medication Quantification Scale	x	x	x	x	x
Brief Pain Inventory	x	x	x	x	x

Patient Daily Diary	x	x	x	x	x
Neuropathic Pain Scale	x	x	x	x	x
The Patient Health Questionnaire	x				x
SF-8 Health Survey	x				x

Demographic Form. Age, race/ethnicity, health insurance, occupation, smoking status, marital status, and level of education, cancer status, cancer treatment, medication, medical history were recorded.

Pain Medication Use. Pain medication quantification was measured using the Medication Quantification Scale Version III (MQS) to compute a single numeric value for a participant's pain medication profile used in the previous 24 hours, according to drug class, dosage, and detriment.

Neuropathic Pain Screening Tool. This tool is usually used for screening neuropathic pain or local pain by clinicians (Bouhassira et al., 2005). The questionnaire includes 10 items, divided into four questions which are characteristics, symptoms, type of stimulation and causation of pain (Bouhassira et al., 2005). Patients can choose either 'yes' or 'no' answer to each item. Each 'yes' equates to 1 point, each 'no' equates to 0 points. At the end of the questionnaire, add up the 'yes' answers giving a total score out of 10. If the score is greater than or equal to 4, it indicates that a patient is likely to be experiencing from neuropathic pain. The Neuropathic Pain Screening Tool sensitivity is 83% and specificity is 90% (Bouhassira et al., 2005).

Pain Severity in the BPI. The BPI was originally developed to measure cancer pain and has been extensively validated and used in many cancer pains studies (Garcia et al., 2014; Yeh et al., 2014). The BPI is simple and easy to understand by potential respondents over other pain questionnaires. The BPI is developed to measure multidimensional phenomena of pain. Many studies have explained that the multidimensional phenomenon is the most important aspect of cancer pain (Cleeland, 2009). The BPI includes two-time-frames which are the present (within 24 hours) and the past week. The dual time frame was chosen to compare pain between present and past. Pain changes over time. This comparison of pain provides researchers or health care providers information about the need of treatment or the effect of treatment. Thus, the time perspective of the BPI is appropriate.

The BPI is divided into 2 parts with 32 items. The first part has two pain sub-scores which are the interest phenomenon, and the second part has general information. The two sub-scores (Short Form BPI) consist of pain severity and pain interference scores (Cleeland, 2009). The pain severity score corresponds to the four items (worst, least, average, and current pain) (Cleeland, 2009). The pain severity score is rated from 0 (no pain) to 10 (pain as bad as you can imagine) with anchor words at either end, or a total score, ranging from 0 to 40 (Cleeland, 2009). The higher scores indicate worse pain levels (Cleeland, 2009).

Pain Interference in the BPI. The pain interference score corresponds to the seven items. The seven items are general activity, walking, work, mood, enjoyment of life, relations with others, and sleep (Cleeland, 2009). This pain interference scale has two

dimensions (factors): emotion and activity (function). The items of emotional dimension in pain interference are mood, enjoyment of life, and relations with others. The items of functional dimension in pain interference are general activity, walking, work, and sleep. The pain interference score is rated from 0 (does not interfere) to 10 (completely interferes) with anchor words at either end, or a total score, ranging from 0 to 70 (Cleeland, 2009). The higher scores indicate worse pain levels (Cleeland, 2009).
The general information which contain a patient's history of pain, its relationship to their diseases, locations of the pain, with drawings on human figure, the cause of pain, pain relief treatment (list of the treatments and amount of relief), pain characteristics, and demographic information (21 items) is followed after pain interference questions (Cleeland, 2009).

Neuropathic Pain Scale. This tool is not a diagnostic or screening tool for neuropathic pain (Rog, Nurmikko, Friede, & Young, 2007). The NPS only uses for assessing neuropathic pain and effects of treatment of neuropathic pain in patients who have already been diagnosed with neuropathic pain, and should not be used to assess. It contains 11 items. The 8 items assess specific NP qualities: "Sharp," "Hot," "Dull," "Cold," "Sensitive," "Itchy," "Deep," and "Surface." Two items are assessing global pain intensity and unpleasantness. Those above item is rated from 0 (no pain) to 10 (worst pain) with anchor words at either end, or a total score, ranging from 0 to 100. The higher scores indicate worse pain levels. The last question is to ask the patient to describe the temporal aspects of their pain and its qualities. The change in the mean NPS score 20 have been shown to be sensitive to various treatments of NP.

The VAS/NRS in Daily Diary. The VAS/NRS has a single item. The main interest of the VAS/NRS is to measure pain severity as a unidimensional, amongst other usages (Ciprandi, Tosca, Signori, & Cirillo, 2011). The VAS/NRS is generally presented as a thick line, ranging from 0 (no pain) to 10 (severe pain) and 1-9 numbers' insertion only for the NRS, with anchor words at either end (Ciprandi, Tosca, Signori, & Cirillo, 2011). The score can also be treated as a continuous or dichotomous variable depending on the research question or preference of the researcher (Ciprandi et al., 2011). The scoring of pain severity of the VAS/NRS is similar with the BPI that the higher score indicates worse pain. However, the VAS/NRS is often used to measure unidimensional of pain (Cleeland, 2009).

Patient Daily Diary. Intervention fidelity is measured using AA practice at home (frequency of AA, amount of time of AA, and adverse effects of AA) for pain and daily analgesic use.

SF-8 Health Survey. It assesses health-related quality of life. This survey is an abbreviated version of an original 36-item health survey. Each item of the SF-8 is assessed using a 5- or 6-point Likert scale. SF-8 health survey included 8 items which are general health, physical functioning, role physical, bodily pain, vitality, social functioning, mental health, and role emotional. The 8 items can be divided into which are summarized into physical component (PCS; general health, physical functioning, role physical, bodily pain, and vitality) and mental component (MCS; social functioning, mental health, and role emotional) (Rog et al., 2007). The sub-scale scores can be

represented as T-scores (mean = 50; standard deviation = 10) that range from 0 to 100. Thus, we can compare those scores based on pain, age, cancer types, gender, education, income etc.

The Patient Health Questionnaire. The Patient Health Questionnaire 2-item (PHQ-2) is a brief screening tool for major depression and anhedonia over the past two weeks. The total score of PHQ-2 ranges from 0-6. If the score of 3 or greater is cut point, a patient is more likely to have a major depressive disorder. Patients who have more than 3 scores in the PHQ-2 need to be further evaluated for major depression and anhedonia.

Treatment Satisfaction and Interview Note. Participants were asked whether or not they are satisfied with AA treatment. Participants were also asked whether or not they recommend AA to their friends or acquaintances. Lastly, participants received an open-ended question of this study such as recommendation for a next study at the last visit.

Procedure for Data Collection

Schedule of the Intervention

	Screening/ Baseline	Wk[a,b]1	wk 2	wk 3	wk 4
Informed consent	x*				
Demographics	x				
Pain related information	x				x
Prior cancer treatment	x				
Co-morbid conditions	x				

Neuropathic pain assessment	x				x
Concomitant medication	x	x	x	x	x
Performance status	x	x	x	x	x
Pain assessment	x	x	x	x	x
Patient daily diary	x	x x x x x x x xx x xx x x x x x			

Notes. * = Patient informed consent will be obtained prior to any study procedures. All procedure applies to all participants. Screening and baseline visits may be performed together if needed.
a = Participants will come to the Rutgers School of Nursing at baseline and through visit 5 for screening, baseline, and last week data collection. Before participants' visit, research team will give a call to remind an appointment for each visit.
b = A research assistant will collect data at participants between week 1 to week 4 of intervention. Wk = intervention week.

Baseline and pain information (2.5 hours)

Consent form

Baseline information:

- Contact Information, Enrollment Form and Demographic form (age, gender, marital status, education, occupation, diagnosis, time since diagnosis/last treatment, treatments, medical and cancer history)

Pain related information:

- Neuropathic Pain Screening Tool– screens neuropathic pain
- The BPI Short Form and Neuropathic Pain Scale (NPS) – measures pain or neuropathic pain level
- PHQ-2 – measures mental health
- SF-8 Health Survey- measures quality of life

: IRB approval from Rutgers University was obtained (#Pro2019000950). If there were

two-time changes of the IRB protocol, protocol amendments were submitted in writing by the PI to the IRB at Rutgers University. The first modification was to add my co-investigators. The second modification was that unexpected event which was falling seeds between visits. The modification of replacing seeds between visits was added. For the usage of the ear seeds, the following two methods are commonly being used in general acupuncture clinics. The first one is done by an acupuncturist in the clinic and the second one is done by a patient at home. Since it is common for ear seeds to typically fall out and a standard of care for an acupuncturist is to teach the participant how to reinsert ear seeds.

A written consent was given to each participant based on The Code of Federal Regulations. Informed consent was obtained in person prior to any study activities, was done in a private space. The level of language in the consent form is 8th grade. The PI reviewed and explained the following to the participant: the purpose of the research, the expected duration of participation including a step-by-step of planned study procedures, a participant eligibility, the foreseeable risks or discomforts that participants may encounter, benefits of AA or others that can be reasonably expected, the efforts of the research team to keep participant documents confidential, a discussion of the availability of medical treatment in proximity to the participant in the event of an injury and disclaim that there is no mechanism for medical cost reimbursement, a discussion about the responsible investigator and the PI was interacting with the participant, provision of contact information for the study team, a discussion about the confidentiality of participant data and specific details about how data were kept private/confidential, participation being voluntary and refusal to participate was involved no penalty or loss of

benefit to the participant. Any questions about the study from participants were answered. The participant was given enough time to decide whether they participated in the study or not before they sign the consent form (Appendix A). All the aforementioned were provided on a written consent document that was signed by both the PI and the participant. Once informed consent was obtained, baseline assessment (Appendix B), The Patient Health Questionnaire (PH-2, Appendix B), Neuropathic Pain Scale (Appendix C), Neuropathic Pain Screening Tool (Appendix D), SF-8 Health Survey (Appendix E), and Brief Pain Inventory (BPI) forms (Appendix F) were done. Participants received an individual education session of AA intervention by the research team. Patient daily diary (Appendix G) was also given to all participants to measure their practice (frequency and duration of treatment), level of pain, and adverse effects at home. The estimated time to complete all instruments in the visit was proximally 2.5 hours. The participant was given a copy of the form and the PI office locked all the original forms in a cabinet.

Through Week 1 (+ or – 1 week) to the end of the study – Week 4 (1 hour)

- The BPI
- Daily diary for the week
- Replacing seeds on the ears

: Auricular acupressure sessions (Week 1 – 4) will be conducted at least 3 times per day by each participant at their home. The following forms were administered to participants at: The BPI and the NPS. The patient daily diary log was returned by participants every week to the PI. For each participant the time spent in each visit (week 1 - 4) will be approximately 1 hour. At the end of week 4, following measures were administered to

participants: The BPI, PHQ-2, SF-8 Health Survey and NPS. The patient daily diary logs were returned by participants every week to the PI.

Experimental Operational Definition

After baseline data collection, three certified acupressure personnel were selected acupoints for each participant, depending on common pain areas and individual pain areas and the literature at the first visit. The certified acupressure personnel applied all seeds and tapes for all participants every week. The acupoints were confirmed with an electronic acupoint finder. Participants were taught to repeatedly press on taped AA acupressure seeds (stimulators) with the fingertips for 3 minutes per point three times per day and whenever pain arises, for 4 weeks. Participants were also taught to remove all seeds on the ear by themselves at the end of 5^{th} day of each week. AA intervention had continued for 4-week AA intervention. Seeds were replaced every week with new seeds by the acupuncturists or participants. For the usage of the ear seeds, the following two methods are commonly being used in general acupuncture clinics. The first one is done by an acupuncturist in the clinic and the second one is done by a patient at home. Since it is common for ear seeds to typically fall out and a standard of care for an acupuncturist is to teach a person how to reinsert ear seeds the following were happened.

1) The acupuncturist taught all study participants how to reinsert ear seeds when they fall out before the session is over.
2) Participants were taught how to replace the ear seeds between appointments.

3) Participants were asked to call me if they are unable to reinsert the ear seeds.

The reliability of AA intervention was maximized by using the same script for AA interventionists, the same equipment for all participants, and delivering AA intervention based on standard Traditional Chinese Medicine practice.

Plan for Data Analysis

The attrition, adherence, and completion rates were calculated throughout the AA intervention. The adherence rate was calculated as the percentage of the number of trials of AA intervention as compared to the total number of the intervention (60 times) during the given 4-week intervention period. Many medication efficacy studies indicated that more than 80% adherence rate is required to get therapeutic effect. The adherence to AA therapy was calculated through the daily diary recordings. The completion rate was calculated as more than 75% of the AA intervention and the daily diary were conducted during the 4 week intervention period.

For 'Pain Severity,' the levels of 'Worst Pain,' 'Least Pain,' 'Average Pain,' and 'Right Now Pain,' in the Brief Pain Inventory (BPI) and the Neuropathic Pain Scale (NPS) data was calculated by the mean at each week. The 'Pain Severity' of 'Least Pain,' 'Average Pain,' and 'Right Now Pain' scores in the BPI-SF was calculated using non-parametric analysis Friedman test. 'Pain Interference' scores devided into functional and emotional dementions. 'Pain Interference' score was calculated from the mean by the BPI-SF; the Friedman test was used. Non-parametric analyses were used because of the small sample and high possibility of non-normal distributions of outcome scores. Wilcoxon signed rank test were used as a post hoc test when the Friedman test found a

statistically significant change over four weeks. Additionally, neuropathic pain change for pain severity was calculated the mean from each visit by the NPS. More than 20 mean score change over an intervention indicates the intervention is effective for neuropathic pain. For depression, the PHQ-2 was analyzed by McNemer test because depression variable was categorical. For quality of life, the SF-8 Health Survey was analyzed by Wilcoxon signed rank test.

Adherence and Contamination Controls

Most of AA studies on pain have had adherence rates of greater than 80% (Barker et al., 2006; Yeh, Morone, et al., 2014; Yeh, Wang, Lin, & Chung, 2014). Participants will be counseled throughout the study to maintain standard AA practice of intervention. For control of confounding factors, participants will be educated and monitored not to use any other alternative therapies and will not change their pain management during the study. Instruction in technique and coaching will also continuously be provided to participants during the study. Participants will be contacted prior to weekly visit by phone call or text message. Participants will return their weekly AA daily diary in every visit. The weekly daily diary will be collected in each participant's record.

Adverse Effect and Adverse Effect Reporting Requirement

Auricular acupressure is a non-invasive method. There have not been reported serious adverse effects in AA studies on pain or cancer pain. There are minimal risks that was assumed associated with participation in this study. Participants may not be unaware

of themselves to have allergies to tape which covers AA seeds. The symptoms of allergies may be itching, rash, and swelling.

The voluntariness of consent, AA participation, and declining of AA participation will be kept until AA intervention is done. During the consent process, above the voluntariness of participation are discussed. A breach of confidentiality is a possibility during this research study. Every effort is made to guard against this risk through procedures for survey and consent handling but the possibility is present that confidentiality could be breached. If all adverse effects occur, they were reported to the Office of Research and Sponsored Programs at Rutgers University.

Subject Confidentiality.

Personal identifiers were recorded on only the following documents: consent, enrollment form, and master linkage document (name, study ID). These forms were identified by ID number and kept in file separate from other participant's documentations. All other data and information about patients de-identified and kept in a confidential and secure area. No information of participant was released without written permission of the subject, except as necessary for monitoring by the IRB, FDA, and OHRP.

Potential Benefits

The potential benefits are that individual subjects may experience less pain and may be able to decrease pain medications. All participants may also increase the knowledge of AA or alternative therapy and pain SM. Furthermore, participants may

receive SM support through this study.

Risk-Benefit Ratio

The low risk and positive results have been shown in the previous AA studies. Thus, the benefits of this study outweigh the risks.

Removal of Patients from Study/Off Study Criteria

There was no reprisal. It was documented in the protocol record that the individual dropped out and the reason was recorded (note – only study ID will be recorded on the Drop-Out document).

There are following possible cases for participants to be removed from this study: Unexpected adverse effect(s), participant's decision to withdraw, noncompliance with AA intervention, and patient's health condition prohibits from the study etc.

Participant Folder

All CRFs, consent forms, AA daily diaries, and participant's documentations were collected in each participant folder.

Ethical and Regulatory Considerations

The PI in the study took responsibility for ethical issues of the study as respecting and protecting participant's right and welfare. This study adhered to the ethical principles laid out in the Belmont Report, Declaration of Helsinki, the Patient's Bill of Right.

Record Retention

All participant records were maintained in a secured location by the PI.

Chapter IV

Analysis of The Data

The purpose of this study was to evaluate the feasibility and potential analgesic effect of an auricular acupressure (AA) intervention on cancer patients experiencing pain. This study was also to evaluate the change of quality of life and depression while the cancer patients conducted AA. Additionally, survey of side effects and satisfaction on AA intervention of this study, and degree of self-confidence on self-administering AA intervention at the end of the study, participant's opinion for recommendation of AA therapy to their friends for improving cancer pain, and any suggestions of future AA intervention study were obtained by participants.

The feasibility of AA was assessed the rate of attrition rate, adherence, and completion of AA intervention. The potential analgesic effect was assessed by three measures which included pain severity, physical function, and pain medication usage. Pain severity was measured by the BPI-SF and the NPS who had neuropathic pain at each visit and the VAS in a daily diary. Physical function and emotion related pain were measured by the BPI-SF at each visit. Pain medication quantification was measured using the Medication Quantification Scale Version III (MQS) in a daily diary. Quality of life was measured by SF-8 Health Survey at pre- and post- AA therapy. Depression was measured by PH-2 at pre- and post- AA therapy. Participants were asked about their satisfaction of the AA intervention, participant's opinion for referral of AA to their friends or oncology physicians, and any recommendations about this AA intervention for a future study with open ended questions. All measurement tools for the study are illustrated in Chapter 3. Study recruitment took place from July through October 2019.

The analysis of the data was presented in this chapter.

Sample Description

For a pilot study, Julious (2005) suggests a minimum sample size of 12 subjects. The sample size of a minimum of 12 subjects for this pilot study is proper (Julious, 2005). However, if the PI planed to recruit more than 12 cancer patients with pain, it would be desirable because it could increase power for this study.

The following table provides summarized the detailed data analysis plan for each variable in the study.

	Baseline	Week 1	Week 2	Week 3	Week 4	What was measured	Statistical Method
Average Pain	X	X	X	X	X	Mean, Standard Deviation, and Significant change	Friedman test and Wilcoxon signed rank test
Least Pain	X	X	X	X	X	Mean, Standard Deviation, and Significant change	Friedman test and Wilcoxon signed rank test
Right Now Pain	X	X	X	X	X	Mean, Standard Deviation, and Significant change	Friedman test and Wilcoxon signed rank test
Worst Pain	X	X	X	X	X	Mean, Standard Deviation, and Significant change	Friedman test and Wilcoxon signed rank test
The NPS	X	X	X	X	X	Mean, Standard Deviation, and Significant change	Friedman test and Wilcoxon signed rank test
Pain Interference	X	X	X	X	X	Mean, Standard Deviation, and Significant change	Friedman test and Wilcoxon signed rank test
The SF-8	X				X	Mean, Standard Deviation, and Significant change	Wilcoxon signed rank test
PHQ-2	X				X	Frequency and significant change over 4 weeks	McNemer test

Statistical Description of the Variables

Descriptive data was analyzed with respect to sociodemographic information, performance status, types and characteristics of pain, past health history, and prior cancer

therapy to characterize the study sample. The attrition, adherence, and completion rates were calculated throughout the AA intervention. The adherence rate was calculated as the percentage of the number of trials of AA intervention as compared to the total number of the intervention (60 times) during the given 4-week intervention period. Many medication efficacy studies indicated that more than 80% adherence rate is required to get therapeutic effect. The adherence to AA therapy was calculated through the daily diary recordings. The completion rate was calculated as more than 75% of the AA intervention and the daily diary were conducted during the 4 week intervention period.

For 'Pain Severity,' the levels of 'Worst Pain,' 'Least Pain,' 'Average Pain,' and 'Right Now Pain,' in the Brief Pain Inventory (BPI) and the Neuropathic Pain Scale (NPS) data was calculated by the mean at each week. The 'Pain Severity' of 'Least Pain,' 'Average Pain,' and 'Right Now Pain' scores in the BPI-SF was calculated using Friedman test (non-parametric analysis) by the mean at each visit. 'Pain Interference' scores devided into functional and emotional dementions. 'Pain Interference' score was calculated from the mean by the BPI-SF; the Friedman test was used. Non-parametric analyses were used because of the small sample and high possibility of non-normal distributions of outcome scores. Wilcoxon signed rank test were used as a post hoc test when the Friedman test found a statistically significant change over four weeks. Additionally, neuropathic pain change for pain severity was calculated the mean from each visit by the NPS. More than 20 mean score change over an intervention indicates the intervention is effective for neuropathic pain.

There has been positive relationships demonstrated between pain and depression (Francis et al., 2019; Cheng, Deng, 程莘农., & 邓良月., 2010). The depression score was

calculated by the Patients Health Questionnaire (PHQ) -2 between pre- and post- AA therapy. The PHQ-2 was analyzed by McNemer test because depression variable was categorical. There has been negative relationships demonstrated between pain and quality of life in other studies (Wilson et al., 2014; McCorkle et al., 2009). Quality of life score was also asessed by the SF-8 Health Survey through Wilcoxon signed rank test was used over four weeks. The results of the analysis of study data was presented in this chapter. SPSS statistical software package (SPSS, version 23) was used to analyze the data.

Data Management

All data were entered into the working data spreadsheet by the PI. Participants were assigned ID numbers as identifiers, thereby maintaining the privacy of each individual and minimizing bias during the analysis. The PI reviewed twice and cleaned the data prior to analysis and assured data integrity by completing a data audit.

Data Screening Prior to Analysis

Data Accuracy. All data were inspected for plausibility, a process was designed to identify data entry error so that original data could be flagged, reviewed again and corrected. The process revealed two instances. First, when the data was reviewed by the PI, it was revealed that the PI entered three incorrect numbers while moving too quickly though an end-of-study participant evaluation. Second, when a participant recorded the wrong pain score in her/his daily diary. In this case, the participant added ‘0’ after her true pain score.

Model Assumption. Most variances were not normally distributed due to the small size of samples. Even if repeated measure on pain severity only, it still cannot assume normally distributed due to the small size of samples. The abnormality was checked by scatter plots, stem and leaf diagrams and box plots.

Outlier Assessment. Outliers were evaluated in order to determine whether they represented true values or not. Univariate outliers were defined as scores 3 standard deviations from the mean. Data meeting this criterion was furthered assessed.

Missing Value. Weekly data was reviewed for completeness when participants visited with their survey and daily diary. The PI texted the study participants every day to ask for pain score entries in the daily diary as a reminder; if missing data was evident, participants were asked to complete their submissions at each visit.

Heterogeneity of Groups. The participants were diverse based on demographic parameters of age, stage of disease or cancer, time since cancer diagnosis in months, treatment received (surgery alone, surgery plus chemotherapy, radiation, immunotherapy, etc.), previous alternative therapy experience, and types of pain.

Friedman Test. Pain severity and pain interference in cancer participants can be changed by 4-week AA intervention (Yeh, Chien, Lin, Bovbjerg, & Van Londen, 2016). The Freidman test was used to compare different levels of pain severity changes over the

4-week period.

Wilcoxon Signed Rank Test. Wilcoxon signed rank test was used as a post hoc test if the Friedman test found a statistically significant change over 4-weeks on pain severity and interference. Quality of life in the participants can be also changed by 4-week AA intervention (Saotome, Iwase, Nojima, Hewitt, & Chye, 2018). Wilcoxon Signed Rank test was used to measure the change of mean of quality of life in the SF-8 between before, and after the 4-week AA intervention.

McNemer Test. Depression scores can be changed by a 4-week AA intervention (Francis et al., 2019). McNemer test was used to compare the change of frequency of depression by the PHQ-2 at baseline and after the 4-week AA intervention. Eventually, how depression can be changed before and after AA intervention over the 4-week over the time.

Psychometric Properties of Instruments

Brief Pain Inventory (BPI)-SF

Wu, Beaton, Smith, & Hagen (2010) validated the psychometric properties of the BPI-SF and its pain severity and interference subscales on 258 cancer patients with bone metastases. High internal consistency of the BPI-SF subscales (pain severity, functional interference, and affect interference) was demonstrated by Cronbach's alpha between .81 and .98 (not including sleep item).

Neuropathic Pain Scale (NPS)

Rog et al. (2007) presented Cronbach's α in the NPS was .78 (95% CI .69; .83). The 10 items of the NPS was correlated with: the short-form McGill Pain Questionnaire (SFMPQ), ρ=.63 (95% CI .49; .74), its Visual Analog Scale (VAS), ρ=.49 (95% CI .33; .64), the transformed Pain domain of the SF-36, ρ=−.49 (95% CI −.63; −.32).

The Visual Analogue Scale/Numeric Rating Scale

The VAS overall internal consistency reliability coefficients (Cronbach's α) ranged from 094 to .97 (Walton et al., 2011). The VAS validity was more than .80 (Phan et al., 2012).

SF-8 Health Survey

Lang et al. (2018)'s study showed test-retest for the SF-8 with a good intraclass correlation of .61 for Physical Component Summary (PCS) and .68 for Mental Component Summary (MCS). Convergent validity of each PCS items (items 1–5) with the PCS summary score, and the each MCS-related item (items 6–8) were also presented at $r \geq .50$.

The Patient Health Questionnaire (PHQ) -2

International studies have found good internal consistency scores (α=0.84) and test-retest reliability (.80) by Zhang et al. (2013). The author had also shown a sensitivity of .89 and a specificity of .97, with an area under the curve of 0.98 (95% confidence

interval: .97-.99).

Participants Characteristics

The mean age of study participants was 63 years old (See Table 1). Fifty-seven percent (N = 8) were male. Most of the participants were married (N = 9, 64.28%). Participants were ethnically diverse; White (N = 5, 35.71%), Asian (N = 5, 35.71%), African American (n = 3, 21.42%), and More than one ethnicity/Hispanic (N = 1, 7.14%). Most of people were retired (N = 7, 50.00%) or unemployeed (N = 3, 21.42%). Most of participants graduated from high school or equivalent (N = 6, 42.86%), followed by from graduate school (N = 4, 28.57%). Six of participants (43.86%) were a former smoker; Five of participants (35.71%) smoked more than 5 cigarettes a day for more than 5 years. Those smokers quitted smoking after cancer was dignosed except for one participant who still continuously smokes (3 cigarettes/day). Seven of the participants (N = 7, 50.00%) were a former alcohol drinker, but only two participants (N = 2, 14.29%) drunk heavily with more than 12 bottles/day. Four participants continuously drink (less than 5 bottles/day). The mean duration of sleep was about 6 hours. Most significant medical histories among participants was HTN and DM respectively (N = 5, 35.71%), followed by hypercholesterol (N = 4, 28.57%) and hypothyroid (N = 3, 21.42%).

Type of cancer was breast cancer (N = 5, 35.71%), followed by prostate cancer (N = 3, 21.42%), stomach cancer (N = 2, 14.29%), myeloma, laygeal cancer, liver cancer, and pituitary gland cancer (N = 1, 7.14%). The mean year of having cancer was 5.7 years with range from 3 months to 23 years. Participants with all stages of cancer had been diagnosed with; Stage 1 (N = 5, 35.71%), stage III (N = 4, 28.57%), Stage II (N = 3,

21.42%), stage IV (N = 2, 14.29%) at the time of diagnosis. Most of participants (N = 10, 71.43%) had at least 2 cancer treatments in a surgery, chemotherapy, radiation, or immunotherapy. All participants (N = 14, 100.00%) had health insurance.

Seven participants did not complete this study. Five participants discontinued right after enrollment and two participants discontinued after the first week of AA intervention. For instance, one participant had started immuno therapy and tried to schedule surgery for his newly diagnosed cancer. The participant also continued to work full time which made it difficult to complete the daily commitment required by the AA intervention. One participant's work schedule varied and had multiple the daily commitment required by the AA intervention. Two participants initially felt less pain symptoms. However, one participant felt little improvement after a few days and the other participant felt a little more pain (1 – 2 scores in the VAS) . Those two participants decided to withdraw from this study.

Table 1. Descriptive Statistics of the Participants

Characteristics		Completed Study (N = 14)	
		N	%
Age (Mean/Range)		63 (42 – 81)	
Gender			
	Male	8	57.14
Ethnithity			
	White	5	35.71

Asian	5	35.71
Afrincan American	3	21.42
More than one ethnicity/Hispanic	1	7.14
Marital Status		
Married	9	64.29
Separate	2	14.29
Divorced	2	14.29
Never married	1	7.14
Employment		
Retired	7	50.00
Unemplyed	3	21.42
Working	4	28.57
Education		
High school graduate or equivalent	6	42.86
Technical or vocational school	2	14.29
College graduates	2	14.29
Postgraduate degree	4	28.57
Smoking Status		
Current Smoker	1	14.29
Former Smoker	6	42.86
Drinking Status		
Current drinker	4	28.57
Former drinker	7	50.00
Health insurance		

Yes	14	100.00
Sleep Hours (Mean/Range)	6 (2.50 – 8.00)	
Previous CAM use	8	57.14
Medical History		
HTN	5	35.71
DM	5	35.71
Hyper-cholesterol	4	28.57
Hypothyroid	3	21.42
Type of Cancer		
Breast	5	35.71
Stomach	2	14.29
Prostate	3	21.42
Liver	1	7.14
Larynge	1	7.14
Pituitary gland	1	7.14
Myeloma	1	7.14
Cancer Stage		
Stage I	5	35.71
Stage II	3	21.42
Stage III	4	28.57
Stage IV	2	14.29
Cancer Treatment		
Chemotherapy	11	78.57
Radiatiotherapy	10	71.43

	Surgery	10	71.43
	Immunotherapy	1	7.14
Years of Cancer		5.7 (0.30 – 23.00)	

Pain Location, Severity, and Pain Medication at the Baseline

The most frequent complained pain locations were feet (N = 10, 71.43%), followed by finger(s) (N = 8, 57.14%), back (n = 6, 42.86%), and arm and shoulder (N = 3, 21.42%). Pain severity was measured 'Worst Pain,' 'Least Pain' 'Average Pain,'and 'Right Now Pain.' The pain severity score is rated from 0 (no pain) to 10 (pain as bad as you can imagine) with anchor words at either end in the BPI-SF and the VAS. The score of 3 is considered a high pain level in all sub-categories' pain. 'Worst Pain' is defined that pain severity was the most unpleasant pain rate among all kinds of pain levels which a person experiences. 'Least Pain' is defined that a person experiences least pain among unpleasant various level of pain. 'Average Pain' is defined that an average rate among all kinds of pain levels which a person experiences. 'Right Now Pain' is pain level you measure a patient experiences at the very moment. The mean'Worst Pain' score was 7.75, ranged from 3 to 10 and more than most of scores were more than 8 (N = 8, 57.14%). The mean 'Least Pain' score was 3.86, ranged from 0 to 8 and most scores were less than 2 (N = 5, 35.71%). The mean 'Average Pain' score was 5.46, ranged from 3 to 10 and the most scores were 3 or 4 (N = 6, 42.86%). The mean 'Right Now Pain' score was 4.57, ranged from 0 to 10 and the most scores between 2 and 3 (N = 7, 50.00%). Thirteen participants (92.86%) in this study had neuropathic pain (NP).

Pain Severity and locations

Pain Severity	Completed Study (N = 14) (Mean/Range)
Worst Pain	7.75 (3 – 10)
Least Pain	3.86 (0 – 8)
Average Pain	5.46 (3 – 10)
Right Now Pain	4.57 (0 – 10)
Pain Medication (N/%)	7 (50.00%)
Neuropatic pain	13 (92.86%)
Pain locations	
Feet	10 (71.43%)
Finger(s)	8 (57.14%)
Back	6 (42.86%)
Arm(s)	3 (21.42%)
Shoulder(s)	3 (21.42%)
Stomach	2 (14.29%)
Neck	2 (14.29%)
Head	1 (7.14%)
Leg(s)	1 (7.14%)
Prostate	1 (7.14%)
Hip	1 (7.14%)
Tongue	1 (7.14%)

Half of the participants (N = 7) utilized pain medication. The remaining

participants did not utilize pain medications due to the undesired side effects or poor efficacy. The mean score of Medication Quantification Scale (MQS) III among all participants at the baseline was 6.06. Additionally, the mean score of MQS III among participants with neuropathic pain was 5.35. There was no difference of the mean score of MQS between all participants and participants with neuropathic pain because only one patient did not have neuropathic pain. The patient did not take pain medications because he or she thought pain medications did not relieve the pain.

Medication Quantification Scale (MQS III)

Participants who completed Study (N = 14)

Drug	Dose (mg/day)	Detrimental Weight	X	Dose Level	X	Frequency (day)	MQS scores
Tylenol	650mg	2.2	x	3	x	0.6	3.96
Aspirin	81mg	3.4	x	3	x	3	30.60
Advil	800mg	2.2	x	3	x	0.03	2.86
Motrin	600mg	2.2	x	3	x	0.5	0.20
Tramadol	50mg	2.3	x	2	x	0.8	3.68
Hydrolochlorothiazid	25mg	2.0	x	2	x	1	4.0
						Total score	42.46

Medication Quantification Scale (MQS III)

Participants who had Neurpathic Pain (N = 13)							
Drug	Dose (mg/day)	Detrimental Weight	X	Dose Level	X	Frequency (day)	MQS scores
Tylenol	650mg	2.2	x	3	x	0.45	3.96
Aspirin	81mg	3.4	x	3	x	3	30.60
Advil	800mg	2.2	x	3	x	0.03	2.86
Motrin	600mg	2.2	x	3	x	0.5	0.20
Tramadol	50mg	2.3	x	2	x	0.8	3.68
						Total score	37.47

Neuropathic Pain Scale (NPS) is a validated tool to measure the effect of an intervention on cancer patients with neuropathic pain (NP). The NPS is rated from 0 (no pain) to 10 (worst pain) with anchor words at either end, or a total score, ranging from 0 to 100. The higher scores indicate worse pain levels. If the level of NP decreases of more than 20 scores, the NP gets better. Ninety three percent of participants had NP. The score of 40 is considered a medium NP level. The mean NPS was 48.60 ±14.69 (22 – 68) which indicated medium and high NP among participants.

Pain Interference at the baseline

The pain interference score corresponds to the seven items. The seven items are general activity, walking, work, mood, enjoyment of life, relations with others, and sleep. This pain interference scale has two dimensions (factors): emotion and activity

(function). The items of emotional dimension in pain interference are mood, enjoyment of life, and relations with others. The items of functional dimension in pain interference are general activity, walking, work, and sleep. The pain interference score is rated from 0 (does not interfere) to 10 (completely interferes) with anchor words at either end.

The mean score of 3 items of emotional dimension in pain interference was 3.85±1.82. The mean score of 4 items of functional dimension in pain interference was 4.32±1.59. The item with the hightest mean score of pain interference scores was general activity at 5.10. The item with the lowest mean score among the 7 items of the pain interference scores was relations with others at 2.00.

Quality of life at the baseline

The SF-8 Health Survey was used to measure quality of life. The SF-8 Health Survey is divided into two components which are physical component score (PCS: the mean of below 5 items: general health (GH), physical functioning (PF), role physical (RP), bodily pain (BP), and vitality (V)) and mental component score (MCS: the mean sum of below 3 item ; social functioning (SF), mental health (MH), and role emotional (RE)) (Rog et al., 2007). Each item of the SF-8 was assessed using a 5- or 6-point Likert scale. Each sum score of PCS and MCS and individual score in PCS and MCS with higher scores indicate lower quality of life. Each item has 5 scores except 2 items which are GH and BP with 6 scores. The mean PCS was 37.75 ± 4.86 (Mean ± SD) and the mean MCS was 47.35 ± 8.96 (Mean ± SD).

Quality of life Statistics of the Participants

Item (score range)	Completed Study (N = 14) Mean±SD
General health (22.81 – 59.45)	42.50±6.63
Physical functioning (21.46 – 54.05)	42.44±7.38
Role physical (23.01 – 53.98)	39.73±4.77
Bodily pain (25.45 – 60.77)	39.24±5.94
Vitality (28.14 – 61.83)	46.07±6.15
Social functioning (23.44 -55.26)	42.92±8.02
Mental health (21.40 – 56.79)	48.19±6.62
Role emotional (21.66 – 52.42)	42.69±6.94
PCS (10.00 -67.00)	37.75±4.89
MCS (8.00 – 70.00)	47.35±8.96

Depression at the baseline

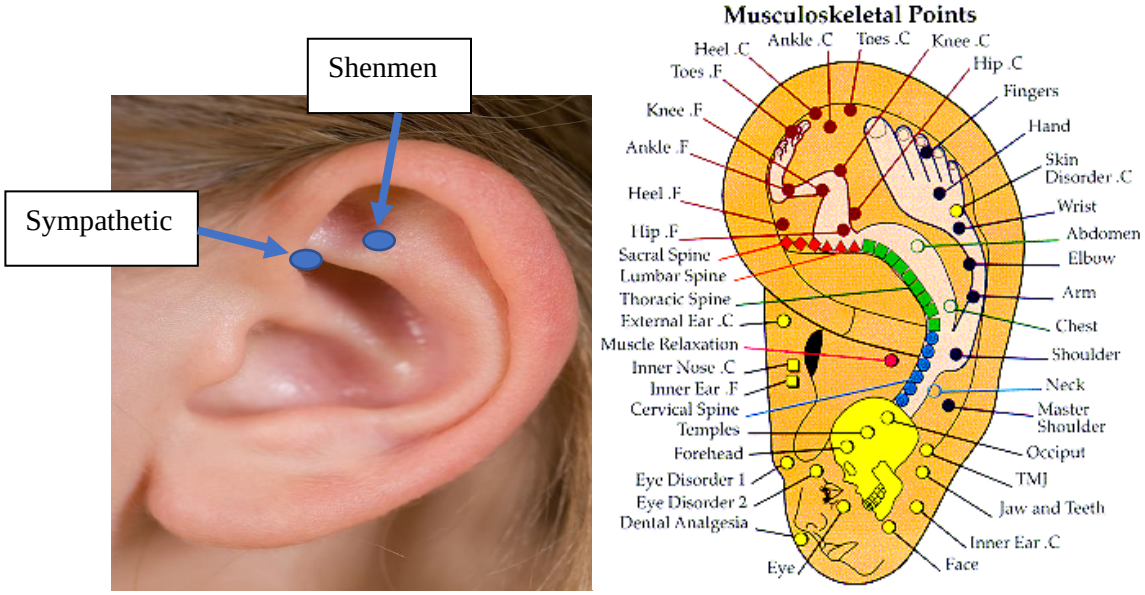
The of PHQ-2 was used to measure depression. The PHQ-2 was ranged the total score from 0 to 6. If the score of 3 or greater is cut point, a patient is more likely to have a major depressive disorder.

Auricular Acupoint(s)

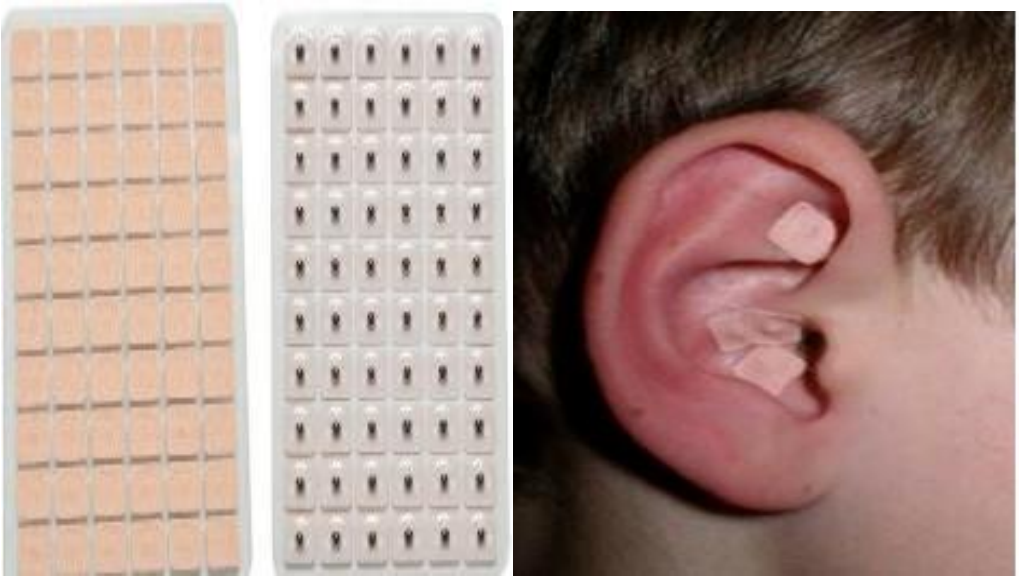
According AA intervention protocol, practice, and acupuncturist's recommendation, two points which are Shenmen and Sympathetic point were used for all participants . ShenMen (also known as Gate of Pain) is believed that it treats many

symptoms and diseases such as pain, stress, anxiety, depression, inflammatory diseases, etc (Cheng, Deng, 程莘农., & 邓良月., 2010). Sympathetic point controls sympathetic nervous system activation with parasympathetic sedation (Cheng et al., 2010). Those two points usually are used and considered to decrease pain and regulate blood circulation and blood pressure.This sympathetic point is usually just attached with a seed without pressing. If a person presses a seed, it results reverse effect of pain and other symptoms. Shenmen acupoint was located on the superior and central to the apex of the triangular fossa. Sympathetic point is located on the inside of the helix following the path of the lower part of the antihelix crus. In addition to those two auricular acupoints, auricular acupoints that correspond to the location of the individual's pain are stimulated. The mean auricular acupoints were 4.60±1.02 points with range from 3 points to 6 points. Those selected acupoints were confirmed by an acupoint finder.

Figure 3. Auricular Acupoints and Instruments



https://sites.google.com/site/acupunctureherbsreiki/home/acupuncture/permanent-ear-acu



https://sites.google.com/site/acupunctureherbsreiki/home/acupuncture/permanent-ear-acu

https://sites.google.com/site/acupunctureherbsreiki/home/acupuncture/permanent-ear-acu

Results of Hypothesis Testing

Hypothesis 1

From July through October 2019, 21 cancer patients with pain were enrolled to participate in this study. All participants met the study's inclusion and were willing to commit to AA intervention for 4 weeks.

All participants signed the Institutional Review Board (IRB) approved informed consent prior to AA intervention. However, 7 participants who dropped out happened right after enrollement (N = 5) and two week after AA treatment (N = 2). They had to drop out of the study for the following reasons: busy work schedule (N = 4), unknown (N = 1), and no improvement in pain symptoms (N = 2). Their data were not included in the final analyses for the study. Fourteen of the 21 cancer participants completed the study. Participants for this study were recruited (N = 600) and additional participants were enrolled (N = 21) more than the target sample size (N = 12) in consideration of an attrition rate of approximately 30% for an intervention study. The attrition rate of this study was 33%.

There were five recruitment strategies for this study. Two recruitment strategies were very successful for this study. First, most participants in local community centers such as Korean community center (N = 2), Spanish community center (N = 1), black community center (N =2) in New Jersey were recruited. Second, the remainder of the participants were recruited by participant's friends (N = 5), family members (N = 1), and aquaintance or church members (N = 3). Among them, most (N = 13) had heard, knew, or experienced some modalities of CAM therapy and 8 participants had previous experience with CAM therapy. However, no participants had experience auricular

acupressure. After one week of AA treatment, there was no additional attrition. Three recruitment strategies had not been successful. First, Facebook social media commercial recruitment was not successful because only one person responded to the PI as compared to smoking cessation studies (Carter-Harris, Hermann, Schreiber, Weaver, & Rawl, 2014). Facebook advertisement was expensive to recruit patients. More than 220 cancer patients or healthcare providers expressed that they liked the AA intervention for cancer patients with pain, but declined due to increased pain from prior pain intervention. Second, many oncology physicians did not refer patients or were not asked for patient referrals because of their lack of knowledge of CAM therapies and AA therapy. Third, cancer survivor organizations were recruited, but they did not give the PI permission or referral from them to solicit their members due to their lack of knowledge of CAM therapies and AA therapy and a trust issue of AA intervention.

The daily diary was the major source of compliance data in the AA intervention. The participants were asked to document the date, any significant pain symptoms, and frequency, amount of time, and adverse effects of AA treatment, pain severity (worst pain) on the Visual Analog Scale (VAS) for pain and daily analgesic use. The recording of daily diary in this study might be unreliable and burdensome for the participants. However, the recording of a daily diary is quite important since the participants need to evaluate their pain levels at their home and the AA intervention. Thus, the PI texted the study participants every day to ask for pain scores and daily diary entries and called every week as well.

Fourteen participants continuously adhered to the protocol (99.40%) and all participants completed (100%) the 4-week intervention study (Table 2). More than half of

the participants reported they thought the first 3 minutes were not long to massage each AA acupoint. However, when they felt 3-minute massage was so long. Some of them reported that it was time consuming to record whenever they conducted AA intervention. Seven participants said that they would continuously use this daily diary after this study because they can monitor themselves and help understand the change of their pain. Compliance data of the daily diary and AA intervention were presented below. Ten of the 14 patients completed 116% of the survey and the AA intervention because those participants completed more than 60 times AA intervention throughout AA intervention duration. Only 2 participants met the required the total number of AA sessions (60 times) on the protocol; one participant missed 3 times and one participant missed 1 time out of 60 times AA intervention over one month intervention period. However, all participants completed AA intervention more than 75%. The range of frequency of usage of AA intervention was from two times (N = 2) to 6 times (N = 2) a day.

Table 2. Compliance Data Analysis

N	Total Mean of Minimum N of AA session	% of Complicance
10	69.40	116%
2	60	100%
1	59	98%
1	57	95%

Hypothesis 2

Pain Severity Change in 4 week AA Intervention

Non-parametric analysis using Friedman's test was used to compare pain severity change ('Worst Pain,' 'Least Pain,' 'Average Pain,' and 'Right Now Pain') of the potential analgesic effect of the AA intervention during the 4 week period. The cut point of adjust *p* value was **0.05**. Wilcoxon signed rank test were used as post hoc tests when the Friedman test found statistically significant change over four weeks within the group.

There were statistically significant differences on all pain levels: 'Worst Pain' [$\chi^2(4) = 43.05$, $p < .01$; a decrease from mean of 7.75 points (baseline) to mean of 2.73 (week 4)]; 'Least Pain' [$\chi^2(4) = 14.11$, $p < .01$; a decrease from mean of 3.86 points (baseline) to mean of 2.11 (week 4)], 'Average Pain' [$\chi^2(4) = 14.17$, $p < .01$; a decrease from mean of 5.46 points (baseline) to mean of 3.18 (week 4)], and 'Right Now Pain' [$\chi^2(4) = 11.75$, $p = .02$; a decrease from mean of 4.57 points (baseline) to mean of 2.00 (week 4)] in 4 weeks on AA treatment. Thus, Wilcoxon signed rank test was conducted on all of them because all those pain levels were statistically significant on the Friedman's test. The number of comparision of each pain level was 10 pairwise comparisons. The 'Worst Pain' scores were significantly decreased during the AA intervention except between week 3 vs. week 4 among 10 pairwise comparisons. Furthermore, Worst pain' scores already attained the greatest decrease of more than 50% worst pain reduction at week 3. Sixty five percent of reduction in 'Worst Pain' among participants was attained at the end of AA intervention. 'Least Pain'score was significantly decreased only between week 1 vs. week 4. 'Average Pain' scores were significantly decreased during the AA intervention except between week 1 vs. week 2,

week 1 vs. week 3, week 1 vs. week 4, and week 3 vs. week 4 among 10 pairs. 'Right now Pain' scores were significantly decreased during the AA intervention except between baseline vs. week 1, baseline vs. week 2, week 1 vs. week 2, week 2 vs. week 3, and week 3 vs. week 4 among 10 pairs.

Table 3. Pain Severity Analysis

Friedman Test for Difference of Pain Severity						
Pain Levels	Baseline	1 week	2 week	3 week	4 week	*p*
	(Mean/Standard Deviation)					
Worst Pain	7.75	4.27	3.37	2.91	2.73	**.00**
	(2.55)	(1.99)	(2.50)	(2.42)	(2.56)	
Least Pain	3.86	3.21	2.29	2.04	2.11	**.01**
	(3.06)	(2.83)	(2.55)	(2.93)	(2.57)	
Average Pain	5.46	4.07	4.00	3.21	3.18	**.01**
	(2.24)	(2.81)	(2.21)	(2.55)	(2.38)	
Right Now Pain	4.57	3.71	2.68	2.07	2.00	**.02**
	(3.52)	(2.81)	(2.77)	(2.64)	(2.57)	

Wilcoxon signed rank test for pain comparison between two weeks				
Compared 2 weeks	Worst Pain	Least Pain	Average Pain	Right Now Pain
(N = 10 pairs)	*p*	*p*	*p*	*p*
Baseline vs. 1 week	**.00**	.48	**.02**	.32
Baseline vs. 2 week	**.00**	.10	**.05**	.09

Baseline vs. 3 week	**.00**	.06	**.02**	**.02**
Baseline vs. 4 week	**.00**	.07	**.02**	**.03**
1 week vs. 2 week	**.01**	.24	.96	.22
1 week vs. 3 week	**.00**	.08	.33	**.04**
1 week vs. 4 week	**.00**	**.04**	.26	**.02**
2 week vs. 3 week	**.01**	.59	**.03**	**.04**
2 week vs. 4 week	**.02**	.75	**.02**	.09
3 week vs. 4 week	.37	.79	.93	1.00

Neuropatic Pain Scale (NPS) Change in 4 week AA Intervention

The NPS was used to measure whether AA intervention can change NP condition among 13 participants in this study. More than 20 mean score change in the NPS over an intervention indicates the intervention is effective for neuropathic pain.

The greatest number of participants who decreased more than 20 scores in the NPS was 8 participants (61.54%) at week 3, followed by 7 participants (53.85%) at week 4 and 6 participants (46.15%) at week 1. There were no participants who were more than 20 scores decreased on the NPS between week 2 and week 3, week 2 and week 4, and week 3 and week 4. There were statistically significant differences in the NPS among 13 participants with NP [$\chi^2(4) = 14.11$, $p = .01$; a decrease from mean of 48.62 points (baseline) to mean of 19.62 (week 4)]. The NPS scores were significantly decreased during the AA intervention except between week 1 vs. week 2, week 1 vs. week 3, week 2 vs. week 3, and week 3 vs. week 4 among 10 pairs.

Table 4. Neuropathic Pain Analysis

Numbers of participants who decreased more than 20 scores in the NPS **(N = 13)**	
Compared 2 weeks (N = 10 pairs)	Number (Percentage)
Baseline vs. 1 week	**6 (46.15%)**
Baseline vs. 2 week	5 (38.46%)
Baseline vs. 3 week	**8 (61.54%)**
Baseline vs. 4 week	**7 (53.85%)**
1 week vs. 2 week	3 (23.08%)
1 week vs. 3 week	4 (30.77%)
1 week vs. 4 week	2 (15.38%)
2 week vs. 3 week	0 (.00%)
2 week vs. 4 week	0 (.00%)
3 week vs. 4 week	0 (.00%)

The NPS mean score had declined by more 20 mean score at the week 2 of AA treatment (26.35 ± 18.64) from the baseline (48.6 ± 14.69) among the 13 participants. The NPS continuously declined again after week 2. At the end of AA intervention (week 4), the NPS score was the lowest point at 19.62 (13.28).

Neuropatic Pain Scale (NPS) Statistics of the participants (N = 13)						
	Baseline	1 week	2 week	3 week	4 week	*p*
		(Mean/Standard Deviation)				
NPS	48.62	31.15	26.35	21.46	19.62	**.00**
	(14.69)	(20.20)	(18.64)	(14.83)	(13.28)	

Wilcoxon signed rank test for neuropathic pain comparison between two weeks	
Compared 2 weeks (N = 10)	NPS *p*
Baseline vs. 1 week	**.00**
Baseline vs. 2 week	**.00**
Baseline vs. 3 week	**.00**
Baseline vs. 4 week	**.00**
1 week vs. 2 week	.43
1 week vs. 3 week	.14
1 week vs. 4 week	**.05**
2 week vs. 3 week	.07
2 week vs. 4 week	**.01**
3 week vs. 4 week	.78

Pain Interference during AA Intervention

Non-parametric analysis using Friedman's test was used to compare pain severity change ('Emotional Pain Interference,' and 'Functional Pain Interference') of the effect of AA intervention during 4 week period. The items of 'Emotional Pain Interference' in the BPI-SF are mood, enjoyment of life, and relations with others. The items of 'Functional Pain Interference' in the BPI-SF are general activity, walking, work, and sleep. The cut point of adjust *p* value was **.05**. Wilcoxon signed rank test were used as a post hoc test when the Friedman test found a statistically significant change over four weeks within the group.

Pain interference is devided into 2 categories which are 'Emotional Pain Interference' and 'Functional Pain Interference,' There were statistically significant differences in 'Emotional Pain Interference' ($\chi^2(4) = 26.75$, $p < .00$) from mean of 3.85 points at the baseline to mean of .97 point at week 4 and 'Functional Pain Interfernce' ($\chi^2(4) = 20.03$, $p < .00$) from mean of 4.32 points at the baseline to mean of 1.91 points at week 4. Thus, Wilcoxon signed rank test were conducted on both 'Pain Interference' scores because those 'Pain Inteference' scores were statistically different on the Friedman's test. The number of comparisions of each pain level was 10 pairs. The 'Emotional Pain Interference' scores were significantly decreased from the baseline to 4 week AA intervention except between week 1 vs. week 2, week 1 vs. 3, week 1 vs. week 4 and week 2 vs. week 3. 'Emotional Pain Interference' scores were than 50% reduction at week 2 from the baseline. ' Emotional Pain Interference' score was continuously decreased by 74.80% at the end of this study. 'Functional Pain Interference' score was significantly decreased between baseline vs. week 1, baseline vs. week 2, baseline vs.

week 3, and baseline vs. week 4 ($p < .05$). 'Functional Pain interference'scores attained more than 50% reduction at week 3 from the baseline as well. 'Functional Pain Interference' score was continuously decreased by 55.79% at the end of this study.

Table 5. Pain Interference Analysis

Friedman Test for Difference of Pain Interference (PI)						
	Baseline	1 week	2 week	3 week	4 week	*p*
	(Mean/Standard Deviation)					
Emotional PI	3.85	2.04	1.69	1.81	.97	**.00**
	(1.82)	(1.53)	(1.45)	(1.62)	(1.24)	
Functional PI	4.32	2.59	2.31	1.91	1.91	**.00**
	(1.59)	(2.37)	(1.74)	(1.66)	(1.66)	

Wilcoxon signed rank test for pain interfernce comparison between two weeks		
Compared 2 weeks (N = 10)	Emotional pain *p*	Functional pain *p*
Baseline vs. 1 week	**.00**	**.01**
Baseline vs. 2 week	**.01**	**.01**
Baseline vs. 3 week	**.01**	**.00**
Baseline vs. 4 week	**.00**	**.00**
1 week vs. 2 week	.59	1.00
1 week vs. 3 week	.81	.33
1 week vs. 4 week	.06	.33
2 week vs. 3 week	.75	.08

2 week vs. 4 week	**.01**	.08
3 week vs. 4 week	**.01**	1.00

Pain Medication during AA Intervention

The mean score of medication on the Medication Quantification Scale (MQS) III at the baseline was 6.06 in all participants and 5.35 in participants with NP. The mean score of medication at week 2 was almost 2 times higher than the mean score of it at the baseline because two patients just started chemotherapy at week 2 of AA intervention in the both groups. The usage of medication had declined by 58% from week 2 to the end of AA intervention among all the participants. The usage of medication had declined by 62% from week 2 to the end of AA intervention among the all participants. There was no big different pain medication usage whether patients had NP or not because one participant without NP usually did not take pain medication.

Table 6. Pain Medication Analysis

	Medication Quantification Scale (MQS) III	
Week	Participants who completed study **(N = 14)**	Participant who had NP **(N = 13)**
Baseline	6.06	5.35
1	5.76	5.05
2	10.16	9.45
3	5.36	4.65
4	4.26	3.55

Quality of Life Status during 4 week AA Treatment

The SF-8 was utilized to assess for quality of life using a 5- or 6-point Likert scale. The mean sum scores of Physical Component Summary (PCS) and Mental Component Summary (MCS) indicate that a higher score indicates higher quality of life. Non-parametric analysis using smWilcoxon signed rank test was used to compare quality of life on the effect of AA intervention from at the end of AA therapy (post-test) to baseline (pre-test). There were statistically significant mean score differences on 'Genral Health ($Z = -2.11$, $p = .04$),' 'Bodily Pain ($Z = -2.54$, $p = .01$),' 'Vitality ($Z = -2.23$, $p = .03$),' 'Social Function ($Z = -2.54$, $p = .01$) and 'PCS ($Z = -3.05$, $p < .00$)' between the pre-test and post-test. Furthermore, 'Bodily Pain' mean scores attained greater than 23% increase at the post-test compared to pre-stest. 'Phsical Component Summary' and 'Social Punction' mean scores was increased by 21% and 17% respectively.

Table 7. Quality of Life Analysis

Wilcoxon signed rank test for quality of life comparison between pre- and post AA **(N = 14)**				
Items (score range)	Pre-test	Post-test	*Z* *(Post - Pre)*	*p*
	(Mean/Standard Deviation)			
General Health (22.81 - 59.45)	42.50 (6.63)	46.54 (5.24)	-2.11	**.04**
Physical Functioning (21.46 - 54.05)	42.44 (7.38)	45.55 (7.79)	-1.48	.14
Role Physical (23.01 - 53.98)	39.73 (4.77)	44.76 (7.34)	-1.92	.06
Bodily Pain (25.45 – 60.77)	39.24 (5.94)	48.39 (7.36)	-2.54	**.01**
Vitality (28.14 – 61.83)	46.07 (6.15)	50.09 (6.11)	-2.23	**.03**

Social Functioning (23.44 – 55.25)	42.92 (8.02)	50.01 (5.84)	-2.54	**.01**
Mental Health (21.40 – 56.79)	48.19 (6.62)	48.50 (8.33)	-.28	.77
Role Emotional (21.66 – 52.42)	42.69 (6.94)	45.19 (7.95)	-1.12	.26
PCS (10.00 – 67.00)	37.75 (4.89)	45.59 (7.06)	-3.05	**.00**
MCS (8.00 – 70.00)	47.35 (8.96)	49.53 (8.26)	-.82	.41

Depression Status during 4 week AA Treatment

Three or greater of total scores of six in the PHQ-2 would indicate a major depressive disorder. McNemar test was conducted to evaluate if the AA intervention can change depression status between pre- and post-test. Even though 30% of participants had been reduced less than 3 scores in the PHQ-2, there was no significant difference between pre-test (N = 7, 50.00%) and post-test (N = 4, 28.57%).

Table 8. Depression Analysis

Depression Scores Statistics of the Participants (N = 14)			
	Pre-test (N/%)	Post test (N/%)	*p*
PHQ (≥3)	7 (50.00%)	4 (28.57%)	.13

Additional Findings of Unexpected Findings

As weeks went by, the compliance rate had increased because all participants complied to the AA intervention after 2 weeks of the intervention period. The side effects

of AA intervention in the study were redness (N = 2, 14.29%), itching (N =1, 7.14%), and uncomfortness (N =5, 35.71%) in the ear. Nothing was major side effect. Participants reported satisfaction with this AA intervention around 95%. At the end of the intervention, either 12 participants or their family members could conduct AA therapy on their own. All participants would recommend AA intervention to any cancer paitent with pain. At the end of the first week, there were two unexpected events that happened. Two participants did not know their acupuncture seeds dislodged during sleep. They became aware of this when they attemped to massage the seeds and found them missing. One participant forgot to wear an ear cap during a shower which was prvided before the AA intervention. These participants had to wait a few hours for replacements which was inconvenient for them. After these incidents, the PI revised the IRB allowing participants to attach one or two seeds before the weekly visit if they were confident after receiving training. Two suggestions to include for the next AA study. When the acupuncturists trained participants in the AA intervention, the PI asked all participants to bring their mirror due to funding limitations. Two participants thought bringing their mirror was inconvenient and used mirrors that were availoable on site. One participant suggested that an increase in the minimum times per day for the AA intervention would be beneficial to force him or her to do additional AA intervention.

Chapter V

Discussion of the Findings

The purpose of this study was to evaluate the feasibility and potential analgesic effect of an auricular acupressure (AA) intervention on cancer patients experiencing pain. This chapter presents a synthethized analysis of all the findings based on the hypothesis and the Chronic Care Model (CCM). Self-management (SM) refers to patients with any disease who manage their symptoms, treatments, and lifestyle changes in daily life using the combined knowledge, skill, and confidence for their health goals. For instance, a patient sets health-related goals, assesses his or her health, implements his or her health goals, solves his or her health problem, or adheres to follow-up health-related visits. There are many advantages in SM interventons. First, SM interventions are likely easy to use by patients in their daily life because patients can be taught to safely self-administer the intervention. Second, SM intervention modalities may decrease medical costs by reducing visits to physicians. Third, patients who use SM intervention can minimize the disruption in their daily life activities due to self-administration (Eun You, 2019).

Self-management support can be valuable for a patient who build an SM for his or her health. One of the best SM supports is healthcare providers who can tailor or enhance SM skills or ability by SM interventions, such as AA therapy, for their unpleasant symptoms. Self-management support according to the CCM should be processed through ongoing **a**ssessment, **a**dvice, **a**greement, **a**ssistance, and **a**rrangement (5A) by healthcare providers. The 5A process, assessment can occur at the beginning of SM support, but advice, agreement, assistance, and arrangement cannot be linearly occurred. The PI assessed how the participants conducted AA intervention and daily diary and level of

pain on the participants when participants started to enroll in the study. After enrollment of this study, assessment was continuously conducted throughout daily diary, every call, or text message. The PI's can decide whether advice, agreement, assistance, arrangement, or combining steps altogether based on the assessment. For example, after assessment of the participants' AA skills and practice, the PI sometimes gave advice and more training of conducting AA intervention. The PI sometimes set up pain goals, more AA training, and recommended to increase the frequency of AA intervention.

Attrition Rate, Self-Adherence, and Completion of 4 week- AA Therapy in Cancer Patient with Pain.

Seven participants who dropped out happened right after enrollment (N = 5) and two week after AA treatment (N = 2). They had to drop out from the study for the following reasons: busy work schedule (N = 4), unknown (N = 1), and no improvement in pain symptoms (N = 2). The 33% attrition rate in this study is similar or slightly greater than the 20-30 % attrition rates seen in three previous AA intervenion studies in cancer patients (Yeh, Chien, Chiang, Ren, & Suen, 2015; Yeh, Chien, Lin, Bovbjerg, & Van Londen, 2016; Yeh, Suen, Park, Londen, & Bovbjerg, 2017) as well as previous AA intervention in other populations (E. You, Kim, Harris, & D'Alonzo, 2018). Although before those participants received instruction and explanation of procedure and process of this study, they still did not think through whether they can commit this study or not. It would be better to remind their committement for this stuy before they sign the consent form. To decrease attrition rate, a research team may carefully reinforce and explain the research process to participants before they decide to participate.

Participants in this study reported that they experienced the benefits of AA intervention over the 4 weeks. As a result, participants adhered to this AA intervention at 99.40% and completed the AA intervention at 100%. Electronic diary can be utilized to enhance adherence rate and completion rate because some people may prefer to electronically fill out daily diary instead of paper and pen method. Most of participants adhered and completed AA intervention because they thought they could have a SM skill sets of AA intervention after the stdy. Thus, they could manage their pain symptoms better due to their SM skill sets. However, more research and practice based on SM theory such as the CCM will be required to effectively deliver an SM intervention.

Eighty six percent of participants or their family members (N = 12) can conduct AA therapy at the end of intervention. Two participants felt needed more time AA therapy on their own due to the difficulty in locating the accupoints attaching seeds to the acupoints. Although high number of the participants and their families reported they could self-administered AA therapy. Further research will be needed in order to have more evidence of their SM experience on AA intervention.

Unlike many critical side effects of pain medications, the side effects of AA intervention in the study were mild such as redness (N = 2, 14.29 %), itching by tape (N =1, 7.14%), and uncomfortness (N =5, 35.71%) in the ear. Participants reported 95% of satisfaction with this AA intervention. All participants would recommend AA intervention to any cancer patient with pain for other cancer patients. Therefore, this high satisfaction of AA intervention and mild side effects of AA intervention explains that AA intervention is safe and can feasibly utilized by cancer patients at their home.

Pain Severity, Neuropathic Pain, Pain Inteference, and Pain Medication Usage

Research has been reported on the positive effects on AA therapy which has been conducted on many kinds of pain severity, pain interference, and pain medications, including cancer pain, lower back pain (Yeh, Chien, Liang, & Glick, 2015; Lin et al., 2015), dysmenorrhea (Cha & Sok, 2016; Yeh, Hung, Chen, & Wang, 2013), post-operative knee pain (He, Tong, Li, Jing, & Yao, 2013), post-operative back pain (Chung, Tsou, Chen, Lin, & Yeh, 2014;), and acute post-partum perineal pain (Kwan & Li, 2014). In this pilot study, AA therapy decreased pain severity ('Worst Pain,' 'Least Pain,' 'Average Pain,' and 'Right Now Pain') pain interference (physical function and emotion) in cancer patients with pain.

In the pain severity, 'Worst Pain'mean scores at 65%, 'Least Pain' scores at 45%, and 'Average Pain' scores at 42%, and 'Right Now Pain' at 56% were decreased at the end of the 4 week-AA intervention from baseline. Furthermore, all levels of pain scores showed a statistically significant decline from baseline through the 4 week of AA intervention. Many studies have reported that 'Worst Pain' scores were the most sensitive and valid among other pain severity domains (Jensen et al., 2015; Cha & Sok, 2016; Yeh, Hung, Chen, & Wang, 2013). Those study results were consistant with previous studies (Jensen et al., 2015; Cha & Sok, 2016; Yeh, Hung, Chen, & Wang, 2013). 'Worst Pain' score in the wilcoxon signed rank test in the study showed statistically significant decrease throughout the 4 week of AA intervention except between week 3 vs. week 4 among 10 pairwise comparisons. 'Worst Pain' score was continuously decreased at the end of the intervention period. However, 'Least Pain'score was significantly declined only between week 1 vs. week 4. Importantly, this AA intervention could not give us a

longer pain severity effect on the AA intervention. Additional research is required to give us more information for an optimal period of relieving pain severity oon AA intervention.

Thirteen participants with NP (92.86%) in this study was greater mix of the general U.S. cancer population (About 40%). However, the common locations of NP in this study were hands and feet. These locations for NP are similar with the general U. S. cancer population. The NPS score had been quickly decreased by more than 20 mean score which indicates improved NP by the AA treatment from the baseline (48.6 ± 14.69) to week 2 (26.35 ± 18.64) among 13 participants. The NPS mean scores was continuously lower from week 2 to the end of this study. Usually NP is difficult to improve because it gets worse and slowly recovered. Thus, research is required to retrieve more evidence of longer effect of AA therapy to improve or retain NP.

There are two dimensions in the "Pain Interference' which are 'Emotional Pain Interference' and 'Functional Pain Interference.' The two 'Pain Interference' scores showed a statistically significant decline throughout the 4 week of AA intervention. In addition, the two 'Pain Interference' scores showed more than a 50% reduction at week 2 from the baseline, 'Emotional Pain Interference' and 'Functional Pain Interference' mean scores had decreased by 74.80 % and 55.79 % respectively at week 2 from the baseline. 'Emotional Pain Interference' mean score at week 2 and 'Functional Pain Interference' mean score at week 3 were less than 3 mean score which equates to mild pain interference. Thus, this short AA intervention period could not give us us a longer pain interference effect on the AA intervention. Additional research is neeed to give us more information for an optimal period of declining pain interference on AA intervention.

The Medication Quantification Scale III was used to measure usage of pain

medication among participants in the study. The mean score of medication consumption at week 2 was almost 2 times increased than at the baseline because two patient just started chemotherapy at week 2 of the AA intervention. However, the usage of medication had been greater decreased from week 2 to the end of the AA intervention by 58% and 62% in both the all participants and participants with NP respectively. Additional research will be required how AA intervention differently affects on sensory pain and NP in cancer patients.

In summary, pain severity, pain interference, and the NP showed a statistically significant decrease throughout the 4-week AA intervention. 'Worst Pain,' 'Right Now Pain,' 'Pain Interference,' and the NPS scores attained more than a 50% reduction throughout AA intervention. There was no different response between 'Pain Severity' and 'Pain Interference. However, some studies have been reported that 'Pain Interference' scores are more sensitive response than 'Pain Severity' scores (Jensen et al., 2017; Bendinger & Plunkett, 2016). This may occur because people are slower to realize that their pain has decreased. Pain medication did not sooner respond as much as 'Pain Severity' and 'Pain Interference. The above results showed that SM intervenion such as AA therapy is very promissing to control cancer pain under SM support. Importantly, in order to get a full benefit for cancer pain, cancer patients should self-administer AA therapy at their home. Healthcare providers also continue to monitor their pain level and their AA intervention.

Quality of Life and Depression as Cancer Pain Changes

Many studies have reported that chronic pain, depression, and quality of life are

associated to each other (Francis et al., 2019; Cheng, Deng, 程莘农., & 邓良月., 2010; Wilson et al., 2014). The mean score of all items in the SF-8 including the PCS or MCS indicates that a higher score in either equates to a higher quality of life. There showed a statistically significant increase on 'General Health,' 'Bodily Pain,' 'Vitality,' 'Social Function and 'PCS' between the pre-test and post-test. The 'Bodily Pain' mean scores was increased by 23%, followed by'PCS (21%)' and 'Social Function (17%).' There was no significant result in the MCS score so it may require a longer AA intervention in order to affect the MCS score on the SF-8. Even though 30% of participants had shown a reduction of less than 3 scores in the PHQ-2 between the pre-test and post-test, there was no statistically significant different changes. It may require a longer AA therapy to improve depression.

In summary, as pain severity and pain interference improved in this study, body pain and physical component in quality of life had also improved during the 4-week AA intervention period. However, the depression score did not show a statistically significant improvement in this study. The above results showed that SM intervenion such as AA therapy is very promissing to control cancer pain under SM support. Consequently, well controlled cancer pain likely enhances quality of life. Thus, a cancer patient tries to engage more self management skill and behavior.

Limitations

Threats to Internal Validity

In an experimental or pilot research, internal validity should be assured that solely an independent variable is impacting on a dependent variable. Thus, a finding from a

study can be seen in the general phononema in every day life. According to Flannelly and Jankowski (2018), internal validity can be threatened by selection bias, maturation, history, regression, instrumentation, testing, and motality. In this study, selection bias, instrumentation, and motality may threaten internal validity.

Selection Bias. All participants voluntarily joined this study and were interested in using CAM therapy. Many cancer patients with pain who did not want to join this study reported various reasons such as their physicians did not recommend, they were not familiar with CAM therapy, there was no scientific evidence on CAM therapy, they were so sick to join this study, and they were to busy to join this study due to cancer treatment, work schedule, or family commitment. The participants who joined this study were so motivated. The participants also joined this study that they thought AA therapy would benefit their pain symptoms. This could lead a positive effect of this study not due to AA intervention. These psychological effects are hardly seperated from true AA intervention effect. The psychological (placebo) effects have been reported any kind of desirable interventions participants receive regarding their symptoms or diseases (Howick & Hoffmann, 2018). Randomization is the solution for selection bias. Further research with a randomized controlled trial will be required to avoid selection bias.

Attrition. Most of the attrition (N = 5) occurred after enrollment. It may carefully reinforce the research process and to attain verbal acknowledgement of the participant's understanding of the AA intervention procedure and commitment prior to enrollment. All participants had similar pain profiles, but there were some different demographics between the participants who left the study and the participants who remained in this

study. For instance, the participants who completed this study tended to be older, married, have medical insurance, have different cancer types such as breast, prostate, and stomach as compared to ovary, cervix, bladder, and kidney. However, all pain and neuropathic pain (NP) charateristics, depression status, and quality of life scores were the same between the two groups.

Instrumentation. Pain level may be affected by three acupuncturists' experience and skill sets although they all had the same NJ acupunture licensed. The acupuncturists used the same transcript when they administered the AA intervention, but the acupuncturists had different years of experience which could affect the study outcomes. However, there was a limited budget, and one acupuncturist could not be hired solely for this study. The availability of three acupuncturists easily met the constraints of the participant's schedules. Yeh et al. (2016) hired one acupuncturist due to adequate funding to conduct their AA intervention research. Furure research is required to avoid the instrumentation bias and hire one acupuncturist to do all of the AA intervention.

External Validity

Although most of the charateristics of this study's participants except the prevalence of NP were similar with the general U.S. cancer population, generalizability is limited due to the small number of participants. According to the National Cancer Institute in 2018, the four most common cancers in the United States were breast cancer, lung cancer and bronchus cancer, and prostate cancer among general cancer population (National Cancer Institute, 2018). This study included participants with a variety of

cancer diagnoses but did not include anyone with lung cancer. Neuropathic pain is prevalent in approximately 40% of cancer patients who report pain in general (National Cancer Institute, 2018). However, 13 participants (92.86%) in this study had NP. The number of participants with NP was recruited showed a large rate. However, the life expectancy for general U.S. cancer patients is often reported as a five-year survival rate. Further research with a randomized controlled trial will increase external validity.

Other limitations

Recruitment. This study utilized a convenience sample. Cancer patients were recruited by self-referral from Facebook social media, pain management clinics, local community centers, cancer survivor groups, Rutgers University School of Nursing building in Newark and New Brunswick and from referrals from participants' family members or friends. Over the four -month period, 600 flyers were distributed in the central New Jersey area by email or visiting the above recruitment sites. A small number of potential participants with cancer (N =17) who experienced pain responded to participate in this study due to lack of knowledge and trust of CAM and AA therapy. Unfortunately, three participants were not able to participate in the study because they did not meet the inclusion and exclusion criteria, the distance from the study site, or they were unable to drive due to their illness or their busy schedule.

Possible Contamination of AA intervention. Contamination of AA treatment effect may occur when participants use other methods of CAM therapy without notice to the PI during the AA intervention period. This can contaminate the pain reports. Inaccurate

reports in the daily diary log for AA treatment such as over report or under report of AA daily treatment can contaminate adherence rate of AA intervention and pain results. Although the participants adhered to AA treatment and diary notations at 99.40%, the participants reported a greater decrease in levels of pain if they adhered to the AA treatment at 100% at least three times per day. Lastly, all participants (N = 14) had postive opinions or views of CAM therapy and 8 participants had previous positive experiences of CAM therapy. These factors could have an influence on subjective pain reports in the surveys. It may contaminate the pain results due to a psychological placebo effect.

Chapter VI

Summary, Conclusions, Implications, and Recommendations

Summary

The purpose of this study was to evaluate the feasibility and potential analgesic effect of an auricular acupressure (AA) intervention on cancer patients experiencing pain. This study was based on the Chronic Care Model (CCM) which is one of the well developed self-management theories. According to the CCM, when patients are well equiped with self-management (SM) skills, knowledge, and ability, the patients can control their diseases and unpleasant symptoms. Eventually, the participants can achieve their health goals, decrease depression, and increase quality of life. Self-management support can assist a patient to build SM for his or her health. One of the best SM supports is the healthcare provider who can use SM interventions such as AA therapy. The process of SM support includes ongoing assessment, advice, agreement, assistance, and arrangement. Auricular acupressure (AA) is a new and innovative SM intervention. Auricular Acupressure is taught to be self-administered in the patient's home. The participant is required to attain knowledge, a skill set, and confidence for AA self-administration. Healthcare providers assess how the participants conducted AA intervention and level of pain on the participants. Assessment for AA therapy is continuously occurred with many ways such as patient follow-up and consults etc. The healthcare providers can decide to process whether advice, agreement, assistance, or arrangement based on the assessment. This study was a pilot study based on the CCM to support cancer patients to control their pain using AA therapy. Thus, this study may warrant a larger study for the future. The first hypothesis was that more than 75% of

cancer participants in this study might complete AA intervention as an adjunctive therapy for the 4 weeks. The second hypothesis was that AA therapy might change pain severity, pain interference (physical function and sleep etc.), quality of life, and depression in cancer patients with pain.

The AA intervention for this study was conducted with adult female and male participants who were diagnosed and treated or treating cancer and experienced pain (more 3 on 0-10 scale). These participants were able to complete AA therapy and speak English because study procedures were conducted in English. Participants were supposed to be recruited through Facebook social media site, a flyer that was posted on public bulletin boards in local community centers and cancer support or survivor groups in New Jersey. Participants were self-referred to this study after hearing of this study from their friends or family members or have seen the flyer. The recruitment goal for the sample size of this study was 12 cancer patients with pain as a minimum number. Survey data was collected on pain severity, neuropathic pain (NP) screening, NP severity, pain interference, pain medications, quality of life, and depression during the 4 week AA intervention period. Study recruitment took place from June through October 2019. At the baseline, participants were taught how to conduct AA therapy and what information to logging in the daily diary for the AA intervention at their home. Participants were also instructed about seed location, attaching seeds, removing seeds, and replacing seeds whenever seeds fell off between visits. At every visit, participant's education was reinforced and retrained on the AA skills and procedure at their home. Participants received a daily text message and weekly discussed over a phone about individual AA intervention, any change in their pain symptoms, any concerns, and next visit schedule.

The BPI and the NPS were given to participants whenever participants weekly visited the research site. Additionally, quality of life and depression were evaluated as levels of pain changed. The SF-8 Health Survey for quality of life and PH-2 for depression were used for this study. Cancer pain were weekly evaluated in this study by pain severity (subjective measure) in the BPI and the NPS and the VAS in the daily diary, pain interference (objective measure) in the BPI and medication use in the daily diary.

The attrition rate was calculated as the percentage of the number of participants left over the given 4-week AA intervention period. The adherence rate was calculated as the percentage of the number of trials of AA intervention as compared to the total number of the AA intervention (60 times) during the given 4-week intervention period. The completion rate was calculated as more than 75% of the AA intervention and the daily diary were conducted during the 4 week intervention period. The 'Pain Severity' of 'Least Pain,' 'Average Pain,' and 'Right Now Pain' scores in the BPI-SF was calculated using Friedman test (non-parametric analysis) by the mean at each visit. 'Pain Interference' scores devided into functional and emotional dementions. 'Pain Interference' score was calculated from the mean by the BPI-SF; the Friedman test was used. Non-parametric analyses were used because of the small sample and high possibility of non-normal distributions of outcome scores. Wilcoxon signed rank test were used as a post hoc test when the Friedman test found a statistically significant change over 4 weeks. Additionally, NP change for pain severity was calculated the mean from each visit by the NPS. More than 20 mean score change over an intervention indicates the intervention is effective for NP.

Of the 21 participants who were enrolled in this study, there was attrition of 7

participants resulting in a 33% attrition rate. Most of the participants who withdrew (N = 5) were immediately after the baseline visit. Most participants were recruited through local community (N = 5), participant's friends (N = 5), family members (N = 1), and aquaintance or church members (N = 3). The 33% attrition rate in this study was similar or little higher than the previous AA intervenion studies at 20-30% in cancer patients (Yeh, Chien, Chiang, Ren, & Suen, 2015; Yeh, Chien, Lin, Bovbjerg, & Van Londen, 2016). Participant adhered this AA intervention at 99.4% and completed AA intervention at 100%. The data from the participants who withdrew from the study was not included in the data analysis as it did not meet the inclusion criteria. All 'Pain Severity' scores were significantly decreased from the baseline to post AA intervention by 'Worst pain' by 65%;'Least Pain' scores at 45%, 'Average Pain' scores at 42%; and 'Right Now Pain' at 56%. Thirteen participants (93%) in this study had NP. It is that more participants in the study had NP than general U.S. cancer population (About 40%). Neuropathic pain commonly affects the hands/fingers and feet and slowly responds to medications or treatments in the general U.S. cancer population (van Hecke, Austin, Khan, Smith, & Torrance, 2014). Neuropathic pain in this study also affected hands and feet which equaled the distribution in the general U. S. cancer population. The NPS mean score had quickly declined by more than 20 by week 1 of AA treatment from the baseline among the 13 participants with NP. The NPS mean scores had been kept decreasing after the first week until the end of this study. The two 'Pain Interference' mean scores were attained more than 50% reduction at week 3 from the baseline; 'Emotional Pain Interference' mean scores and 'Functional Pain Interference' mean scores had been decreased by 75% and 56% respectively. 'Emotional Pain Interference' mean score at week 2 and

‘Functional Pain Interference’ mean score at week 3 were less than 3 (equates to mild pain) out of 0-10. The mean comsumption of pain medication continously and slowly declined throughout the study except for week 2 where it had increased by 2 times from the baseline. This could possibly be explained as 2 participants started chemotherapy at week 2 and the mean NPS was worse than the previous visit. However, the usage of medication was decreased by 30% from the baseline to the end of AA intervention. For quality of life in the study, Physical Component Sumary (PCS) mean score statistically decreased by 21% ($p < .05$). Although the Mental Component Summary (MCS) mean score had decreased by 17%, its mean score decrease in the study was not statistically significant between pre-and post- test. For depression score, there was 30% of participants decreased depressive symptoms between the pre-test and post-test, however, the difference was not statistically significant.

Conclusion

Many studies have reported that AA therapy is a good SM intervention method since a patient can administer it themselves (Yeh, Chien, Chiang, Ren, & Suen, 2015; Yeh, Chien, Lin, Bovbjerg, & Van Londen, 2016; Yeh, Suen, Park, Londen, & Bovbjerg, 2017). It empowers patients to engage their health care, is cost effective, and is effective to control their pain symptoms (You, 2019). Most participants in this study (N = 12) were able to apply, replace, and massage seeds at their home as utilizing the proces of SM support in the CCM. The PI assessed AA skill, knowledge, and confidence on each participant in the study. Based on the assessment of AA intervention skill, knowledge, and confidence, either advice, agreement, assistance, or arrangement were followed.

Thus, the 12 participants and their family members were able to conduct AA therapy on their own at the end of the intervention. Participants were also satisfied at 95% with this AA therapy and expressed that they would recommend this treatment modality to their friends and other cancer patients who experience pain.

This AA intervention study had shown a statistical significance in pain severity and pain interference like three previous AA studies among the participants. Unlike previous AA studies, this study had examined on NP severity, quality of life, depresion as cancer pain changed. Neuropathic pain severity and the PCS in quality of life scores had shown a statistical significant reduction in this study. However, depression and the MCS in quality of life scores had not shown a statistical significant enhancement.

Implication for Nursing

Cancer pain can be caused by a tumor, infiltration of a tumor, progression of cancer (inflammatory or infection), and treatments (surgeries, chemotherapy, radiation, immunotherapy) (National Cancer Institute, 2018). Many cancer patients seek better solutions to manage their pain other than pharmachologic treatment, including forms of complementary or alternative medicine (CAM) such as AA therapy bcause pain medications have many serious side effects including addiction (You, 2019).

Self-management refers to patients with any disease who manage their symptoms, treatments, and lifestyle changes in daily life. Self-management support can be worthwhile for a patient who builds an SM for his or her health. One of the best SM supports is healthcare providers who can utilize SM skills or ability by SM interventions. According to the process of SM support in the CCM (ongoing assessment, advice,

agreement, assistance, and arrangement), it would be more effective utilizing a multidisciplinary team including an oncologist, nurse, social worker, peer group, and patient's family members (Coleman, Austin, Brach, & Wagner, 2009). Thus, this CCM based systematic approach is effective to support SM for cancer patients with pain. The PI assessed how the participants conducted AA intervention and daily diary and level of pain on the participants when participants started to enroll in the study. After enrollment of this study, assessment was continuously conducted throughout daily diary, every call, or text message. The PI's can decide whether advice, agreement, assistance, arrangement, or combining steps altogether based on the assessment. In order to understand evidence of the process of SM support in the CCM for cancer patients with pain, further research is required.

Recommendations

Further research with AA therapy is required to build on the evidence on the effect of AA intervention due to the small number of AA studies, the lack of scientific evidence of AA therapy, pain mechanism, and protocols of AA therapy (frequency, duration, and intensity). In order to advance the science of AA therapy, the future AA research should include relevant physiological biomarkers and assure that high-quality methodologies such as randomized controlled trial (RCT).

Auricular acupressure education for health professionals is required to enhance their understanding of the usage and mechanism of AA therapy for their patients. Most of physicians hardly referred their patients to licensed CAM practitioners because they do not have a proper understanding, knowledge, and education of CAM (Wahner-Roedler et

al., 2014). Physicians and nurses need basic education of CAM so they can communicate about AA therapy with their patients who are interested in using it. Thus, healthcare providers should feel confident considering this AA therapy as pain management plan for their patients. Importantly, nurses are the largest of the healthcare professions and the most-trusted profession in the United States. Nurses can educate AA therapy as a SM intervention to decrease patients'pain symptoms.

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Appendix A

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Auricular acupressure as an adjunct treatment in cancer patients with pain: A pilot study.
Principal Investigator: Eunhea You, MSN, RN-BC
Co-Investigators: William Holzemer, PhD, RN, Judith Barberio, PhD, Peija Zha, PhD, Karen WeiRu Lin, MD, MS, FAAFP

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. The purpose of the research is to evaluate the feasibility and effect of auricular acupressure (AA) intervention on cancer patients experiencing pain. If you take part in the research, you will be asked to sign this informed consent form. Your time in the study will take 4 weeks. Possible harms or burdens of taking part in the study may be minor ear discomfort and itching in AA studies when applying AA activity and this may happen to you and possible benefits of less pain and high body function. An alternative to taking part in the research study is exercise and acupuncture. Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After all of your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research study?
Principal Investigator (PI) You, PhDc, MSN, RN is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

PI. You may be reached at Rutgers University, School of Nursing
110 Paterson Street, New Brunswick, NJ 08901
Phone: 347-604-0071
Email: ey100@sn.rutgers.edu

The principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

SPONSOR OF THE STUDY: The Graduate School at Rutgers University, The State University of New Jersey, is sponsoring this study.

Why is this study being done?
The purpose of this study is to evaluate the application and effect of auricular acupressure (AA) intervention on cancer patients experiencing pain. The research that tests the effectiveness of AA has been conducted in many samples of persons who experience pain, including dysmenorrhea, postoperative pain, hip fracture, and low back pain. However, there are few studies that have assessed the effect of AA on cancer pain. AA is one type of complementary or alternative medicine (CAM) therapy that has been used to treat and manage pain; it is usually used as an adjunctive therapy. AA is a type of acupressure therapy that is used on the ear. AA uses the same acupoints as acupuncture but is performed without needle insertion. This study may provide evidence that AA can assist cancer patients to better self-manage their pain especially pain intervention study at their home.

Who may take part in this study and who may not?
You may participate in this study if:

- You have been diagnosed with pain in cancer and had pain intensity of 3 or higher on a 10-point numerical pain scale
- You have completed your cancer therapy at least 90 days before enrollment in this study.
- You are willing to follow instructions on applying pressure on your ears (acupressure points) at least three times and whenever you have pain.
- Able to speak, read, and understand the English language. Rationale: study procedures will be conducted in English.

You may not participate in this study if:

- Inability/unwillingness to undergo questionnaire completion or AA treatment.
- Having received any ear acupressure or acupuncture 3 months prior to entry into this study.

Why have I been asked to take part in this study?
You may or may not have direct effect on cancer pain management. However, your participation can help us understand if it can be to use AA in management of pain in cancer patients. AA intervention study may decrease your pain and the consumption of pain medications.

How long will the study take and how many subjects will take part?
You are one of approximately 20 participants who will be invited to take part in the study. This study is being done at a site. The site is:

Rutgers, The State University of New Jersey The School of Nursing
110 Paterson Street

New Brunswick, NJ 08901 or
180 University Avenue, Newark, NJ, 07102
Study and Site Principal Investigator, Eunhea You, MSN, RN
Once your participation starts, your participation will be for five (5) visits (Baseline visit, the end of 1st week, 2nd week, 3rd week, and 4th week) during the month.

What will I be asked to do if I take part in this study?
When you agree to participate in this study you will sign this informed consent document and we will give you a copy of it. As a participant you will be asked to come to the study site for five visits. The activities for each visit are listed below.

Visit 1: Baseline and pain information (2.5 hours)

At this visit you will fill out these questionnaires:

Consent form

Baseline information:

- Contact Information, Enrollment Form and Demographic form (age, gender, marital status, education, occupation, diagnosis, time since diagnosis/last treatment, treatments, medical and cancer history)

Pain related information:

- Neuropathic Pain Screening Tool– screens neuropathic pain
- The BPI Short Form and Neuropathic Pain Scale (NPS) – measures pain or neuropathic pain level
- PHQ-2 – measures mental health
- SF-8 Health Survey- measures quality of life

Auricular Acupressure Intervention Training

We will use one group (AA intervention group) to evaluate the feasibility of AA intervention on cancer patients experiencing pain. Once the baseline assessment is completed, AA group will be taught to apply tape and acupressure seeds (stimulators) by repeatedly pressing the AA acupoints with the fingertips for 3 minutes per point three times per day and whenever pain arises, for one month. The AA therapy will be taught to patients based on standard practice by certified acupressure personnel. Prior to implementing AA intervention, all staff will have a 3 weeks' orientation for training AA intervention and data collection. All the acupoints will be selected by the certified acupressure personnel, depending on common pain areas for cancer patients and the literature. An electronic acupoint finder will be used to identify the selected acupoints at the first week of intervention. Seeds will be replaced every week with new seeds, and whenever cancer patients request. For the usage of the ear seeds, the following two methods are commonly being used in general acupuncture clinics. The first one is done by an acupuncturist in the clinic and the second one is done by a patient at home. Since it is common for ear seeds to typically fall out and a standard of care for an acupuncturist is to teach a person how to reinsert ear seeds the

following will happen. An acupuncturist will teach all study participants how to reinsert ear seeds when they fall out before the session is over. Patients will be taught how to replace the ear seeds between appointments. I will ask the participants to call me if they are unable to reinsert the ear seeds. Phone calls will remind you of your follow-up visits and the weeks you must monitor your pain and AA intervention 24 hours a day. You will also be given a daily diary. Intervention fidelity is measured using AA practice at home (AA frequency, level of pain before and after AA, amount of time to apply AA, adverse effects, and usage of pain medications). The daily diary will be collected every visit.

Week	Baseline	1	2	3	4
Baseline Questionnaire	X				
Pain Questionnaires	X	X	X	X	X
Phone follow-up	X	X	X	X	X
Daily Diary/ BPI short Form	X	X	X	X	X

<u>Visits 2 - 5</u>: Through Week 1 (+ or – 1 week) to the end of the study – Week 4 (1 hour)

- You will fill out the BPI
- You will return daily diary for the week
- Replace seeds on the ears
- The table below shows the scheduled activities you will be doing during the study.

Feasibility of the auricula acupressure

We are interested in whether this AA intervention is easy to administer to cancer patients with pain. So, we will collect your opinions. We will collect your opinions when we make our weekly phone calls and during your clinic visits.

What are the risks and/or discomforts I might experience if I take part in this study?

Auricular acupressure, when properly prescribed; carries a low risk of injury. You will receive individual directions for AA intervention and contact information whenever you need help. There have reported some side effects such as minor ear discomfort and itching in AA studies when applying AA activity and this may happen to you. If you have those side effects while you are applying AA, which can pose a risk of snapping back and hurting you. For that reason, we teach you the proper use of AA.

Are there any benefits to me if I choose to take part in this study?

The benefits of taking part in this study may be less pain and high body function.

However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
The following alternative treatments are available if you choose not to take part in this study: Acupuncture or exercise

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you during or after the study is completed, you will be personally contacted by PI, Eunhea You or the research assistant.

Will I receive the results of the research?
In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. Again, during the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you during or after the study is completed, you will be personally contacted by PI You or the research assistant.

Will there be any cost to me to take part in this study?
There will be no cost to you to participate in this study.

Will I be paid to take part in this study?
Participants will be provided with a total of $70.00 in gift cards (as compensation for their time), plus reimbursement for transportation required for each visit. The gift cards will be issued at each visit ($20 at baseline and $10 for the next three visits, and $20 for the final visit).

Who might benefit financially from this research?
None of the researchers will benefit financially from this study.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.
To protect your identity, you will be assigned a code number. The list of names of participants with the assigned identification numbers will be securely stored and kept locked, at the study site, separately from all the data collected. Participating and answering questions is completely voluntary, and your responses are confidential. All data forms will be securely stored in a locked cabinet in Rutgers Nursing School at the study site. All data will be entered in a password protected, web-based, study specific, database with encryption capability. At the end of the study all data forms will be kept securely and destroyed by shredding after 6 years as per standard Rutgers IRB protocol.

What will happen to my information or biospecimens collected for this research after the study is over?
The information collected about you for this research will not be used by or distributed to investigators for other research.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.
If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled. You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to *Eunhea You (principal investigator), 110 Paterson Street, New Brunswick, New Jersey, 08901.*
If you withdraw your consent, all data collected will be immediately shredded and destroyed using recycling services provided by Rutgers University. All information entered in the computer will also be erased and not included in the analysis or any other part of the study. At any time, the Principal Investigator or research assistant can take you out of this study because it would not be in your best interest to stay in it. Your study PI can stop AA even if you are willing to stay in the study. If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can I call if I have questions?
If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the PI:
Eunhea You, MSN, RN-BC, Tel: (347) 604-0071
Rutgers University, School of Nursing, 110 Paterson Street, New Brunswick, NJ
If you have questions about your rights as a research subject, you can call the IRB Director at:
: Newark HealthSci (973)-972-3608; or the Rutgers Human Subjects Protection Program at (973) 972-1149.

AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____

Appendix B

CASE REPORT FORM

AURICULAR ACUPRESSURE AS AN ADJUNCT TREATMENT IN CANCER PATIENTS WITH PAIN: A PILOT STUDY

Participant Study Number:	| | | | | |
Date:	| | | | | |

General Instructions for Completion of the Case Report Forms (CRF)

Completion of CRFs

- A CRF must be completed for each study participant who is successfully enrolled
- For reasons of confidentiality, the name and initials of the study participant should **not** appear on the CRF.

General

- Please print all entries in BLOCK CAPITAL LETTERS using a **black** ballpoint pen.
- All text and explanatory comments should be brief.
- Answer every question explicitly; do not use ditto marks.
- Do not leave any question unanswered. If the answer to a question is unknown, write "**NK**" (Not Known). If a requested test has not been done, write "**ND**" (Not Done). If a question is not applicable, write "**NA**" (Not Applicable).
- Where a choice is requested, **cross (X)** the appropriate response.

Dates and Times

- All date entries must appear in the format DD-MMM-YYYY e.g. 05-May-2009. The month abbreviations are as follows:

January	=	Jan	May	=	May	September	=	Sep
February	=	Feb	June	=	Jun	October	=	Oct
March	=	Mar	July	=	Jul	November	=	Nov
April	=	Apr	August	=	Aug	December	=	Dec

In the absence of a precise date for an event or therapy that precedes the participant's inclusion into the study, a partial date may be recorded by recording "NK" in the fields that are unknown e.g. where the day and month are not clear, the following may be entered into the CRF:

N	K	N	K	2	0	0	9
DD		MMM		YYYY			

- All time entries must appear in **24-hour format** e.g. 13:00. Entries representing midnight should be recorded as 00:00 with the date of the new day that is starting at that time.

Correction of Errors

- **Do not** overwrite erroneous entries, or use correction fluid or erasers.
- Draw a straight line through the entire erroneous entry without obliterating it.
- Clearly enter the correct value next to the original (erroneous) entry.
- Date and initial the correction.

PARTICIPANT INFORMATION		
Participant Number	☐☐☐☐☐	
Date of Enrolment	D D M M M Y Y Y Y	
Inclusion/exclusion criteria	Met all ☐1.	Not met* ☐2.
Date of Informed Consent	D D M M M Y Y Y Y	
Date of Birth	D D M M M Y Y Y Y	Or estimated age _____
Gender	☐1 Male ☐2 Female	
Ethnicity	☐1 White ☐2 African American ☐3 Asian ☐4 American Indian/Alaska Native ☐5 Native Hawaiian ☐6 More than one ethnicity ☐7 Choose not to answer	
Hispanic or non-Hispanic	☐1 Yes ☐2 No ☐3 Choose not to answer	
Marital Status	☐1 Married ☐2 Living with partner ☐3 Separated ☐4 Divorced ☐5 Widowed ☐6 Never Married	
Employment	☐1 Working ☐2 Not employed Occupation:	
Education Level	☐1 High school graduate or equivalent ☐2 Technical or vocational school ☐3 College graduates ☐4 Postgraduate degree	
Health Insurance	☐1. Yes	☐2. No

Has the subject ever smoked?	☐1. Yes, complete below	☐2. No	
☐ Current Smoker ☐ Former Smoker	Average number smoked per day: Smoked for _____months / years.		
Has the subject ever drank?	☐1. Yes, complete below	☐2. No	
Alcohol consumption	Wine units per: _____week / month Beer units per: _____week / month Spirits units per: _____week / month		
Approximately, how many hours do you sleep a day?	_____Hrs		
Date of Cancer Diagnosis	D D M M M Y Y Y Y		
Location of Cancer			
Stage of Cancer	☐1 I ☐2 II ☐3 III ☐4 IV		
Chemotherapy	☐1. Yes **Date:**	☐2. No	☐9. Unknown
Radiation therapy	☐1. Yes **Date:**	☐2. No	☐9. Unknown
Surgery for cancer removal	☐1. Yes **Date:**	☐2. No	☐9. Unknown
Immunotherapy	☐1. Yes **Date:**	☐2. No	☐9. Unknown

MEDICATION HISTORY (within the last 30 days)

- Make multiple copies of this page if required

Medication Name (write NK if unknown)	**Start Date**	**Stop Date**
____________	D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
____________	D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
____________	D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
____________	D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
____________	D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
____________	D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
____________	D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
____________	D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
____________	D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
____________	D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
____________	D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing
____________	D D M M M Y Y Y Y OR ☐1 Unknown	D D M M M Y Y Y Y OR ☐1 Ongoing

SIGNIFICANT MEDICAL HISTORY (within the past 5 years)

- Make multiple copies of this page if required

Does the participant have a history of any background/concomitant conditions/symptoms according to the following schedule? ☐1 Yes ☐2 No

If **Yes**, detail in the table below and reference the ICD10 system code
http://apps.who.int/classifications/apps/icd/icd10online/

Code	Title	Code	Title
1	Certain infectious and parasitic diseases	12	Diseases of the skin and subcutaneous tissue
2	Neoplasms	13	Diseases of the musculoskeletal system and connective tissue
3	Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	14	Diseases of the genitourinary system
4	Endocrine, nutritional and metabolic diseases	15	Pregnancy, childbirth and the puerperium
5	Mental and behavioural disorders	16	Certain conditions originating in the perinatal period
6	Diseases of the nervous system	17	Congenital malformations, deformations and chromosomal abnormalities
7	Diseases of the eye and adnexa	18	Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified
8	Diseases of the ear and mastoid process	19	Injury, poisoning and certain other consequences of external causes
9	Diseases of the circulatory system	20	External causes of morbidity and mortality
10	Diseases of the respiratory system	21	Factors influencing health status and contact with health services
11	Diseases of the digestive system	22	Codes for special purposes

SIGNIFICANT MEDICAL HISTORY (within the past 5 years)

Code	Condition/Symptom	Onset Date	Stop Date
		D D M M M Y Y Y Y *OR* ☐1 Unknown	D D M M M Y Y Y Y *OR* ☐1 Ongoing
		D D M M M Y Y Y Y *OR* ☐1 Unknown	D D M M M Y Y Y Y *OR* ☐1 Ongoing
		D D M M M Y Y Y Y *OR* ☐1 Unknown	D D M M M Y Y Y Y *OR* ☐1 Ongoing
		D D M M M Y Y Y Y *OR* ☐1 Unknown	D D M M M Y Y Y Y *OR* ☐1 Ongoing

Appendix C

Participant study Number: Date:

The Patients Health Questionnaire

Over the past 2 weeks, how often have you been bothered by any of the following problems?	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3

Appendix D

Participant study Number: Date:

Neuropathic Pain Scale

1. Please use the scale below to tell us how intense your pain is. Circle the number that best describes the intensity of your pain.

No pain 1 2 3 4 5 6 7 8 9 10 The most intense pain sensation imaginable.

2. Please use the scale below to tell us how sharp your pain feels. Words used to describe "sharp" feeling include "like a knife, "like a spike," "jabbing" or "like jolts."

No sharp 1 2 3 4 5 6 7 8 9 10 The sharpest sensation imaginable ('like a knife")

3. Please use the scale below to tell us how hot your pain feels. Words used to describe very hot pain include "burning" and "on fire."

No hot 1 2 3 4 5 6 7 8 9 10 The hottest sensation imaginable ("on fire")

4. Please use the scale below to tell us how dull your pain feels. Words used to describe very dull pain include "like a dull toothache," "dull pain," "aching' and "like a bruise."

No dull 1 2 3 4 5 6 7 8 9 10 The dullest sensation imaginable

5. Please use the scale below to tell us how cold your pain feels. Words used to describe very cold pain include "like ice" and "freezing"

No cold 1 2 3 4 5 6 7 8 9 10 The coldest sensation imaginable ("freezing")

6. Please use the scale below to tell us how sensitive your skin is to light touch or clothing, Words used to describe sensitive skin include "like sunburned skin" and "raw skin."

No sensitive 1 2 3 4 5 6 7 8 9 10 The most sensitive sensation imaginable ("raw skin")

7. Please use the scale below to tell us how itchy your pain feels. Words used to describe itchy pain include "like position oak" and "like a mosquito bite"

No itchy 1 2 3 4 5 6 7 8 9 10 The itchiest sensation imaginable ('like position oak")

8. Now that you have told us the different physical aspects of your pain, the different types of sensations, we want you to tell us overall how unpleasant your pain is to you. Words used to describe very unpleasant pain include “miserable” and “intolerable.” Remember, pain can have a low intensity, but still feel extremely unpleasant, and some kinds of pain can have a high intensity but be very tolerable. With this scale, please tell us how un pleasant your pain feels

Not unpleasant 1 2 3 4 5 6 7 8 9 10
The most unpleasant sensation imaginable (“intolerable”)

9-10. Lastly, we want you to give us an estimate of the severity of your deep versus surface pain. We want to rate each location of pain separately. We realize that it can be difficult to make these estimates, and most likely it will be a “best guess,” but please give us your best estimate.
No

Deep pain 1 2 3 4 5 6 7 8 9 10
The most intense deep pain sensation imaginable

No Surface pain 1 2 3 4 5 6 7 8 9 10
The most intense surface pain sensation imaginable

11. Which of the following best describes the time quality of your pain? Check only one answer
( ) I feel a background pain all of the time and occasional flare-ups (break-through pain) some of the time.
( ) I feel a single type of pain all the time.
( ) I feel a single type of pain only sometimes. Other times, I am pain free.

Appendix E

Neuropathic Pain Screening Tool

Participant study Number:
Date:

Please choose Yes or No.

- Does the pain have one or more of the following characteristics?

Burning:	☐1. Yes	☐2. No
Painful cold:	☐1. Yes	☐2. No
Electric shocks:	☐1. Yes	☐2. No

- Is the pain associated with one or more of the following symptoms in the same area?

Tingling:	☐1. Yes	☐2. No
Pins and needles:	☐1. Yes	☐2. No
Numbness:	☐1. Yes	☐2. No
Itching:	☐1. Yes	☐2. No

- Is the pain located in an area where the physical examination may reveal one or more of the following characteristics?

Little stimulation to touch:	☐1. Yes	☐2. No
Little stimulation to pinprick:	☐1. Yes	☐2. No

- In the painful area, can the pain be caused or increased by:

Brushing:	☐1. Yes	☐2. No

Patient's Score: /10

Appendix F

Participant study Number: Date:

SF-8 Health Survey

This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities. Answer every question by circling an answer as indicated.

1. Overall, how would you rate your health during the **past 4 weeks**?
Excellent Very Good Good Fair Poor Very Poor

2. During the **past 4 weeks**, how much did physical health problems limit your physical activities (such as walking or climbing stairs)?
Not at all Very little Somewhat Quite a lot Could not do physical activities

3. During the **past 4 weeks**, how much difficulty did you have doing your daily work, both at home and away from home, because of your physical health?
Not at all Very little Somewhat Quite a lot Could not do physical activities

4. How much bodily pain have you had during the **past 4 weeks**?
None Very mild Mild Moderate Severe Very Severe

5. During the **past 4 weeks**, how much energy did you have?
Very much Quite a lot Some A little None

6. During the **past 4 weeks**, how much did your physical health or emotional problems limit your usual social activities with family or friends?
Not at all Very little Somewhat Quite a lot Could not do physical activities

7. During the **past 4 weeks**, how much have you been bothered by **emotional problem** (such as feeling anxious, depressed or irritable)?
Not at all Slightly Moderately Quite a lot Extremely

8. During the **past 4 weeks**, how much did personal or emotional problems keep you from doing your usual work, school or other daily activities?
Not at all Very little Somewhat Quite a lot Could not do physical activities

Appendix G

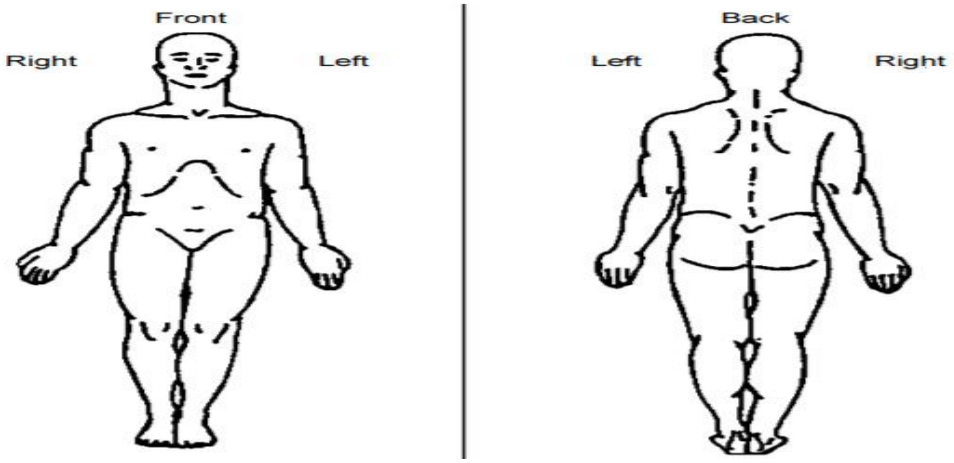
Participant study Number: Date:

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than theses everyday kinds of pain today?

☐1. Yes ☐2. No

2. On the diagram, shade in all the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the number that best describes your pain at its ***worst*** in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

4. Please rate your pain by circling the number that best describes your pain at its ***least*** in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

5. Please rate your pain by circling the number that best describes your pain on the ***average***.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

6. Please rate your pain by circling the number that tells how much pain you have ***right now***.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

_____

_____

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle below the percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No Relief										Complete Relief

9. Circle the number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

C. Walking ability

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

D. Normal Work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

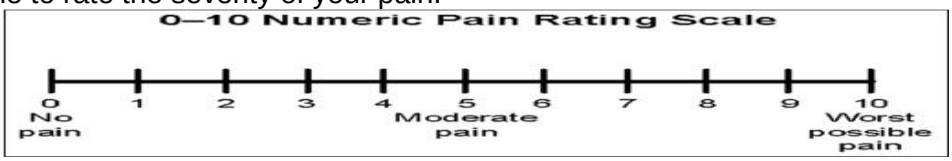
G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Appendix H

Daily Diary

Use this diary to record details about your pain, including how effective the auricular acupressure (AA) treatment was. This will help you keep track of whether AA therapy works or not. Bring this to the research team at your next appointment so your research team can better understand your pain level and how you're doing about AA practice. Use this scale to rate the severity of your pain.



Date	Time	Where was the pain?	Rate from 0-10, Describe pain (Write down words from the back as much as you want)	How many minutes did you press on AA points?	Medicine or supplements: What did you take and how much?	After AA, rate pain again (1-10)	Any side effects of AA therapy	Any other effects? Comments?

Words for pain description

Flickering, Quivering, Pulsing, Throbbing, Beating, Pounding
Jumping, Flashing, Shooting
Pricking, Boring, Drilling, Stabbing, Lancinating
Sharp, Cutting, Lacerating
Pinching, Pressing, Gnawing, Cramping, Crushing
Tugging, Pulling, Wrenching
Hot, Burning, Scalding, Searing
Tingling, Itchy, Smarting, Stinging
Dull, Sore, Hurting, Aching, Heavy
Tender, Taut, Rasping, Splitting
Tiring, Exhausting
Sickening, Suffocating
Fearful, Frightful, Terrifying
Punishing, Grueling, Cruel, Vicious, Killing
Wretched, Blinding
Annoying, Troublesome, Miserable, intense, Unbearable
Spreading, Radiating, Penetrating, Piercing
Tight, Numb, Drawing, Squeezing, Tearing
Cool, Cold, Freezing
Nagging, Nauseating, Agonizing, Dreadful, Torturing