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Acupuncture for the Management of Hot Flashes in Breast Cancer Survivors

AN EVIDENCE-BASED PROJECT

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By

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## Acupuncture for the Management of Hot Flashes in Breast Cancer Survivors

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In the United States, more women are diagnosed with breast cancer than any other type of cancer. As earlier diagnosis and new treatment modalities increase survival for these women, health care practitioners must address long-term problems secondary to cancer therapy. The development of severe hot flashes, affecting up to 85% of breast cancer survivors, can significantly affect quality of life. Many hot flash treatments are ineffective, have intolerable side effects, or are contraindicated for breast cancer survivors. Research supports the use of acupuncture as an effective, safe treatment for minimizing hot flashes in breast cancer survivors.

**Purpose:** The purpose of this evidence-based practice project was to determine if acupuncture is effective at decreasing the number and severity of hot flashes and improving sleep in breast cancer survivors at an urban hospital. The acceptability of acupuncture as a treatment for hot flashes was also explored.

**Design:** The study design for this project was a quasi-experimental pretest-posttest design. Qualitative data was also obtained by interview after participants completed acupuncture treatments.

**Methods:** Eligible women completed a Pittsburgh Sleep Quality Index (PSQI) and recorded hot flash frequency and severity in a hot flash diary for a week before and after acupuncture treatment. Acceptability of acupuncture was assessed using a Likert Scale (1-10). Participants received twice weekly acupuncture treatments for four weeks. Pre and post acupuncture hot flash frequency and severity, PSQI sleep disturbance score, and acceptability ratings were

compared. Participants were interviewed and descriptions of the acupuncture experience examined for themes.

Results: Paired t-test revealed significant improvement in night time hot flash frequency ( $p = 0.04$ ) and severity ( $p = 0.001$ ). Daytime hot flash severity significantly improved ( $p < 0.001$ ) although no significant difference was noted in hot flash frequency ( $p = 0.089$ ). PSQI score was significantly improved following acupuncture ( $p = 0.021$ ). No significant difference was found between pre and post acceptability scores ( $p = 0.428$ ). Participants' descriptions of acupuncture encompassed three themes; acupuncture is (1) effective, (2) relaxing, and (3) painful at times.

Conclusion: Acupuncture can be effective in reducing the severity and frequency of hot flashes in breast cancer survivors.

This Evidence-Based Project by Hollis McClellan Misiewicz fulfills the requirement for the doctoral degree in Doctor of Nursing Practice approved by Janice Agazio, PhD, CRNP, RN as Director, and by Susan Moreland, DNP, CRNP, RN and Susan Appling, PhD, CRNP, RN as Readers.

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Janice Agazio, PhD, CRNP, RN  
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## Dedication

I would like to thank everyone who has helped me through this Evidence-Based Project from start to finish. I am grateful to Janice Agazio, PhD, CRNP, RN who mentored me and kept me on the right track, providing support throughout the project. I would also like to thank Susan Moreland, DNP, CRNP, RN who was always available whenever I had a question or encountered a problem. I am grateful to Susan Appling, PhD, CRNP, RN who helped me navigate the world of research at Mercy Medical Center. I want to thank all the nurses, physicians and supporting staff at Outpatient Chemotherapy and Hematology/Oncology at Mercy Medical Center who encouraged and supported me in this endeavor. I could not have done this without them. A special thanks to my husband, Peter, who spent many hours fixing the computer errors I created and guiding me through the world of IT. Thank you also to my children, Tara, Tracy, Matthew, Brian, and Jeffrey who made me believe this was possible. A special thank you to Tracy who shared her doctoral endeavor stories with me and gave me advice on how to survive.

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## CHAPTER ONE: NATURE OF THE PROJECT

### Introduction

In the United States, more women are diagnosed with breast cancer than any other type of cancer. A woman in this country today has a 12% chance of developing breast cancer in her lifetime (Howlader et al., 2012). In 2011 the number of estimated new cases of breast cancer in women in the United States was 230,480 (American Cancer Society, 2011). Current survival rates for women diagnosed with breast cancer are 89% after 5 years and 75% after 15 years. Since 1990 the mortality rate for breast cancer has been steadily declining. Earlier detection of breast cancers and new modalities for treatment are cited as reasons for this trend. In January of 2008 about 2.6 million women in the United States were alive who had been previously diagnosed with breast cancer (American Cancer Society, 2011). As the number of breast cancer survivors grows, health care practitioners need to address the long-term problems secondary to cancer treatment that these women now face.

### The Problem

For women who have received treatment for breast cancer, one of the most frequent, long-term effects of chemotherapy, selective estrogen-receptor modulators (SERM), and aromatase inhibitors (AI) is the development of the vasomotor symptoms of menopause, most notably, hot flashes (Berger, Treat Marunda, & Agrawal, 2009; Mouridsen, 2006). Hot flashes are described as “recurrent transient periods of flushing, sweating and the sensation of heat, often accompanied by palpitations and a feeling of anxiety, and sometimes followed by chills” (Mohyi, Tabassi, & Simon, 1997, p. 204). These hot flashes can last from two to four minutes (Drisko, 2004). The hot flashes induced by breast cancer treatment occur more frequently and

are more severe than those experienced by the healthy postmenopausal woman (Gross, 2006; Kontos, Agbaje, Rymer, & Fentiman, 2010; Savard, Savard, Quesnel, & Ivers, 2009). The incidence of hot flashes in breast cancer patients ranges from 68% to 85% (Cumins & Brunt, 2000; Hunter, Coventry, Mendes, & Grunfeld, 2009; Schultz, Klein, Beck, Stava, & Sellin, 2005). The cause of hot flashes is attributed to an estrogen deficiency. Cytotoxic agents used to treat breast cancer can induce ovarian failure in premenopausal women causing menopausal symptoms (Savard et al., 2009). The majority of breast cancers are estrogen receptor positive; thus, endocrine treatments, such as SERMs and AIs, are the indicated treatment after chemotherapy or as primary adjuvant therapy. Tamoxifen induces estrogen deficiency symptoms by blocking estrogen receptors at the cellular level (Morales et al., 2004). Aromatase inhibitors prevent the synthesis of estrogen thereby decreasing the circulating estrogen in the body (Morales et al., 2004; Savard et al., 2009). Frequent, severe hot flashes have been linked to a decline in the quality of life (Drisko, 2004; Fenlon & Rogers, 2007; Schultz et al., 2005). Hot flashes experienced by women who have had breast cancer have been shown to cause a significant disruption in sleep (Berger et al., 2009; Fenlon, Corner, & Haviland, 2009; Hunter et al., 2009; Savard, Savard, Trudel-Fitzgerald, Ivers, & Quesnel, 2011). A significant number of breast cancer patients will stop their endocrine treatments early because of severe hot flashes even though this could increase the risk of cancer recurrence (Filshie, Bolton, Browne, & Ashley, 2005; Savard et al., 2009).

Although many therapies have been studied for the treatment of hot flashes in postmenopausal women, not all are effective, nor are all of them appropriate for the treatment of hot

flashes in the breast cancer survivor population. Hormone replacement therapy is most effective in alleviating vasomotor symptoms of menopause but this is contraindicated for women with a history of breast cancer as hormones have been linked to an increase in cancer recurrence (Goodwin et al., 2008; Kenemans et al., 2009; Loprinzi et al., 2006; Marsden, Whitehead, A'Hern, Baum, & Sacks, 2000). Selective serotonin reuptake inhibitor antidepressants (SSRI) have been shown to be effective in decreasing hot flashes (Kimmick, Lovato, McQuellon, Robinson, & Muss, 2006; Stearns, Beebe, Iyengar, & Dube, 2003). SSRIs, however, have the potential to interfere with the effectiveness of tamoxifen in women who are receiving this adjuvant therapy for their breast cancer (Desmarais & Looper, 2009; Kimmick et al., 2006). Other pharmacological interventions have limited effectiveness or significant side effects decreasing their desirability as a treatment for hot flashes (Biglia et al., 2005; Gross, 2006; Kontos et al., 2010; Rada et al., 2010). Many non-pharmacological interventions for the treatment of post-menopausal hot flashes have been shown to be ineffective or there is little data to support their use (Kontos et al., 2010; Rada et al., 2010).

One non-pharmacological intervention that has been investigated in multiple studies and shown to decrease post-menopausal hot flashes in healthy postmenopausal women is acupuncture (Avis et al., 2008; Borud et al., 2009; Cohen, Rousseau, & Carey, 2003; Huang, Nir, Chen, Schnyer, & Manber, 2006; Kim et al., 2010; Nir, Huang, Schnyer, Chen, & Manber, 2007; Painovich et al., 2012; Venzke, Calvert, & Gilbertson, 2010; Vincent et al., 2007). Several studies have also shown efficacy in the management of hot flashes with breast cancer survivors (Deng et al., 2007; de Valois, Young, Robinson, McCourt, & Maher, 2010; Filshie et al., 2005;

Frisk et al., 2008; Hervik & Mjaland, 2009; Nedstrand, Wijma, Wyon, & Hammar, 2005; Porzio et al., 2002; Tukmachi, 2000; Walker, de Valois, Davies, Young, & Maher, 2007; Walker et al., 2010). Acupuncture has few side effects and so might appeal to a breast cancer population who often avoid additional medications.

### Justification

Oncology healthcare professionals, particularly nurse practitioners and nurses, are integral in the assessment, management and counseling of women with breast cancer from the time of diagnosis through treatment and beyond. Dealing with survivorship issues is becoming an important focus of patient care, and often managed by nurse practitioners, given the growing shortage of oncologists today. Vasomotor symptoms, including hot flashes, are a significant issue for many breast cancer survivors. Insufficiently treated hot flashes can profoundly affect the ability of these survivors to carry out everyday activities of living such as working and taking care of children. One study found that “participant’s desperation meant that they would have tried anything” (Walker et al., 2007, p. 252).

Effective counseling incorporating evidence-based interventions for hot flash management can help breast cancer survivors deal with this issue and thus, significantly improve overall quality of life. The nurses at Mercy Medical Center’s Outpatient Chemotherapy Clinic observed that many breast cancer survivors complained of hot flashes that adversely affected their daily life. Often this issue was insufficiently addressed as it was not seen as life threatening and patient appointments were focused on treating the cancer or assessing for cancer recurrence. Patients expressed an aversion to adding medications to an already cumbersome regimen of pills.

The nurses were interested in nonpharmacological interventions to assist these patients deal with debilitating hot flashes. Acupuncture is offered to patients at Mercy Medical Center but its effectiveness for managing hot flashes in Mercy's breast cancer survivor population has never been studied.

#### Evidence Based Practice Project Purpose

In a setting where acupuncture is currently offered as a treatment for hot flashes, the purpose of this evidence based practice (EBP) project was to determine if acupuncture is effective at decreasing the number and severity of hot flashes and improving sleep in the population of breast cancer survivors at Mercy Medical Center. The acceptability of acupuncture as a treatment for hot flashes with this population was also explored.

#### **EBP Project Questions:**

1. Does acupuncture decrease the number of daytime hot flashes experienced by breast cancer survivors?
2. Does acupuncture decrease the severity of daytime hot flashes experienced by breast cancer survivors?
3. Does acupuncture decrease the number of nighttime hot flashes experienced by breast cancer survivors?
4. Does acupuncture decrease the severity of nighttime hot flashes experienced by breast cancer survivors?
5. Does acupuncture improve the quality of sleep in breast cancer survivors experiencing hot flashes?

6. Do breast cancer survivors consider acupuncture an acceptable form of treatment for managing hot flashes?

### Limitations

One limitation of this project is the recruitment of participants from only one site. Although patients treated at Mercy Medical Center come from all over Maryland, the majority are from Baltimore and thus represents mostly an urban population. All participants in this project were breast cancer survivors. Other patient populations, such as women with other cancers or men with prostate cancer also experience severe hot flashes secondary to treatment. Results from this project may not be generalizable to these other patient groups. A single acupuncturist provided treatment for the project participants and results will reflect the effectiveness of her practice of acupuncture. These results may not be generalizable to acupuncture administered by other practitioners.

### Definition of Terms

*Breast cancer survivor:* Any individual diagnosed with breast cancer “from the time of diagnosis, through the balance of his or her life” (Twombly, 2004, p. 14).

*Hot flashes:* “recurrent transient periods of flushing, sweating and the sensation of heat, often accompanied by palpitations and feeling of anxiety, and sometimes followed by chills” (Mohyi et al., 1997, p. 204). Hot flashes are quantified through use of a hot flash diary where hot flash frequency is documented and a severity score applied based on the degree of severity of the hot flashes.

*Hot flash diary:* Diary in which patients record the occurrence of their hot flashes noting both the severity and frequency of the flashes during the day and night.

*Sleep disturbances:* The subjective sense that one has not slept well related to sleep duration, trouble falling asleep, number of awakenings or perceived depth of sleep. Sleep quality is quantified by the Pittsburgh Sleep Quality Index (PSQI) (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989).

*Acceptable form of treatment:* Feelings about the acceptability of acupuncture as a treatment for hot flashes as rated on a Likert scale of 1-10.

## Organizational Assessment

### **Organizational capacity**

Lusthaus, Anderson, and Adrien (1997) developed a framework to guide the assessment of an organization that contends that internal factors (organizational capacity and organizational motivation) and external influences (environment) all contribute to that organization's ability to perform. It is the organizational capacity that supports performance within that organization and is concerned with internal features. Leadership and structure are important factors. Mercy Medical Center's Hematology and Oncology physician practice and the on-premises Medi-Spa will be the setting for this EBP project. This is a hospital-owned physician practice located in downtown Baltimore. The physician practice is comprised of four physicians and approximately thirty to eighty patients are seen on a daily basis. The Medi-Spa is a privately owned spa that is located on the premises of Mercy Medical Center and employs an acupuncturist two days a week.



The physicians' practice is in an office that adjoins the chemotherapy clinic. The clinic supports the physicians by providing chemotherapy and supportive therapies for cancer patients. The nursing staff in the clinic are all experienced oncology nurses who are nationally certified by the Oncology Nursing Certification Corporation (ONCC). On average, eight to nine nurses work in the clinic every day with one nurse designated as charge nurse and a second nurse as "fast-track" for taking care of patients with short treatments. The chemotherapy clinic has a manager who is physically located on the unit and available on a daily basis. A full time nurse practitioner is situated within the clinic as well. A full time social worker is available to the patients at the clinic to assist with psychosocial and financial issues.

Within the chemotherapy clinic the manager is responsible for leadership decisions. She supports unit governance and nurses on the unit believe that they each contribute to the success of the clinic and are self-directed, taking responsibility for their own actions. The nurse practitioner role exerts informal leadership because of specialized knowledge and skills which others perceive as important. Decision-making between physicians and the chemotherapy clinic is collaborative although this process is informal as meetings with both physicians and clinic staff are rare.

### **Organizational motivation**

Organizational motivation is another internal factor that is evaluated in an organizational assessment. The chemotherapy clinic and oncology physician practice are guided by Mercy Medical Center's Mission. The hospital's mission is "Like the Sisters of Mercy before us, we witness God's healing love for all people by providing excellent clinical and residential services

within a community of compassionate care” (Mercy Medical Center, 2010b, p. 1). Nursing’s mission is “In the tradition of Catholic Health Care and the Sisters of Mercy, nursing at Mercy Medical Center supports innovative and compassionate care for all people within the communities we serve, regardless of creed, color, economic or social conditions” (Mercy Medical Center, 2010b), p. 1).

The vision statement of the Institute for Cancer Care is “In partnership with patients and their families, the Institute for Cancer Care provides a unique patient-centered healing experience. We facilitate the healing process for each patient by meeting his or her medical, emotional and spiritual needs in a respectful and compassionate manner. We are a passionate team of professionals who use our expertise, medical knowledge and modern technology to provide values-based patient care. We extend the healing experience through an attractive and comfortable environment” (Mercy Medical Center, 2010a, p. 1).

One of the hospital’s corporate goals from the Strategic Plan and Nursing’s Goals for 2008-2011 is “Driven by our values, strengthen our culture of quality and high performance, committed to innovation, celebrating diversity and the development of our human potential” (Mercy Medical Center, 2010b, p. 8). The specific nursing goal stated within as part of this hospital goal is to; (1) “Build upon current EBP and research initiatives while creating a spirit of inquiry.” and; (2) “Support an environment conducive to advancement and participation in the nursing profession and cultivate an environment focused on lifelong learning and clinical competence.” (Mercy Medical Center, 2010b, p. 8).

Nursing ties their goals to Mercy's Mission and Nursing's vision by "promoting a culture of nursing and service excellence based on education, evidence-based practice and research" (Mercy Medical Center, 2010b, p. 8). Mercy Medical Center has achieved Magnet Status and the nursing staff are supported and encouraged to pursue EBP projects. Overall, the motivation of the organization supports innovative ideas that can be used to benefit patients and this extends to the Outpatient Chemotherapy Clinic and the Hematology and Oncology physician practice as well.

### **Environment**

An evaluation of the environment of an organization takes external factors into account. Mercy Medical Center is located in an urban setting. Many of the patients treated at the hospital and its facilities are uninsured or underinsured. In the management of side effects from chemotherapy or survivorship issues of cancer patients, often the choice of treatment is insurance driven. This can be a barrier to the use of acupuncture for managing hot flashes if insurance does not cover this or the patient has no insurance. Financial assistance is available for cancer patients who cannot afford acupuncture. Mercy Medical Center's low income program covers the cost of eight treatments at the Medispa, such as acupuncture or massage, for cancer patients with financial hardship. The Red Devils, a Maryland charitable organization, also provides services and financial assistance to breast cancer patients treated in Maryland hospitals or breast centers (The Red Devils, 2011). Potential recipients are identified by social workers or staff at the chemotherapy clinic. Insurance and funding for health care treatments are significant

external factors and were considered when choosing this EBP project that required receiving a specific therapy.

### **Organizational performance**

The Outpatient Chemotherapy Clinic is staffed by experienced oncology nurses and the unit has had little turnover in staff in the last ten years. They treat a large number of patients in an efficient manner on a daily basis. The Outpatient Chemotherapy Clinic consistently performs above hospital standards scoring 97-98% in safe medication administration, correctly administering chemotherapy, prevention of intravenous infiltration and management of pain (Outpatient Chemotherapy, 2011). The nurses feel that they have adequate time and knowledge to educate their patients and discuss issues with them. They are self-motivated and express an interest in research findings and other areas of new knowledge.

One physician in the oncology practice specializes in treating breast cancer patients. Management of treatment, side effects of treatment and sequelae of chemotherapy is accomplished collaboratively with the nurse practitioner and staff nurses in the clinic. Both physicians and clinic staff are involved in clinical research trials and aware of how research and EBP differ.

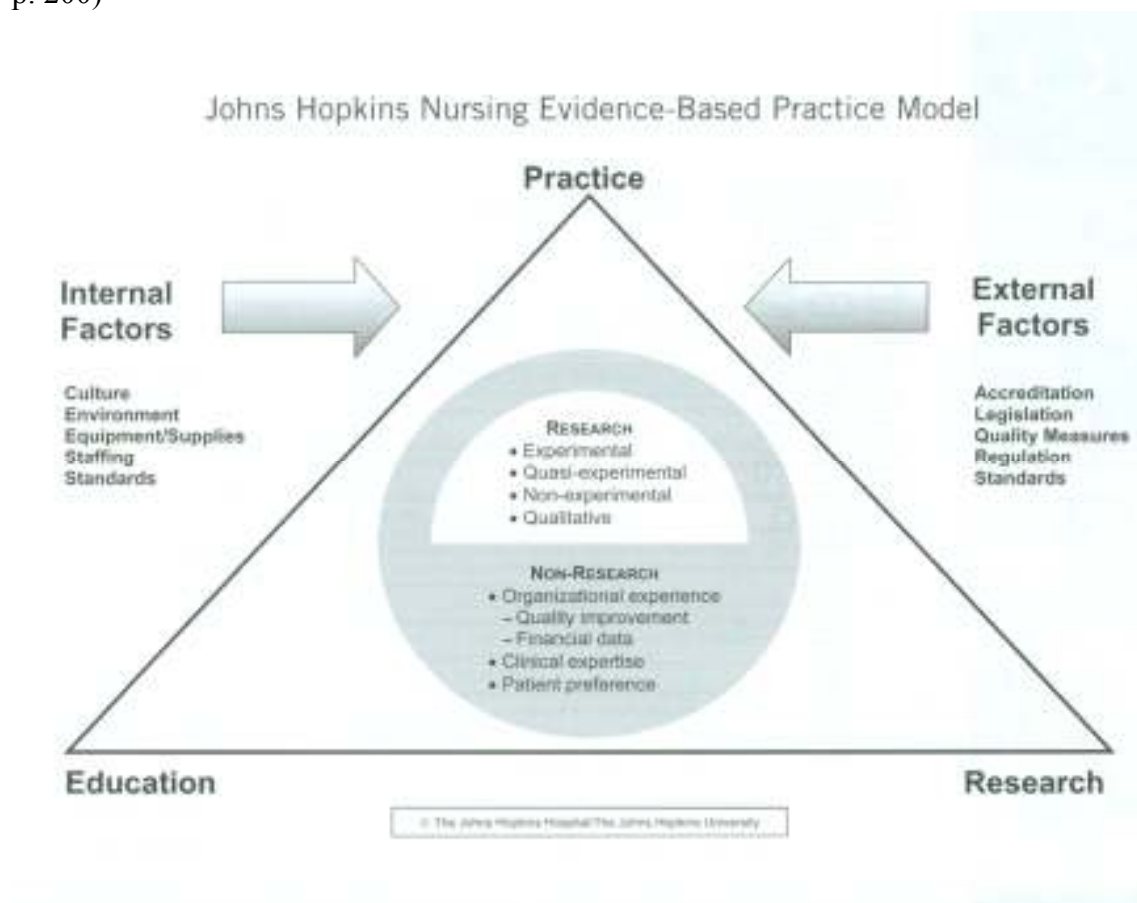
## CHAPTER 2

### **Evidence Based Framework:**

#### **Johns Hopkins Nursing Evidence Based Practice Model**

As stated by Newhouse, Dearholt, Poe, Pugh, & White (2007a, p. 36) “The Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) model depicts three essential cornerstones that form the foundation for professional nursing. These cornerstones are practice, education, and research” (Figure 2.1). As the cornerstones of the model, these are the entities that will both affect and be affected by the pursuit of evidence-based practice. Nursing practice changes to reflect practices supported by research. Educational programs for nursing are incorporating evidence-based practice and knowledge of research into their curriculums. Research is a major foundation of evidence-based practice (Ciliska, Pinelli, DiCenso, & Cullum, 2001). The process of the JHNEBP model involves the development of a practice question, evaluation and synthesis of the evidence, and translation of that evidence into practice (PET) (Newhouse, Dearholt, Poe, Pugh, & White, 2007b).

**Figure 2.1: Johns Hopkins Nursing Evidence-Based Practice Model** (Newhouse, et al., 2007, p. 200)



### Practice Question

The initial phase of any EBP project is the development of an EBP question. The PET format utilizes the PICO approach which identifies the population or problem, the intervention, the comparison group and the outcome. This question should be specific and focused in order to guide the evidence search. The PICO questions for this project are: Does acupuncture decrease the perceived incidence and severity of hot flashes and improve sleep in breast cancer survivors at Mercy Medical Center? Is acupuncture considered an acceptable form of treatment for hot flashes by breast cancer survivors at Mercy Medical Center?

## Evidence

At the center of the JHNEBP model is evidence. This evidence can be obtained from multiple sources, but the strongest evidence is from quality research (Newhouse et al., 2007a). The use of acupuncture for the management of hot flashes in women with breast cancer is supported by research. This includes experimental, quasi-experimental, qualitative, and retrospective studies. Expertise of clinicians such as oncologists specializing in treating patients with breast cancer is also an important source of evidence. Patient preference plays a large part in the implementation of an evidence based initiative. Each woman with breast cancer has a unique situation that will have a bearing on whether that woman decides if acupuncture is an acceptable choice of treatment for the management of her hot flashes. Patient factors such as educational level, socioeconomic status and views on traditional and nontraditional medicine will all influence her choice.

## Translation

### **Internal Factors**

The JHNEBP model describes an open system that is influenced by both internal and external factors. These factors are influential in determining the feasibility of practice changes and the development of an action plan, or translation, to initiate the desired changes (Newhouse et al., 2007a). Internal factors to be considered within the setting of an EBP project implementation are many. The values and mission of an organization are important internal factors that influence the care of patients. The support of hospital leadership for the implementation of EBP is integral to the success of a project. Magnet status or being involved in

obtaining Magnet status provides an atmosphere that encourages the use of EBP. Characteristics of the particular setting and patient population at which the EBP project is directed are all internal factors. Resources allocated for the support of indigent, non-insured or inadequately insured patients need to be considered. Health care professionals involved in the chosen patient setting are part of the internal environment. How is staffing in the setting and what professionals are included? Internal factors include the nurses, nurse practitioners, physician's assistants, physicians, social workers, managers and other staff working within the setting. The education and experience of involved staff and their attitude towards EBP is another internal factor to be considered.

### **External Factors**

External factors that can influence the implementation of evidence-based practice within an institution can include legislation, accrediting organizations, and practice standards (Newhouse et al., 2007a). Currently the only published standard or position statement on the treatment of postmenopausal vasomotor symptoms is from The North American Menopause Society (2004) and this does not specifically address breast cancer patients. A significant external factor is insuring bodies, including private companies and government-based programs such as Medicare or Medicaid. Insurance coverage of interventions can be very important in determining what care will be given. Charitable organizations that provide funding for breast cancer patients are another external factor. Licensing and accreditation bodies are external factors that influence practice within the health professions. The evaluation of the evidence that



is at the core of the process, internal influences within the organization, and influences external to the organization will impact implementation of evidence-based nursing practice.

#### Related Evidence

##### **Pharmacologic Treatments for Hot Flashes**

Hot flashes are a symptom of estrogen deficiency and hormone replacement therapy is currently the most effective treatment available for alleviating this symptom. For breast cancer survivors, however, hormone therapy is contraindicated because its use has been linked to an increased risk of cancer recurrence (Goodwin et al., 2008; Kenemans et al., 2009; Loprinzi et al., 2006; Marsden et al., 2000). Tibolone, a synthetic steroid that appears to have less influence on breast tissue than traditional hormone replacement therapy has been used for the treatment of hot flashes in breast cancer survivors. A recent study determined that tibolone increased the risk of breast cancer recurrence when compared to placebo (Kenemans et al., 2009). While a single dose of depomedroxyprogesterone acetate given intramuscularly was shown to reduce hot flashes by 79% in healthy postmenopausal women there is not enough data to support its safety in breast cancer survivors (Loprinzi et al., 2006).

Research has supported the use of antidepressants for the treatment of menopausal hot flashes in healthy postmenopausal women. Selective serotonin reuptake inhibitors (SSRIs) and venlafaxine, which is a serotonin-norepinephrine reuptake inhibitor, have effectively reduced hot flashes by 30% to 65% in women without a history of breast cancer (Carroll & Kelley, 2009). Studies of antidepressants for reduction of hot flashes with breast cancer survivors have demonstrated similar results. Venlafaxine, fluoxetine, paroxetine and sertraline have all been

shown to reduce hot flashes in breast cancer survivors by 37% to 68% (Barton et al., 2002; Biglia et al., 2005; Bordeleau et al., 2010; Kimmick et al., 2006; Mariani et al., 2005; Stearns, Beebe, Iyengar, & Dube, 2003). The SSRIs, fluoxetine, paroxetine and sertraline are not recommended for women taking tamoxifen as they are inhibitors of the CYP2D6 enzyme. This can decrease the concentration of endoxifen, the active metabolite of tamoxifen, in breast cancer survivors and so decrease the effectiveness of this treatment with the possibility of increasing the chance of breast cancer recurrence (Desmarais & Looper, 2009; Kimmick et al., 2006). Venlafaxine and the SSRIs have been associated with such side effects as mood changes, nervousness, anorexia, nausea, constipation, dry mouth, insomnia, and dizziness (Biglia et al., 2005; Loprinzi et al., 2000; Mariani et al., 2005).

Gabapentin, a medication used for treating seizures and neuralgias, has shown effectiveness in treating postmenopausal symptoms, decreasing the incidence of hot flashes by 45% to 54%. Side effects secondary to gabapentin include dizziness and somnolence usually diminishing within several weeks of starting treatment. One long term effect of gabapentin, however, is weight gain (Gross, 2006). This side effect discourages many women from using it as a treatment for their hot flashes as some adjuvant treatments for breast cancer also cause weight gain. (Ruhstaller et al., 2009).

Clonidine, a drug used to treat hypertension, can reduce postmenopausal hot flashes, although the impact is modest. Clonidine has frequent side effects such as insomnia, xerostomia, constipation, and drowsiness making it an unattractive choice for the treatment of hot flashes for many women (Kontos et al., 2010; Rada et al., 2010). Although several pharmacologic

treatments have shown benefit in decreasing menopausal hot flashes in breast cancer survivors, many women are reluctant to take additional medications while receiving adjuvant treatment for their cancer (Walker et al., 2007).

### **Non-pharmacologic Treatments for Breast Cancer**

Stellate ganglion blocks have been used for more than sixty years for the treatment of pain. They are now being used for the treatment of hot flashes as the block theoretically affects the temperature regulating mechanism of the sympathetic nervous system decreasing the occurrence of hot flashes. A small quasi-experimental study with no control group showed a 90% decrease in frequency of hot flashes from baseline. This improvement lasted from two weeks to several months. Repeating the block increased the length of time that hot flashes were diminished (Lipov et al., 2008; Lipov, Joshi, Xie, & Slavin, 2008). Although this is an effective intervention for post-menopausal hot flashes, it is an expensive alternative to other more conventional treatments with a cost of \$1000 to \$3000 per treatment in the United States (Kontos et al., 2010).

In the search for non-pharmacological treatments for hot flashes, herbal supplements, vitamins, and isoflavones have been studied. Black cohosh and multibotanicals with black cohosh did not show any advantage over placebo (Newton et al., 2006). Chinese herbs, such as dong quai were also ineffective in diminishing hot flashes compared with placebo (Kontos et al., 2010). The use of soy products demonstrated either no difference in decreasing hot flashes compared to placebo or an actual increase in menopausal symptoms over a year's time (Newton et al., 2006; Van Patten et al., 2002). Isoflavones alone and with melatonin did not improve hot

flash frequency or severity any more than placebo (Secreto et al., 2004). Red clover did not show any greater reduction in hot flashes than placebo (Kontos et al., 2010). Vitamin E had only a minimal effect on hot flashes with a 10% reduction in frequency (Biglia et al., 2009).

One study addressing hypnosis as an intervention for the reduction of hot flashes of breast cancer survivors did show a decrease in hot flashes of 68% compared to a control group. Patients were followed for only five weeks so it is unknown if the effect of hypnosis is long lasting (Elkins et al., 2008). Relaxation therapy has shown mixed results for treating postmenopausal hot flashes. One study showed no benefit in decreasing hot flashes, another demonstrated a significant decrease in hot flashes after one month but no significant difference after three months, and a third study showed benefit through twelve weeks (Nedstrand et al., 2006; Rada et al., 2010).

### Review of the Evidence

#### **Acupuncture for the Management of Hot Flashes for Breast Cancer Survivors**

Acupuncture is a non-pharmacological intervention that has been investigated in multiple studies shown to decrease postmenopausal hot flashes in healthy postmenopausal women (Avis et al., 2008; Borud et al., 2009; Cohen et al., 2003; Huang et al., 2006; Kim et al., 2010; Nir et al., 2007; Venzke et al., 2010; Vincent et al., 2007). To find research that addressed acupuncture as a treatment for hot flashes in breast cancer survivors, a systematic search was conducted of the PubMed and CINAHL databases with no date restrictions. The subject headings used were *breast cancer, acupuncture, hot flashes, hot flushes, and vasomotor symptoms*. The limits placed on the search were English and female only. The search identified 307 articles. Fifty-four of

these were determined to not address the treatment of hot flashes. Forty-six articles were studies of interventions for hot flashes other than acupuncture. Five articles did not address hot flashes, breast cancer or acupuncture. After reviewing the abstracts for the remaining 202 articles, 190 of them addressed treatment of vasomotor symptoms in healthy postmenopausal women but did not include breast cancer survivors. Twelve articles remained that addressed the use of acupuncture for the treatment of hot flashes in the breast cancer population. Four of these articles described two studies twice and were published in different journals. The ten remaining studies are reviewed in this paper. Reviewing the cited references in these articles did not produce any additional relevant studies. The articles were rated on evidence hierarchy and quality of evidence using the Agency for Healthcare Research and Quality (AHRQ) Evidence Hierarchies and the United States Preventive Services Task Force (USPSTF) Grading for strength of evidence. Of the ten articles reviewed, five were randomized, controlled trials; three were quasi-experimental studies; one was a qualitative study; and one was a retrospective study. Table 2.1 contains a summary of the articles.

Ten studies were identified that evaluated the effectiveness of acupuncture for treatment of menopausal hot flashes in the breast cancer population. The first study by Deng et al. (2007) included seventy-two women with breast cancer randomized to receive either true or sham acupuncture. They received treatment twice weekly for four weeks. At the end of the four weeks, participants who had received sham acupuncture were allowed to cross over and receive true acupuncture if they chose. Although hot flash frequency decreased in both groups, there was no significant difference between the groups. Those who crossed over did have an

additional 20% reduction in hot flashes. This study did not assess the severity of hot flashes, only frequency, so any differences here would have been missed. The duration of treatment was only four weeks. Further reductions may possibly have been seen with a longer length of acupuncture treatment.

Frisk et al. (2008) conducted a randomized, controlled study to compare the effectiveness of acupuncture in reducing hot flashes with hormone therapy in women with breast cancer. Forty-five women were randomized to receive electro-acupuncture twice weekly for two weeks and then weekly for ten weeks or sequential hormone therapy with either estrogen/progesterone or estrogen alone if the participant had had a hysterectomy. Electro-acupuncture significantly reduced hot flashes at 12 weeks, 12 months and 24 months. A significant difference was noted between interventions in favor of hormone therapy with fewer hot flashes over 24 hours and less distress caused by flashes. This study had no untreated control group. The results of the study are limited by the small sample size and high attrition rate in both groups.

Hervik & Mjaland (2009) conducted a randomized, controlled trial to investigate the effectiveness of acupuncture in alleviating hot flashes in women with breast cancer who were treated with anti-estrogen medication. Fifty-nine women with breast cancer being treated with tamoxifen were randomized to receive either true or sham acupuncture. Acupuncture was administered twice weekly for five weeks and then weekly for five weeks. Hot flash frequency decreased by 50% in the true acupuncture group during treatment and an additional 30% after treatment. No significant changes were noted within the sham acupuncture group. Menopausal symptoms as measured by Kupperman Index were significantly reduced in both groups during

treatment but this was reversed in the sham acupuncture group after treatment. This study had an adequate sample size to detect significant differences between groups.

Nedstrand, Wyon, Hammar, & Wijma (2006) conducted a small clinical trial randomizing to either electro-acupuncture or applied relaxation for effectiveness in decreasing the number of hot flashes and menopausal symptoms in women with breast cancer. Participants were randomized to receive either applied relaxation sessions weekly for twelve weeks or electro-acupuncture twice a week for two weeks and then once a week for ten weeks. Those who were randomized to the relaxation group received twelve training sessions that included “progressive relaxation, release-only relaxation, cue-controlled relaxation, differential relaxation, rapid relaxation, application training, and maintenance program” (Nedstrand et al., 2006, p. 245). A hot flash diary and Kupperman Index were used to evaluate frequency of hot flashes and severity of menopausal symptoms, respectively at baseline, four, eight, and twelve weeks and three and six months. Results showed that the frequency of hot flashes and menopausal symptom severity decreased significantly across all time periods for both groups. The study had no untreated control group. Results from this study are limited by the small sample size and high attrition rate in the relaxation group.

In a study conducted by Walker et al. (2010) venlafaxine was compared to acupuncture for the reduction of vasomotor symptoms in women with breast cancer. Fifty women were randomized to receive either venlafaxine 37.5 mg daily for one week and then 75 mg daily for eleven weeks or acupuncture twice a week for four weeks and then weekly for eight weeks. Both groups had a significant decrease in hot flash frequency, severity, depressive symptoms,

menopausal quality of life symptoms and improvements in mental health. Acupuncture was shown to be at least as effective as venlafaxine. Sample size was adequate to detect differences between groups. Attrition rate was high in both groups for follow up at six, nine, and twelve months after treatment limiting the results of long term effectiveness of both interventions after three months.

A quasi-experimental study by Tukmachi (2000) attempted to determine the effect of acupuncture on the frequency and severity of hot flashes in women with breast cancer. Twenty-two women received acupuncture twice a week for a total of 6-14 sessions. Participants were also counseled on life style changes and dietary modification that might decrease hot flashes. Daytime and nocturnal hot flashes were significantly decreased from 14.32 to 1.41 and 6.95 to 0.86 respectively by the last treatment. Results from this study are limited by the lack of a control group and small sample size. Counseling participants on life style changes and diet introduces another variable that could influence the findings in addition to the effect of acupuncture.

deValois et al. (2009) conducted a quasi-experimental study to determine the effect of acupuncture on hot flash frequency and physical and emotional well-being. Participants received eight acupuncture treatments over a period of eight weeks. Hot flash frequency was reduced by 49.8% at the end of treatment and this effect continued at four and eighteen weeks after treatment was completed. Improvements were noted in anxiety/fear, memory/concentration, menstrual problems, sexual problems, somatic symptoms and vasomotor symptoms. Some of the participants did not adhere to the treatment schedule limiting the generalizability of the



findings. The study had no control group to evaluate placebo effect. No attempt was made to limit the therapeutic relationship between the acupuncturist and the participant which could be a part of a placebo effect.

A quasi-experimental pilot study by Porzio et al. (2002) was conducted to determine the effect of acupuncture on menopausal symptoms assessing depression, somatic symptoms, vasomotor symptoms, and libido using the Greene Menopause Index. Fifteen women with breast cancer taking tamoxifen received weekly acupuncture for three months and then monthly thereafter for maintenance. Anxiety, depression, somatic symptoms, and vasomotor symptoms were significantly improved by treatment. No change was noted in libido. Generalizability of the results is limited by the lack of a control group and a small sample size.

Walker, deValois, Davies, Young, and Maher (2007) conducted a qualitative study to describe the experience of women with breast cancer who had received eight treatments of ear acupuncture in a group setting for treatment of their hot flashes. Of the fifty women who did receive ear acupuncture, only sixteen chose to participate in this study. The group described their experience as positive and felt that ear acupuncture helped the frequency of their hot flashes. They found the group to be a support and obtained benefit from sharing experiences. The small sample in this study was self-selected from a larger group that had previously received ear acupuncture so the results from this study do not necessarily reflect the views of those who chose not to participate.

The final study reviewed was a retrospective study conducted by Filshie, Bolton, Browne, & Ashley (2005) of 194 patients who had previously received acupuncture for hot

flashes. Of the 194 patient, 182 were women who had a history of breast cancer. The majority of the patients (74%) were self-treated with semi-permanent acupuncture needles. Seven percent were self-treated with standard needles. Review of the data showed a greater than 50% reduction in frequency of hot flashes following acupuncture. Results obtained from self-acupuncture might not be generalizable to a population treated with acupuncture performed by an acupuncturist.

For women with breast cancer experiencing debilitating hot flashes options for effective treatment are limited. Although women with breast cancer experience more severe and frequent hot flashes than healthy women, they are more averse to taking medication for relief than healthy post-menopausal women (Fenlon & Rogers, 2007). Of non-pharmacological therapies for management of hot flashes, acupuncture has been the most thoroughly researched. Different types of acupuncture have been studied such as traditional acupuncture, electro-acupuncture, ear acupuncture and self-administered acupuncture. All studies demonstrated the efficacy of acupuncture in reducing the incidence of hot flashes in the breast cancer population. Different methods of acupuncture make it difficult to compare results between studies; however, two sufficiently powered randomized, controlled trials using traditional acupuncture showed a significant reduction in hot flash severity and frequency from baseline of at least 50%. For this reason acupuncture is a viable alternative to medication for the treatment of hot flashes in the breast cancer population.

**Table 2.1: Review of Literature on Acupuncture for Treatment of Hot Flashes in Breast Cancer Survivors**

Study	Design and Sample	Conclusions	Limitations	Ratings
Deng et al., 2007	Randomized, controlled, blinded study. 72 participants with breast cancer with 3 or more hot flashes per day. Randomized to receive true or sham acupuncture twice weekly for 4 weeks. Cross over at week 7 to sample receiving sham acupuncture if participants wanted to. Use of hot flash diary to assess frequency at days 7,14,21,28 and 35. Randomly assigned to true acupuncture completed diary at week 26. If agreed to crossover, dairy completed at weeks 12 and 32. Fisher's exact test used to test for differences between groups.	Hot flash frequency decreased by 20 % in both groups at 1 week. Afterwards sham group did not change but true acupuncture decreased another 10%. No significant difference between the 2 groups. Greater reduction in hot flashes between groups at 6 months but not statistically significant.	Evaluated only hot flash frequency, not severity. Short period of time for intervention (4 weeks). No power analysis.	Level II Strength B
deValois et al., 2010	Quasi experimental, single arm observational study. 50 participants with breast cancer, 6 months or more post treatment received 8acupuncture treatments over 8 weeks. Hot flash diary for recording frequency of hot flashes and Women's Health Questionnaire (WHQ) for assessing physical and emotional well-being and Hot Flashes and Night Sweats Questionnaire (HFNSQ) to assess HF and NS monitored over 30 weeks with 5 measurement points. Parametric t-tests for comparison with baseline scores. Student's t-test to analyze data from WHQ and HFNSQ	Frequency of hot flashes and night sweats reduced by 49.8% at end of treatment. Continued effect at 4 and 18 weeks after end of treatment. Improvements in anxiety/fear, memory/concentration, menstrual problems, sexual behavior, sleep problems, somatic symptoms and vasomotor symptoms	Quasi-experimental with no control group to evaluate placebo effects. No attempt to limit therapeutic relationship between acupuncturist and participant. Use of one study site only. Some participants did not adhere to treatment schedule.	Level III Strength B

**Table 2.1: Review of Literature on Acupuncture for Treatment of Hot Flashes in Breast Cancer Survivors (cont.)**

Study	Design and Sample	Conclusions	Limitations	Ratings
Frisk et al., 2008	Randomized, controlled trial comparing electro-acupuncture to hormone therapy in reducing number of hot flashes and distress caused by them. 45 women with history of breast cancer with previously completed treatment. Randomized to electro-acupuncture or hormonal therapy (N=27 acupuncture, N=18 for hormones). Acupuncture twice weekly X 2 then weekly for 10 weeks. Hormone therapy with sequential estrogen/progesterone or if hysterectomized, estrogen alone. Hot flash diary with daily entries of 1-3 weeks before treatment and first 12 weeks of treatment, thereafter 1 week per month for 24 months. Kupperman's Index used to assess menopausal symptoms at screening, 12 weeks, and 6,9,12,18 and 24 after start of treatment. ANOVA to analyze Kupperman's Index scores and changes in frequency of hot flashes. 7 women in hormone arm excluded for recurrence of cancer, DVT, moved or changed to acupuncture.	Electroacupuncture with decrease of hot flash frequency from 9.6/24 hr to 4.3 after 12 weeks, 4.8 at 12 months and 2.9 at 24 months. Distress from hot flashes decreased from 5.5 at baseline to 2.4 at 12 weeks, 3.9 at 12 months and 2.3 at 24 months. Significant differences between acupuncture and hormones in favor of hormones with fewer hot flashes/24 hr. and distress caused by flashes ( $p=0.002$ ) at 12 months.	Small sample size with significant attrition in both arms. (19 of 23 completed the acupuncture treatment and 11 of 18 completed the hormone treatment)	Level II Strength B

**Table 2.1: Review of Literature on Acupuncture for Treatment of Hot Flashes in Breast Cancer Survivors (cont.)**

Study	Design and Sample	Conclusions	Limitations	Ratings
Hervik, 2009	Randomized, controlled trial to compare true acupuncture to sham acupuncture in decreasing hot flashes and menopausal symptoms. Sample of 59 women with breast cancer receiving Tamoxifen and experiencing hot flashes. Received either true or sham acupuncture twice weekly for 5 weeks and then weekly for 5 weeks. Hot flashes recorded on the same day weekly for 4 weeks prior to treatment, during the 10 weeks of treatment and for 12 weeks after treatment. Kupperman Index to evaluate menopausal symptoms at baseline and 12 weeks after treatment ended. Independent t-tests and Chi-square to compare baseline data. General Linear Model to test for group x time interaction for response to acupuncture.	Hot flashes during the day reduced by 50% in the true acupuncture (TA) group during treatment and an additional 30% after treatment ( $p<0.001$ , $p<0.017$ ). No significant change seen with sham group ( $p=0.382$ , $p=0.86$ ). Night hot flashes decreased by 60% during treatment with additional 30% after treatment ( $p<0.001$ , $p<0.006$ ). A significant reduction was seen with sham during treatment but reversed following treatment ( $p=0.01$ , $p=0.22$ ). KI mean decreased by 44% in TA group ( $p<0.001$ ). Sham decreased KI mean by 10% ( $p=0.06$ ).		Level II Strength A

**Table 2.1: Review of Literature on Acupuncture for Treatment of Hot Flashes in Breast Cancer Survivors (cont.)**

Study	Design and Sample	Conclusions	Limitations	Ratings
Nedstrand et al., 2006	Randomized, controlled trial that compared electro-acupuncture to applied relaxation for effect on number of hot flashes and menopausal symptoms. Sample was 38 women with breast cancer who had completed treatment except Tamoxifen randomized to either applied relaxation sessions, weekly X 12 or electropuncture twice a week for the first 2 weeks and then once a week for 10 weeks. Hot flash logs kept daily starting 2 weeks before treatment and for 12 weeks through treatment. For 6 months afterwards it was fill in every 4 <sup>th</sup> week. Kuppermans Index to assess menopausal symptoms was completed at baseline, 4,8 ,12 weeks and 3 and 6 months after treatment. ANOVA and Spearmans Rank Correlation used.	Hot flashes per 24 hours decreased from 9.2 at baseline to 4.5 at 12 weeks and 3.9 at 6 months for relaxation group ( $p<0.001$ ). Hot flashes per 24 hours decreased from 8.4 at baseline to 4.1 at 12 weeks and 3.5 at 6 months for the acupuncture group ( $p<0.0001$ ). Kuppermans Index decreased significantly for both groups ( $p<0.001$ ) at 4, 12, and 6 months.	Small sample size. High attrition rate in relaxation group (14 of 19 completed treatment) No untreated control group.	Level II Strength B
Porzio et al., 2002	Quasi-experimental pilot study to determine the effect of acupuncture on menopausal status using the Greene Menopause Index to assess depression, somatic symptoms, vasomotor symptoms and libido. From January 1999-June 2000 fifteen women taking Tamoxifen for breast cancer treatment were enrolled. Acupuncture done weekly for 3 months and then monthly for maintenance. Greene Menopause Index was administered at baseline after 1 month, 3 months and 6 months at in interview with participants. Friedman test used to determine significance for each dimension of Greene Menopause Index at each evaluation period. Wilcoxon matched-pairs signed test analysis to determine changes over time.	Anxiety ( $p<0.001$ ), depression ( $p<0.001$ ), somatic symptoms ( $P<0.001$ ), and vasomotor symptoms ( $P=0.001$ ) were improved by treatment. Libido was not changed. Progressive improvement noted in anxiety, somatic symptoms and vasomotor symptoms. Depression did not ameliorate until after 3 months.	Small sample size. No control group.	Level III Strength B

**Table 2.1: Review of Literature on Acupuncture for Treatment of Hot Flashes in Breast Cancer Survivors (cont.)**

Study	Design and Sample	Conclusions	Limitations	Ratings
Tukmachi, 2000	Quasi-experimental clinical series study to determine effect of acupuncture on frequency and intensity of hot flashes. From 1995-1999 twenty-two breast cancer patients received acupuncture twice a week for a total of 6-14 sessions. Treatment discontinued after 8 treatments if no improvement in hot flashes. Participants also counseled on life-style and diet. Hot flash diary kept daily and evaluated at first and last acupuncture treatment and 3 to 5 weeks after completion of treatment. Paired t-test to determine pre and post significance.	Average number of daytime hot flashes decreased from 14.32 to 1.41 on last day of treatment . Nocturnal hot flashes decreased from 6.95 to 0.86 on last day of treatment. Benefit maintained at 1.5 and 1.18 at follow up visit. ( $p < 0.001$ ) for overall decrease in hot flash frequency.	Small sample size. No control group. Dietary and life style counseling is additional variable that could influence decrease in hot flash frequency. Short follow up period.	Level III Strength B
Walker, G. et al., 2007	Qualitative descriptive research to detail the experience of 50 women with breast cancer on adjuvant hormonal treatment who participated in a study to decrease hot flashes and received 8 ear acupuncture treatments in a group setting at least 6 months earlier. Topics covered included the reason for participating in the study, anticipation of the treatment and its results, the experience of having the treatment, experience of being treated in a group, the effects of the treatment and what they felt influenced the effects. Of the 50 women who participated in the study, only 16 women took part in the focus groups. The session was audiotaped and transcripts analyzed for themes.	Ear acupuncture may help decrease hot flash frequency. Group treatment was found acceptable. Benefit obtained from sharing experiences and receiving support from the group.	Small self-selected sample .	Level IV Strength B-

**Table 2.1: Review of Literature on Acupuncture for Treatment of Hot Flashes in Breast Cancer Survivors (cont.)**

Study	Design and Sample	Conclusions	Limitations	Ratings
Walker, E. et al. 2010	Randomized, controlled trial to compare acupuncture to venlafaxine in the reduction of vasomotor symptoms. Sample of 50 women with breast cancer on hormonal therapy with Tamoxifen or Arimidex. Participants in the control arm (venlafaxine) took 37.5 mg daily of venlafaxine for the first week and then 75 mg daily for 11 weeks. The acupuncture arm received treatments twice a week for 4 weeks and then once a week for 8 weeks. Hot flash diary measured frequency of hot flashes; Menopause Specific Quality of Life Questionnaire (MenQOL) measured health status relative to menopause symptoms; Beck Depression Inventory-Primary Care (BDI-PC) measured mental health and mood; National Cancer Institute Common Toxicity Criteria scale measured side effects of treatment. Hot flash frequency evaluated pre and post treatment and 1,2,3,4, weeks and 3,6,9,12 months post treatment. ANOVA to determine significance of time and between groups.	Both groups had 50% reduction of hot flashes at post-treatment, at 2 weeks after treatment the venlafaxine group had significant increases in hot flashes and the acupuncture group stayed low. Hot flash frequency remained low at 3 and 4 weeks post treatment then increased at 3 month and decreased again at 6 and 9 months with slight increase at 12 months. Venlafaxine with higher frequency of hot flashes at all time points except 3 months. Both groups had significant decreases in hot flash severity ( $p<0.001$ ), depressive symptoms ( $p<0.001$ ), menopausal QOL symptoms ( $p<0.002$ ) and improvements in mental health ( $p<0.007$ )..		Level II Strength A



## CHAPTER THREE: PROJECT METHODS

### **Project design**

The project design for this study was a quasi-experimental pretest-posttest design. Qualitative data was also obtained by interview after participants completed acupuncture treatments.

### **Setting**

The setting was Mercy Medical Center's Hematology and Medical Oncology Practice, Mercy Outpatient Chemotherapy Clinic and the onsite Medi-Spa. This is a hospital-owned physician practice, hospital-based outpatient chemotherapy infusion clinic and a privately owned spa on the premises of Mercy Medical Center which is located in downtown Baltimore. The physicians treat patients with all types of cancer including breast cancer. The Outpatient Chemotherapy Clinic provides infusion services, including chemotherapy. The Medi-Spa offers a wide array of health care services that encourage a holistic approach to physical and spiritual well-being. Acupuncture is offered at the spa and an acupuncturist is onsite two days a week.

### **Sampling plan**

A convenience sample of patients at Mercy Medical Center was used for this study. Inclusion criteria included: (1) female, (2) previous diagnosis of breast cancer, (3) currently experiencing hot flashes that are described as bothersome, and, (4) seeking acupuncture treatment for their hot flashes at the Medispa. Premenopausal and postmenopausal women were included as well as women with either local or metastatic disease. Women receiving treatment with chemotherapy, radiation therapy, or endocrine therapy or receiving routine follow up care after completion of treatment were eligible. Participants were not excluded from the study if

they were currently trying other interventions to control hot flashes. Exclusion criteria included the inability to read and write English.

## **Methods**

Women at Mercy Medical Center with breast cancer were assessed by their oncology physician for complaints of hot flashes that were described as distressing by the patient. The physician then discussed options for treating hot flashes, including acupuncture. If the patient expressed an interest in acupuncture as a treatment for their hot flashes, the physician referred them to the acupuncturist at the Medi-Spa. When the patient presented to the acupuncturist, she informed them of the research study and asked them if they would be interested in participating. If they indicated an interest, the acupuncturist gave them the contact information of the project director. After the patient contacted the project director, a one-on-one meeting was arranged at which time the project director explained the study. If the patient agreed to participate in the study, informed consent was obtained. Once the patient agreed to participate and signed the informed consent the following steps took place:

1. At the first meeting demographic data and information was obtained from the participant including: age, race, marital status, educational level, current or past cancer treatment including endocrine treatment, and current or past interventions used to control hot flashes, including medications. The participant was asked to complete the PSQI to obtain a baseline assessment of sleep disturbances. They were asked how acceptable they felt acupuncture would be as a treatment for hot flashes with responses based on a 1-10 Likert scale with 1 = very unacceptable and 10 = very acceptable. The participant also

received a hot flash diary and was instructed about how to record frequency and severity of hot flashes. This diary was filled out on a daily basis for one week beginning the week prior to starting acupuncture and then collected by the project director at completion.

This week established the baseline hot flash status for the participant.

2. After the participant completed the hot flash diary for one week prior to the intervention, the acupuncturist arranged twice a week acupuncture treatments for four weeks.
3. The acupuncturist assessed the participant at each session to determine the acupuncture points that would provide the most effective treatment in keeping with traditional acupuncture philosophy. This consisted of a core protocol but with the option to use other points based on the acupuncturist's assessment.
4. After eight treatments, participants were asked to complete the hot flash diary for another week. Upon completion of the hot flash diary after the final week, the diary was collected and the PSQI was administered again. The participant was asked how acceptable they felt acupuncture was for treating their hot flashes using the 10 point Likert scale. They were also asked the following questions: (1) What did you feel was the best part of your acupuncture treatment?, (2) What did you feel was the worst part of your acupuncture treatment?, (3) What problems did you encounter during your acupuncture treatment?, and, (4) Would you recommend acupuncture to a family member or friend? Responses were documented for later qualitative analysis.

## Instruments

1. Hot flash diary: Hot flash frequency and severity were assessed through entries made in the hot flash diary. Participants made daily entries in the hot flash diary, recording the number of hot flashes during the day and night and severity (1 = mild, 2 = moderate, 3 = severe) of the hot flashes. Daily entries were made for one week prior to initiation of acupuncture and repeated for one week following the eighth acupuncture treatment. Hot flash diaries have been shown to be a valid and reliable instrument for the assessment of hot flash activity (Sloan et al., 2001).
2. Pittsburgh Sleep Quality Index: Sleep disturbances were assessed using the Pittsburgh Sleep Quality Index. The PSQI is a self-rating questionnaire which can be completed in five minutes (Backhaus, Junghanns, Broocks, Riemann, & Hohagen, 2002). The questionnaire consists of nineteen items which generate seven component scores with a sum global score range from 0-21. Sleep quality, latency, duration, efficiency and disturbances are assessed along with the use of sleep medication and daytime dysfunction (Buysse et al., 1989). A lower score is associated with better sleep quality. The Pittsburgh Sleep Quality Index has been shown to be a valid and reliable instrument for measuring sleep quality (Backhaus et al., 2002). The PSQI was administered prior to initiation of acupuncture and again after completion of the post-acupuncture hot flash diary.

## **Evaluation**

Primary outcome measures for the project were hot flash frequency and severity, sleep quality, and the acceptability rating of acupuncture as a treatment for hot flashes. Pre and post intervention hot flash frequency and severity (day and night), PSQI sleep disturbance scores, and acceptability of acupuncture were compared. An Excel spreadsheet was created and demographic data were entered on all 20 consenting participants. Also included in this spreadsheet were the data obtained for each of the seven days of both pre and post hot flash diaries for hot flash frequency and severity, night and day, pre and post values of each category of the PSQI, and the pre and post acceptability question rating. Other than demographic data, any data obtained from participants who did not complete the study were not included in the statistical analysis. The number and severity of hot flashes, day and night, was averaged for the week for each participant. PSQI scores were calculated according to the PSQI Form Administration Instruction, References, and Scoring form (Buysse et al., 1989). The differences between baseline and post intervention data were calculated and significance determined by a paired t-test. SPSS was used to analyze the data. Participants' descriptions of the acupuncture treatment were examined for themes and described qualitatively.

## **Anticipated outcomes**

1. Participants will have fewer hot flashes during the day.
2. Participants will have less severe hot flashes during the day.
3. Participants will have fewer hot flashes during the night.
4. Participants will have less severe hot flashes during the night.

5. Participants will have better sleep quality.

**Protection of human subjects**

This EBP project was approved by the Institutional Review Boards (IRB) of The Catholic University of America and Mercy Medical Center. Participation was voluntary and patients could end their participation at any time during the project. Informed consent was obtained from patients who wished to receive acupuncture for treatment of their hot flashes. Participants were known to the acupuncturist and project director but their identity is protected by coding for any outside review or presented, written, or published form of this project.

## CHAPTER FOUR: RESULTS

The purpose of this EBP project was to determine if acupuncture is an effective treatment for decreasing the frequency and severity of hot flashes and improving sleep quality of breast cancer survivors at Mercy Medical Center. The acceptability of acupuncture as a treatment was evaluated before and after completion of acupuncture sessions.

### **Demographics**

Of the twenty breast cancer survivors who agreed to participate in this project, only ten completed all eight acupuncture treatments. Of those ten women who did not complete the treatments, nine did not attend any acupuncture sessions. Five of these participants felt they could not begin treatment because of life events that occurred shortly after they consented to the study. These included: (1) recurrence of breast cancer and need for subsequent treatment, (2) need to care for elderly father, (3) problems with depression, (4) health problems that precluded getting out of the house, and (5) unable to find the time to start because of holiday responsibilities. One participant completed five acupuncture treatments but then cancelled the remainder of her acupuncture appointments because of development of pain unrelated to breast cancer diagnosis. The other four participants who did not begin acupuncture treatments did not return phone calls and were lost to follow-up.

The mean age of all participants was 51.1. Twelve (60%) were African American and eight (40%) were non-Hispanic white. Eight participants (40%) were married, eight (40%) were single and 4 (20%) were divorced. The group was predominantly well educated with seventeen (35%) having some college education and ten (50%) with undergraduate or graduate degrees. The majority of the participants (90%) had received chemotherapy for treatment of their cancer.

Fifteen (75%) were on endocrine treatment, either tamoxifen or an aromatase inhibitor. (See Table 4.1)

Ten participants (50%) had tried previous interventions for their hot flashes, either medication or non-pharmacological treatments. The two who tried medication (10%) had used venlafaxine. The eight (40%) who tried non-pharmacologic means to control their hot flashes varied greatly in their choice of treatment. Participants cited the following interventions: (1) soy, (2) putting head in freezer, drinking cold water, (3) vitamin mixtures, (4) decreasing caffeine and increasing exercise, (5) baked sweet potato daily, (6) vitamin D and calcium, (7) evening primrose oil, (8) sage tea, (9) “change of life” herbs, and (10) black cohosh. None of these interventions are supported by research findings and participants reported they did not work. Half of the participants had not tried any measures to decrease their hot flashes. (See Table 4.1)

Ten (50%) of the participants qualified for Mercy’s low income program which made them eligible to receive their eight acupuncture treatments for the cost of a \$15 copay per treatment. The Red Devils, a charitable organization that supports breast cancer patients, agreed to cover the cost of the copay for all ten of these women. The remaining ten (50%) had insurance coverage for acupuncture, but copays and number of treatments covered varied. (See Table 4.1)

With an attrition rate of 50% it was necessary to compare the demographics of the participants who completed the study with those who did not. As seen in Table 4.1, only two significant differences were noted in the group that completed the study: (1) fewer women were single, and (2) fewer women had tried non-pharmacological means to control their hot flashes. Overall the two groups were fairly homogeneous.



**Table 4.1: Demographics**

	Total # participants N = 20 (%)	# Participants who completed study N= 10 (%)	# Participants who did not complete study N=10 (%)	Difference in percentage required at 95% confidence level
Age, mean (SD)	51.1 (7.4)	49.7 (6.9)	52.5 (7.9)	
Race				
African American	12 (60.0)	5 (50)	7 (30)	42.04/NS
Non-Hispanic White	8 (40.0)	5 (50)	3 (30)	
Education				
Did not graduate from HS	2 (10.0)	0 (0)	2 (20)	24.7/NS
High School graduate	1 (05.0)	1 (10)	0 (0)	18.59/NS
Some College	7 (35.0)	3 (30)	4 (40)	41.58/NS
Undergraduate Degree	3 (15.0)	2 (20)	1 (10)	30.99/NS
Graduate degree	7 (35.0)	4 (40)	3 (30)	41.58/NS
Marital Status				
Married	8 (40.0)	5 (50)	3 (30)	42.04/NS
Single	8 (40.0)	2 (20)	6 (60)	39.2/IS
Divorced	4 (20.0)	3 (30)	1 (10)	33.95/NS
Received Chemotherapy	18 (90.0)	10 (100)	8 (80)	24.79/NS
Currently taking Tamoxifen	5 (25.0)	3 (30)	2 (20)	37.7/NS
Currently taking aromatase inhibitors	7 (35.0)	3 (30)	4 (40)	41.58/NS
Not on endocrine therapy	8 (40.0)	4 (40)	4 (40)	42.94/NS
Have tried medication for hot flashes	2 (10.0)	2 (20)	0 (0)	24.79/NS
Have tried other treatments for hot flashes	8 (40.0)	2 (20)	6 (60)	39.2/IS
No intervention for hot flashes	10 (50.0)	6 (60)	4 (40)	42.9/NS
Qualify low income program	10 (50.0)	5 (50)	5 (50)	43.84/NS
Insurance coverage for acupuncture	10 (50.0)	5 (50)	5 (50)	43.84/NS

Note. IS = is significant; NS = not significant

## Data analysis

Data were analyzed using a two-tailed, paired t-test with significance set at the .05 level. SPSS software was used to complete the analysis. The significance for the difference between the two means was analyzed for pre and post acupuncture treatment nocturnal hot flash frequency, nocturnal hot flash severity, daytime hot flash frequency and daytime hot flash severity. The number of hot flashes was averaged over the seven days that the participants filled out the hot flash diary. Nighttime and daytime hot flashes were recorded separately. Severity was rated using a scale of 0 = no hot flashes, 1 = mild, 2 = moderate, and 3 = severe. Severity for nighttime and daytime hot flashes was also recorded separately and the scores were averaged over the seven days.

All ten participants experienced a decrease in the average number of nighttime hot flashes following the eight acupuncture treatments. Pre-treatment range was 1-20.2 compared to post-treatment range of 0-5. A 71% decrease was noted in the average number of nighttime hot flashes. Paired t-test revealed a significant difference in the number of nighttime hot flashes pre and post acupuncture ( $p = 0.04$ ). All participants also reported decreased severity of nighttime hot flashes after acupuncture. This difference was also found to be significant ( $p = 0.001$ ).

All ten participants reported a decrease in the number of daytime hot flashes; however, this difference was not found to be significant ( $p = 0.089$ ). A 60% decrease was noted in the average number of daytime hot flashes. One participant averaged 36 hot flashes per day, much higher than the remainder of the study population with 9.14 being the next highest reported average. This contributed to the high standard deviation of 7.6. All ten participants had a

decrease in the severity of their daytime hot flashes and this was found to be significant ( $p < 0.001$ ). (See Table 4.2)

**Table 4.2: Hot flash frequency and severity**

	Pre-Acupuncture Mean (SD)	Post-Acupuncture Mean (SD)	Significance (* $p = 0.05$ )
Number of Nocturnal Hot Flashes	5.5 (6.0)	1.6 (1.6)	$p = 0.04^*$
Severity of Nocturnal Hot Flashes	2.2 (0.5)	1.1 (0.9)	$p = 0.001^*$
Number of Daytime Hot Flashes	7.6 (10.3)	3.1 (3.4)	$p = 0.089$
Severity of Daytime Hot Flashes	2.3 (0.7)	1.2 (0.7)	$p < 0.001^*$

Quality of sleep was assessed among the participants with the PSQI questionnaire, pre and post acupuncture, using scores based on the self-rating of sleep over the previous week. Global scores improved for all ten participants with pre and post acupuncture range from 7-19 and 2-17, respectively. The differences between the pre and post PSQI scores was found to be significant ( $p = 0.021$ ). (See Table 4.3)

**Table 4.3: Pre and post PSQI scores**

	Pre-Acupuncture Mean (SD)	Post-Acupuncture Mean (SD)	Significance (* $p = 0.05$ )
PSQI Total Score	13.0 (4.4)	9.5 (4.3)	$p = 0.021^*$

How participants perceived the acceptability of acupuncture as a treatment for hot flashes was evaluated using a Likert scale rating acceptance from 1-10 with 1= very unacceptable and 10 = very acceptable. Scoring ranged from 7-10 pre-acupuncture and 4-10 post-acupuncture. Three of the participants scored lower on the post acupuncture score, five participants' scores did not

change and two participants reported a higher acceptance score following acupuncture. The difference pre and post acupuncture was not found to be significant ( $p = 0.428$ ). (See Table 4.4)

**Table 4.4: Pre and post acceptability scores**

	Pre-Acupuncture Mean (SD)	Post-Acupuncture Mean (SD)	Significance (* $p = 0.05$ )
Acceptability Score	9.1 (1.2)	8.4 (2.1)	0.428

Following the completion of all eight acupuncture treatments, participants were interviewed to determine what they felt was the best and worst part of their acupuncture sessions and what problems they may have encountered. See Table 4.5 for a synopsis of responses to the four questions. All the participants commented that they either found the acupuncture treatments to be relaxing or felt that their hot flashes were improving. The most common negative comment concerned the pain of needle insertion. All participants stated that they would recommend acupuncture to their family or friends.

**Table 4.5: Post-acupuncture interview responses**

Interview Question	Responses to Post-Acupuncture Acceptability Questions
What did you feel was the best part of your acupuncture treatment?	<p>“It was relaxing during the treatment.”</p> <p>“It minimized my hot flashes. I liked talking to the acupuncturist.”</p> <p>“It decreased my hot flashes and I sweat a lot less.”</p> <p>“I always fell asleep during the treatment.”</p> <p>“It was relaxing. I enjoyed the quietness.”</p> <p>“I liked the relax mode.”</p> <p>“I liked the quietness and customer care.”</p> <p>“I noticed improvements immediately in sleep patterns. I didn’t wake in the middle of the night with hot sweats. My hot flashes were less often even during the day.”</p> <p>“They actually worked. I also enjoyed the total wellness.”</p> <p>“I felt relaxed, calm, and in control of my emotions.”</p>

**Table 4.5: Post-acupuncture interview responses (cont.)**

Interview Question	Responses to Post-Acupuncture Acceptability Questions
What did you feel was the worst part of your acupuncture treatment?	<p>“The needles hurt sometimes.”</p> <p>“The pain of the needles in my toes.”</p> <p>“Paying out of pocket.”</p> <p>“Needles in my foot were sometimes painful.”</p> <p>“Needles going in.”</p> <p>“Occasional needle sticks in areas that really hurt!”</p> <p>4 participants responded “nothing”.</p>
What problems did you encounter during your acupuncture treatment?	<p>“One time I couldn’t remember where I parked my car. Think I needed more treatments because the hot flashes returned.”</p> <p>“Scheduling treatments was challenging.”</p> <p>“Having to go to the bathroom after the needles were inserted.”</p> <p>7 participants reported having no problems.</p>
Would you recommend acupuncture to a family member or friend?	<p>9 participants stated “Yes”.</p> <p>1 participant stated “Yes, already have!”</p>

## CHAPTER FIVE: CONCLUSIONS

Hot flashes resulting in disruptions in sleep and decreased quality of life are a common occurrence for many breast cancer survivors (Berger et al., 2009; Drisko, 2004; Fenlon & Rogers, 2007; Fenlon, Corner, & Haviland, 2009; Hunter et al., 2009; Savard, Savard, Trudel-Fitzgerald, Ivers, & Quesnel, 2011). Although numerous interventions have been tried to alleviate this problem, very few of these are supported by research. Data exist that support the use of acupuncture for decreasing the frequency and severity of hot flashes without the side effects associated with medications (Deng et al., 2007; Frisk et al., 2008; Hervik & Mjaland, 2009; Nedstrand et al., 2006; Tukmachi, 2000; Walker et al., 2010). This evidence based practice project demonstrated that acupuncture treatments were effective in significantly decreasing the number of hot flashes, diminishing the severity of hot flashes, and improving sleep in a breast cancer survivor population at Mercy Medical Center.

### **Discussion**

Women in this study received acupuncture twice a week for four weeks. Other studies demonstrating significant improvement in breast cancer survivors' hot flashes using acupuncture also initiated treatment on a twice a week schedule (Deng et al., 2007; Frisk et al., 2008; Hervik & Mjaland, 2009; Nedstrand et al., 2006; Tukmachi, 2000; Walker et al., 2010). Although all participants reported a decrease in number and severity of hot flashes at the completion of treatment, one participant noted that her hot flashes returned once she had completed four weeks of acupuncture. It is documented that longer term, or maintenance acupuncture, extends the length of the effectiveness of treatment (Frisk et al., 2008; Frisk, Kallstrom, Wall, Fredrikson, & Hammar, 2012; Hervik & Mjaland, 2009; Nedstrand et al., 2006; Porzio et al., 2002; Walker et

al., 2010). Frisk et al. (2012) found that after twelve weeks of electroacupuncture, vasomotor symptoms in women with breast cancer were improved for up to two years. Several of the women who participated in this project continued their acupuncture sessions on their own following completion of the final hot flash diary. Mercy Medical Center's low income program only paid for eight acupuncture sessions so participants who qualified for this did not receive additional treatment beyond four weeks.

This project showed a significant decline in the number of nighttime hot flashes that the participants experienced following acupuncture treatment ( $p = 0.04$ ). A 71% decrease in the average number of nighttime hot flashes was noted. A retrospective chart audit by Filshie et al. (2005) determined that the chance of a prolonged effect from acupuncture increased if patients experienced at least a 50% decrease in symptoms after treatment. Although all the participants reported fewer daytime hot flashes as well, this difference was not significant. This could be attributed to one participant whose average number of thirty-six hot flashes per day was much greater than the other women ( $SD = 7.6$ ). While the decrease in the average number of daytime hot flashes was not statistically significant ( $p = 0.089$ ), this one participant's experience with acupuncture was significant. Following her chemotherapy, this patient was placed on tamoxifen to decrease the risk of cancer recurrence. She reported her hot flashes to be so frequent and severe they totally disrupted her life to the point where she was going to discontinue her tamoxifen. Following acupuncture, her symptoms improved drastically and she no longer considered stopping her medication. As tamoxifen is associated with a 31% decrease in annual breast cancer deaths, this could have a profound effect on this participant's long-term survival (Hickey, Peate, Saunders, Friedlander, 2009).

This project did show a significant decrease in the severity of both daytime and nighttime hot flashes ( $p < 0.001$ ,  $p = 0.001$ , respectively). As the severity of the women's hot flashes diminished, two participants noted that they did not sweat as much and the hot flashes they did have were less bothersome. These findings are supported by other research. Painovich et al. (2012) examined the effect of true acupuncture (TA), sham acupuncture (SA) and a waiting control on hot flash severity. They found severity improved for both TA and SA compared to the control. The TA group had continued improvement in severity of hot flashes for the three month evaluation period compared to the SA group whose hot flash severity remained static after five weeks. The study also examined the effect of TA and SA on the hypothalamic-pituitary-adrenal axis which influences vasomotor symptoms. Adrenocorticotrophic hormone stimulation tests and 24-hour urine cortisol and metabolites showed that only TA impacted this axis suggesting that the effect of TA is more than a placebo effect. Frisk et al. (2008) addressed distress from hot flashes and noted a decrease in distress scores following electroacupuncture from 5.5 at baseline to 2.4 at two years. Liljegren et al. (2012) found twice a week treatments for five weeks of true acupuncture significantly decreased the severity of hot flashes in breast cancer patients compared to control acupuncture (non-insertive stimulation at non-acupuncture points).

Hot flashes in breast cancer survivors have been linked to substantial disruptions in sleep (Berger et al., 2009; Fenlon et al., 2009; Hunter et al., 2009). One would suppose that as hot flashes improved, so would sleep. This study showed significant improvement in overall sleep quality as evidenced by decreased scores on the PSQI following acupuncture treatments ( $p = 0.021$ ). de Valois et al. (2010) evaluated the effect of acupuncture on menopausal symptoms in breast cancer survivors using the Women's Health Questionnaire (WHQ). Three items in this



tool address sleep problems and de Valois' study did show a significant improvement in sleep following eight acupuncture treatments over eight weeks.

Several of the participants in this study noted in the PSQI other reasons for not sleeping well in addition to hot flashes. These included: (1) being unable to shut off their brain to stop thinking about the cancer, (2) fear or worry about their cancer, (3) tinnitus, a toxicity of one of the chemotherapy agents, and (4) pain, both related and unrelated to their cancer diagnosis. Whether acupuncture has a role in improving sleep in ways other than reducing hot flashes needs to be considered.

Participants in this project found acupuncture an acceptable treatment for hot flashes although the average acceptability score decreased following acupuncture treatment (9.1 vs. 8.4,  $p = 0.428$ ). Interestingly, even those participants who rated acupuncture lower after receiving treatment still stated they would recommend acupuncture to their family and friends. A recent qualitative study by Mao et al. (2012) found acupuncture to be acceptable to both white and African American breast cancer survivors. The study also found that African American women were more likely to prefer acupuncture over taking another pill because they were concerned about the number of medications they were already on. Both whites and African Americans voiced their belief that acupuncture was a natural alternative for the management of hot flashes.

Upon examining statements made by participants in response to the question "What did you feel was the best part of your acupuncture treatment?" two themes were noted; (1) the relaxing and soothing aspects of the experience, and; (2) the perceived positive clinical effects. Six participants noted that it "was relaxing", "enjoyed the quietness", "felt relaxed, calm, and in control of my emotions", "liked the relax mode", and "fell asleep during treatments". Four

participants stated that “it minimized my hot flashes”, it decreased my hot flashes and I sweat a lot less”, “I noticed improvements immediately in sleep patterns...didn’t wake in the middle of the night with hot sweats”, and “they actually worked”.

Five participants described the worst part of the acupuncture was the pain that sometimes occurred with the needle insertion. This pain could account for the decreased acceptability scores following completion of acupuncture although no participants stated this as a specific reason for a lower acceptability rating. All five of these participants completed their acupuncture sessions and recommended acupuncture to friends and family. Four participants felt there was “nothing” that they disliked about the acupuncture treatment. No participants experienced any side effects following treatment. In light of these findings, it would seem that acupuncture is very well tolerated, a finding also shared by de Valois et al (2010) and Filshie et al. (2005).

All acupuncture treatments were administered by a single acupuncturist employed by the Medi-Spa on the premises of Mercy Medical Center. She is a licensed acupuncturist in Maryland and has specialized in oncology acupuncture. In order to closely replicate what would be standard practice in true Chinese acupuncture, she tailored her choice of acupuncture points to fit her assessment of the participant at each visit. No attempt was made to standardize treatment. This most accurately reflects the practice of acupuncture in the community at large where treatments are individualized. Otte, Carpenter, Zhong, & Johnstone (2011) utilized community acupuncturists in their study of sleep disturbances and hot flashes in breast cancer survivors and found short-term benefit for the use of acupuncture in diminishing hot flashes and improving sleep.

## **Limitations**

Several limitations of the study directly threatened the internal validity of this project: (1) the use of a one group pretest-posttest design lacks a control group, (2) the participants were self-selected and may have pre-existing biases that could affect their response to acupuncture, and (3) the project had an attrition rate of 50%. Threats to external validity include: (1) participants drawn from a single site in an urban setting, (2) small sample size, and (3) use of one acupuncturist.

The placebo effect can decrease hot flash frequency by 20-30% with a month of treatment. Occasionally it has been noted that research subjects randomized to placebo treatments have reported decreases in hot flashes greater than 50% (Sloan et al., 2001). The placebo effect generally does not persist for longer than twelve weeks (Frisk et al., 2008). Participants in this project were only treated for four weeks and the effects of acupuncture were assessed one week after completion of treatment. Placebo effect cannot be ruled out as at least a partial cause for the decrease in frequency and severity of hot flashes.

Financial constraints limited who could participate in the project. If insurance did not cover acupuncture and the women did not qualify for the low income program, they usually could not afford to participate. The on-site acupuncturist who provided the treatments to the participants had limited hours at Mercy's Medi-Spa. She was only available two days a week and this made it difficult for some women to arrange treatment times that fit into their schedule. These two factors prevented many interested women from participating in this EBP project.

## **Cost analysis**

There are no previous studies that analyze the cost effectiveness of acupuncture for managing hot flashes in breast cancer survivors. Acupuncture has been shown to be cost effective versus standard of care for many other health problems such as neck pain, arthritis and sinusitis (Whitehurst et al., 2011; Witt, Reinhold, Jena, Brinkhaus, & Willich, 2009). As the most effective pharmacological treatment for hot flashes is currently venlafaxine, an attempt was made to consider the comparative cost effectiveness of acupuncture and venlafaxine.

Costs for physician, nurse, and nurse practitioner time will be similar for both initiating treatment with acupuncture or venlafaxine as the process is equivalent for assessment, referral, and prior authorization of each. The cost of acupuncture is about \$85 per session in the Baltimore area. The total cost of acupuncture alone would range from \$680-\$1020 for 8-12 sessions. The cost of venlafaxine ranges from \$25-95 per month for a total of \$300-\$1140 for one year's treatment. The use of venlafaxine involves finding transportation to the pharmacy and this may occur 4 or 12 times in a year depending on how the prescription is written and how much insurance will pay for at one time. Transportation to acupuncture would occur 8-12 times. Childcare during acupuncture might be a consideration as treatments last one hour and children cannot be present.

The decrease in hot flashes and improvement in menopausal quality of life symptoms and mental health are similar between the venlafaxine and acupuncture groups. The quality-adjusted life-years (QALY) utility gained is determined by the average of the before and after utility value of venlafaxine minus the average utility value of acupuncture. Since the improvement in symptoms was similar between groups this will be assigned a value of one. The incremental cost

effectiveness ratio (ICER) equals the mean cost of acupuncture minus the mean cost of venlafaxine/QUALY utility gained.

The average cost of acupuncture sessions is \$850. The average cost of venlafaxine for a year is \$720. To add in extra cost of transportation and childcare for acupuncture sessions we will assign a value of \$18 for 1 ½ hours babysitting in Baltimore at an average of 10 sessions which is equal to \$180. A one-way unreduced bus fare is \$1.60 so the two-way bus fare cost for 10 sessions would equal \$32. The average cost of bus fare for travel to the pharmacy with an average of 8 trips for a year would equal \$25.60. If children are brought along to avoid babysitting costs the overall fares would increase.

Assuming the cost of one child either for babysitting or brought to the pharmacy, the direct care cost of acupuncture compared to venlafaxine would be; 1) difference in treatment cost,  $\$850 - \$720 = \$130$ ; 2) difference in childcare,  $\$180 - \$0 = \$180$  and; 3) difference in travel,  $\$32 - \$51.20 = -\$19.20$ . The total cost of acupuncture would be \$290.80 more than the cost of venlafaxine.

Walker's (2010) study did not quantify the lack of adverse events in the acupuncture group compared to a 72% incidence of adverse side effects secondary to venlafaxine. This could potentially have an effect on QUALYs and the ICER. In a trial comparing venlafaxine to placebo for controlling hot flashes in breast cancer survivors, 21% of subjects on venlafaxine withdrew because of side effects (Carpenter et al., 2007).

The direct cost of care would appear to be greater for acupuncture than venlafaxine although patient circumstances could influence this greatly. Increased quality of life and lack of adverse events secondary to acupuncture could increase QUALY for women getting acupuncture

compared to venlafaxine. Currently data do not exist to determine this. For women who are unable or unwilling to take venlafaxine for management of hot flashes, acupuncture is an effective alternative that is only modestly more costly than venlafaxine.

### **Barriers to the utilization of acupuncture**

In this project a significant barrier to patient participation was cost. Insurance and finances were major determinants in deciding whether to enroll in the study. Many women who were suffering from hot flashes and interested in participating were unable to do so because; (1) they did not have insurance coverage for acupuncture and could not afford it out of pocket, (2) they did not qualify for Mercy's low income program, or (3) the acupuncturist at Mercy was not a preferred acupuncture provider for their insurance. Recently, states have had to finalize what will become mandatory services covered by health insurance as guaranteed by the new health care law. Maryland has chosen acupuncture for managing pain, nausea and other health problems as a required benefit beginning in 2014 (Goodnough, 2012; Health CMI, 2012). Insurance coverage for acupuncture and the ability to access all community acupuncturists will do much to remove the financial barrier to utilizing acupuncture for the management of hot flashes for patients at Mercy Medical Center.

A second barrier that was noted during the project was time constraints. Patients had busy lives and were unable to make the commitment to attend two acupuncture sessions a week. Life events such as health problems or needing to care for ill parents made it difficult to leave the house. In this project only one acupuncturist was utilized who was available just two days a week making scheduling appointments even more difficult. The availability to use any

acupuncturist in the community would help with this last problem but the other life events and time constraints cannot be changed.

### **Implications and sustainment plan**

This project supported the use of acupuncture as effective for the management of hot flashes in breast cancer survivors at Mercy Medical Center. The JHNEBP model depicts the cornerstones of practice, education, and research as the foundation of professional nursing influenced by both internal and external factors (Newhouse et al., 2007a). The staff in the Outpatient Chemotherapy Clinic has remained stable for many years. They have been educated about appropriate treatments for hot flashes, including pharmacological and non-pharmacological interventions. The strongest evidence supports the use of venlafaxine and acupuncture for diminishing the frequency and severity of hot flashes. This evidence will be presented to all the nurses at the monthly staff meeting. The nurses are already consistent in evaluating patients for any problems, both acute and related to survivorship issues.

This EBP project increased the physician's awareness of the use of acupuncture for managing hot flashes for breast cancer survivors. The physicians routinely assess these patients for problems with hot flashes and since the inception of the project, offer acupuncture as a treatment more frequently than before. Often patients do not understand acupuncture or the acupuncture options that exist. They are not familiar with where and how to obtain acupuncture treatment.

Internal factors include resources available within the institution in which the evidence-based practice is being implemented. In order to assist patients in obtaining acupuncture as a treatment, a pamphlet or small book will be constructed that explains what acupuncture is, what

to expect during treatments, and include a list of acupuncturists available in the area and what insurances they accept. The low income program at Mercy will be presented by the social worker to patients who do not have insurance coverage and are unable to afford acupuncture. If patients receive information regarding acupuncture, it will be noted in the electronic medical record. When they return for their next visit, the oncology provider will receive a prompt in the system to ask the patient if they have scheduled acupuncture appointments. This process will reflect a change in practice.

The most notable external factor which will have a strong influence on patient's ability to pursue acupuncture as a treatment for hot flashes is the new health care law. In Maryland, acupuncture will be a required benefit of health insurances beginning in 2014. Patients who previously could not receive acupuncture due to insurance coverage and cost will now have this option open to them.

## **Summary**

Acupuncture is an effective, non-pharmacological treatment for the management of hot flashes in breast cancer survivors. This project supports its use for decreasing the frequency and severity of hot flashes and improving sleep quality. Patients find it an acceptable method of treatment. Our sample was made up of women who were more educated than the general population and the influence this might have had on the acceptance of acupuncture as a legitimate form of therapy is unknown. The use of complementary alternative medicine (CAM) is greater among women with higher education levels (U.S. Department of Health and Human Services, 2008). Although acupuncture was sometimes described as painful, most participants



found it to be relaxing and effective. Acupuncture is cost effective, safe, and does not have the side effects of medication.

### **Recommendations**

Research supports the use of acupuncture as an effective treatment for the management of hot flashes in breast cancer survivors. What is not known is what the ideal schedule of sessions should be and how long acupuncture should be continued. It is also not known if acupuncture will be as effective with cancer survivors such as women with gynecological cancers or men with prostate cancer on endocrine treatments who also experience debilitating hot flashes. Long term studies addressing optimal treatment schedules are necessary to determine how acupuncture can be most effectively applied. Research studies incorporating other cancer survivor populations would provide additional evidence for oncology practitioners regarding the optimal use of acupuncture. While research shows CAM is more readily accepted by women with higher educational levels, it is not known if this also applies to acupuncture. Research addressing the influence of socioeconomic status and educational level on the use of acupuncture could provide findings that would assist health care providers provide patient-specific information and recommendations about acupuncture

Although the oncology physicians and nurses at Mercy Medical Center are knowledgeable about the use of acupuncture and recommend it to their patients, this may not be true of all settings. At this time, acupuncture is not widely used for managing the hot flashes of breast cancer survivors. It may be that patients are not informed of this modality by their health care providers. Research addressing the knowledge level of health care practitioners about

acupuncture and their willingness to recommend this to patients could provide valuable information.

Education that encompasses the evidence supporting acupuncture as an effective treatment for hot flashes is important for both oncology care providers and cancer survivors. Patients should be offered alternatives to medications. Informational sessions can be offered to health care providers in the practice setting. Booklets prepared for patients about acupuncture and what to expect during treatment can be used as a stepping stone for suggesting alternative treatments for hot flash management. Education based on research evidence will provide the foundation of practice change.

Mercy Medical Center does have an onsite Medispa where acupuncture treatments are available. Patients are more likely to seek acupuncture to treat their hot flashes if the location for treatment is readily accessible. A recommendation for administration at health care facilities to include an acupuncturist on staff, or to have one available on the premises, might increase the use of acupuncture among breast cancer survivors and other patient populations as well.

## **Conclusion**

As the number of breast cancer survivors increases, health care providers, and nurses in particular, must address the problems that arise with survivorship. One debilitating sequelae of cancer treatment is hot flashes that disrupt sleep and diminish quality of life. Many different medications and non-pharmacological alternatives have been recommended to patients with no data to support these recommendations. Research evidence supports acupuncture for managing the hot flashes experienced by breast cancer survivors. As patients search for alternative

treatments to medication for minimizing their hot flashes, nurses are in a key position to make evidence-based recommendations regarding the use of acupuncture.

## **Appendix A**

### **CONSENT TO PARTICIPATE IN EVIDENCE-BASED PRACTICE PROJECT**

#### **Acupuncture for the Management of Hot Flashes in Breast Cancer Survivors**

You are invited to participate in a study conducted by Hollis Misiewicz who is a doctoral student from the School of Nursing at The Catholic University of America. Ms. Misiewicz will be the project director of this study.

Your participation in this study is entirely voluntary. You should read the information below and ask questions about anything you do not understand before deciding whether or not to participate. You are being asked to participate in this study because you are a breast cancer survivor who has hot flashes that are interfering with your quality of life and have chosen acupuncture as a treatment for this.

### **PURPOSE OF THE PROJECT**

The purpose of this project is to determine if acupuncture is an effective treatment for reducing hot flashes and improving quality of sleep in breast cancer survivors at Mercy Medical Center. It will also determine if patients feel that acupuncture is an acceptable form of treatment for hot flashes both before and after receiving acupuncture.

### **PROCEDURE**

If you volunteer to participate in this project, we will ask you to do the following:

1. Provide information about your age, marital status, and educational level. Provide information about any treatment for breast cancer you have had or are receiving and about any remedies you have tried for your hot flashes.
2. Prior to starting your acupuncture treatment you will fill out the Pittsburgh Sleep Quality Index (PSQI). This is a questionnaire that can be completed in 5 minutes that rates how well you sleep. You will also be asked how acceptable you feel acupuncture will be to you as a treatment for hot flashes..
3. You will also be given a hot flash diary to take home where you will record the severity and the number of hot flashes that you have during the day and during the night. You will record hot flashes in your diary for one week before starting your acupuncture treatment.
4. Your acupuncturist at the Medi-Spa will set up appointments for 8 acupuncture treatments. These appointments will be 2 times a week. You will be expected to keep your appointments or let us know if you are unable to do so.
5. After you have completed your 8 acupuncture treatments you will once again be asked to fill out the PSQI questionnaire. You will again be asked how acceptable you found the acupuncture treatments to be on a 1-10 scale. You will be asked to describe what you liked about your acupuncture experience and describe any problems that you had. You will again be given a hot flash diary to take home to record your hot flashes for the week after you have finished acupuncture. When this is completed you will return the diary to the project director.

## **WITHDRAWAL FROM THE PROJECT**

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. There is no penalty if you choose not to participate or if you withdraw from the project and you will not lose any benefits to which you are otherwise entitled. Withdrawal from the study will not affect your acupuncture treatments.

## **POTENTIAL RISKS AND DISCOMFORTS**

There is no risk for you in participating in this study. The risks of acupuncture have been explained to you by your acupuncturist at the time of your initial consultation with her.

## **POTENTIAL BENEFITS TO PARTICIPANTS**

There are no direct benefits to you for participating in this study, however, the findings of this study will be used to advance knowledge related to treatments for hot flashes experienced by breast cancer survivors.

## **CONFIDENTIALITY**

Any information that is obtained in connection with this project and that can be identified with you will remain confidential and will be disclosed only with your permission. You will not be identified by name in any database or publication resulting from this project. Confidentiality will be maintained by means of a code number that will let the project director know who you are. All study questionnaires and forms will be stored in a locked cabinet in a controlled access area. By signing this form, you are giving permission to the project director, the project director's committee, and the nursing faculty at The Catholic University of America to look at and review data related to this study including your demographic data and the information discovered during this study. Once data collected in the study is released by the project director to the committee and nursing faculty mentioned above, it is possible that this data may no longer be protected by federal privacy laws. You have the right to revoke this authorization for use of your data in writing. If you withdraw from the project, all data already collected will be excluded from use in the project. Signing this consent form does not give permission to the project director to view your medical records.

## **IDENTIFICATION OF PROJECT DIRECTOR**

If you have any questions or concerns about the project, please feel free to contact:  
Hollis Misiewicz, CRNP  
Project Director  
Doctoral Candidate, Catholic University of America  
51misiewicz@cardinalmail.cua.edu  
410-562-7234

Mercy Medical Center IRB  
Dr. Ronald Geckler  
410-332-9692

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I understand the procedures described above. My questions have been answered to my satisfaction and I agree to participate in this study. I have been given a copy of this form.

\_\_\_\_\_  
Printed Name of Subject

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Date

Appendix B

**Demographic Data**

**Participant ID:** \_\_\_\_\_

**Age:** \_\_\_\_\_

**Marital Status:** \_\_\_\_\_

**Race:** \_\_\_\_\_

**Educational level:** \_\_\_\_\_

**Current or past breast cancer treatments (includes chemotherapy, biological therapy, radiation, endocrine treatment):**

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**Current or past interventions used to control hot flashes (includes medication) and approximate dates used:**

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Appendix C

ID # \_\_\_\_\_

Date: \_\_\_\_\_

Pre ( ) Post ( )

**PITTSBURGH SLEEP QUALITY INDEX**

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INSTRUCTIONS: The following questions relate to your usual sleep habits during the past week only. Your answers should indicate the most accurate reply for the majority of days and nights in the past week.

Please answer all questions.

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1. During the past week, what time have you usually gone to bed at night?

BED TIME \_\_\_\_\_

2. During the past week, how long (in minutes) has it usually taken you to fall asleep each night?

NUMBER OF MINUTES \_\_\_\_\_

3. During the past week, what time have you usually gotten up in the morning?

GETTING UP TIME \_\_\_\_\_

4. During the past week, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed).

HOURS OF SLEEP PER NIGHT \_\_\_\_\_

**For each of the remaining questions, check the one best response. Please answer all questions.**

5. During the past week, how often have you had trouble sleeping because you...

- a) Cannot get to sleep within 30 minutes

Not during the past week \_\_\_\_\_ Less than once a week \_\_\_\_\_ Once or twice a week \_\_\_\_\_

Three or more times a week \_\_\_\_\_

- b) Wake up in the middle of the night or early morning

Not during the past week \_\_\_\_\_ Less than once a week \_\_\_\_\_



Once or twice a week \_\_\_\_\_ Three or more times a week \_\_\_\_\_

c) Have to get up to use the bathroom

Not during the past week \_\_\_\_\_ Less than once a week \_\_\_\_\_

Once or twice a week \_\_\_\_\_ Three or more times a week \_\_\_\_\_

d) Cannot breathe comfortably

Not during the past week \_\_\_\_\_ Less than once a week \_\_\_\_\_

Once or twice a week \_\_\_\_\_ Three or more times a week \_\_\_\_\_

e) Cough or snore badly

Not during the past week \_\_\_\_\_ Less than once a week \_\_\_\_\_

Once or twice a week \_\_\_\_\_ Three or more times a week \_\_\_\_\_

f) Feel too cold

Not during the past week \_\_\_\_\_ Less than once a week \_\_\_\_\_

Once or twice a week \_\_\_\_\_ Three or more times a week \_\_\_\_\_

g) Feel too hot

Not during the past week \_\_\_\_\_ Less than once a week \_\_\_\_\_

Once or twice a week \_\_\_\_\_ Three or more times a week \_\_\_\_\_

h) Had bad dreams

Not during the past week \_\_\_\_\_ Less than once a week \_\_\_\_\_

Once or twice a week \_\_\_\_\_ Three or more times a week \_\_\_\_\_

i) Have pain

Not during the past week \_\_\_\_\_ Less than once a week \_\_\_\_\_

Once or twice a week \_\_\_\_\_ Three or more times a week \_\_\_\_\_

j) Other reason(s), please describe

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How often during the past week have you had trouble sleeping because of this?

Not during the past week \_\_\_\_\_ Less than once a week \_\_\_\_\_

Once or twice a week \_\_\_\_\_ Three or more times a week \_\_\_\_\_

6. During the past week how would you rate your sleep quality overall?

Very good \_\_\_\_\_

Fairly good \_\_\_\_\_

Fairly bad \_\_\_\_\_

Very bad \_\_\_\_\_

7. During the past week, how often have you taken medicine to help you sleep (prescribed or over the counter)?

Not during the past week \_\_\_\_\_ Less than once a week \_\_\_\_\_

Once or twice a week \_\_\_\_\_ Three or more times a week \_\_\_\_\_

8. During the past week, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past week \_\_\_\_\_ Less than once a week \_\_\_\_\_

Once or twice a week \_\_\_\_\_ Three or more times a week \_\_\_\_\_

9. During the past week, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all \_\_\_\_\_

Only a very slight problem \_\_\_\_\_

Somewhat of a problem \_\_\_\_\_

A very big problem \_\_\_\_\_

# Appendix D

Hot Flash Diary Participant ID: \_\_\_\_\_

Please record EACH Day: (1) The Date; (2) the number of nighttime hot flashes/sweats you had; (3) the number of daytime hot flashes you had; (4) the severity of your hot flashes/night sweats; (5) the time you fell asleep and woke up; If you did not have any hot flashes or night sweats, write "0" in the box for that day or night.

## Hot Flash Diary

Day Number	1	2	3	4	5	6	7
Date:	MM / DD / YY	MM / DD / YY	MM / DD / YY	MM / DD / YY	MM / DD / YY	MM / DD / YY	MM / DD / YY
Total # of <u>Nighttime</u> Hot Flashes/Sweats <u>last night?</u>	# Nighttime = _____	# Nighttime = _____	# Nighttime = _____	# Nighttime = _____	# Nighttime = _____	# Nighttime = _____	# Nighttime = _____
How severe were your hot flashes/sweats <u>last night?</u>	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
About what time did you fall asleep <u>last night?</u>	_____ : _____ Hr Min	_____ : _____ Hr Min	_____ : _____ Hr Min	_____ : _____ Hr Min	_____ : _____ Hr Min	_____ : _____ Hr Min	_____ : _____ Hr Min
Total # of <u>Daytime</u> Hot Flashes <u>today?</u>	# Daytime = _____	# Daytime = _____	# Daytime = _____	# Daytime = _____	# Daytime = _____	# Daytime = _____	# Daytime = _____
How severe were your hot flashes <u>today?</u>	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
About what time did you wake up <u>today?</u>	_____ : _____ Hr Min	_____ : _____ Hr Min	_____ : _____ Hr Min	_____ : _____ Hr Min	_____ : _____ Hr Min	_____ : _____ Hr Min	_____ : _____ Hr Min

## Appendix E

### **Initial Interview**

Acupuncture Acceptability question:

“On a scale of 1-10, with 1 being very unacceptable and 10 being very acceptable, how would you rate your feelings about acupuncture as a treatment for your hot flashes?”

1      2      3      4      5      6      7      8      9      10

## Appendix F

### **Final Interview**

Acupuncture Acceptability question:

“On a scale of 1-10, with 1 being very unacceptable and 10 being very acceptable, how would you rate your feelings about acupuncture as a treatment for your hot flashes?”

1      2      3      4      5      6      7      8      9      10

“What did you feel was the best part of your acupuncture treatment?”

“What did you feel was the worst part of your acupuncture treatment?”

“What problems did you encounter during your acupuncture treatment?”

“Would you recommend acupuncture to a family member or friend?”

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