5-4-2021

Guided Imagery and Sentinel Lymph Node Biopsy Pain

Brandy Alicia Kirk

GUIDED IMAGERY AND SENTINEL LYMPH NODE BIOPSY PAIN

by

BRANDY ALICIA KIRK RN, BSN

EVIDENCE-BASED PRACTICE PROJECT REPORT

Submitted to the College of Nursing and Health Professions

of Valparaiso University,

Valparaiso, Indiana

in partial fulfillment of the requirements

For the degree of

DOCTOR OF NURSING PRACTICE

2020

Brandy A Kirk 5/4/21 Jeffrey A. Coto Digitally signed by Jeffrey A. Coto Date: 2021.04.28 21:23:00 -05'00'

Student Date Advisor Date

ACKNOWLEDGMENTS

Thank you to my advisor Dr. Jeff Coto who was instrumental in helping me navigate an unfamiliar organization, introducing me to key stakeholders and ensuring I was aware of upcoming meetings where I could introduce my project intentions. A special thank you also is warranted for the participating facility surgeon who allowed me to contact and implement my EBP intervention on her patients and last the facility Breast Navigator for her insight and facility statistical information provided on SLN injections and breast cancer treatment. This project is dedicated to the women diagnosed with breast cancer who allowed me to participate in the attempt to improve this aspect of their breast cancer treatment.

TABLE OF CONTENTS

LIST OF TABLES

Table **Page**

LIST OF FIGURES

ABSTRACT

The standard of care in the treatment for women diagnosed with breast cancer includes identification and biopsy of the sentinel lymph nodes (SLN) of the breast (Chaterjee et al., 2017; Kneece, 2017). The process of identifying the SLNs involves radioisotope injections into or near the areola. Because this area is highly sensitive, women report this procedure to be considerably painful. The purpose of this evidence-based practice (EBP) project was to determine if the provision of a 5-minute session of guided imagery (GI), as a complementary alternative medicine, prior to SLN injections was effective in mitigating reports of procedural pain. A systematic review of the literature was conducted within five databases to evaluate the efficacy of GI in reducing pain. A convenience sample of six women, undergoing SLN injections, was provided with a 5-minute session of GI prior to their procedures. Their pain scores were rated pretest and posttest using a visual analogue scale. Posttest pain scores were compared to the pain ratings of women who previously underwent the procedure without the 5-minute session of GI. These pain scores had been recorded as part of an ongoing quality improvement project at a central Illinois hospital. Posttest pain ratings of the intervention and comparison groups were evaluated via an independent samples *t*- test. There was a significant difference between the intervention and comparison group (t (2)= 2.864, p = 0.012). However, the mean pain scores of the GI group (n = 6, *M* = 6.67, *SD*= 1.86) was not significantly less than the non-GI group (n = 13, *M* = 3.46, *SD* = 2.96). Future research, using a larger sample size, is needed to further clarify the efficacy of GI as a pain control measure for minimally invasive procedures.

Keywords: guided imagery, pain, breast cancer, breast neoplasm

CHAPTER 1

INTRODUCTION

Background

Treatment for breast cancer is multifaceted and varies from woman to woman depending on the type, advancement, and severity of her diagnosis. To reduce morbidity and better direct operative planning, the standard of care for patients with early-stage invasive breast cancers includes identification of the sentinel lymph nodes and subsequent biopsy (Whitman et al., 2019). This is based on the sentinel lymph node (SLN) concept, which is related to lymph system drainage. The SLN is the major lymph node where cancer cells from the primary tumor spread first (National Cancer Institute, 2020). The SLN concept predicts the health of the surrounding or regional lymph nodes based on the histologic status of the SLN (Whitman, et al., 2019). After the SLN is identified and analyzed, if it is cancer free there is no need to remove the surrounding lymph nodes fed by it. The SLN biopsy both helps physicians stage the cancer's progress by analyzing the presence of cancer and prevents the unnecessary removal of healthy lymph nodes (NIC, 2020; Whitman et al., 2019).

The removal of too many lymph nodes, cancerous or not, has adverse effects including infection, damage to nerve and blood vessels, increased risk for lymphedema, infection, seroma formation and limited mobility (NIC, 2020; Whitman et al., 2019). In years past the standard of care was to remove all the of axillary lymph nodes of women diagnosed with breast cancer, but subsequent research has shown that women who only receive SLN biopsy or dissection fare better than those who were provided the historical approach of complete axillary lymph node dissection (Giuliano et al., 2017; NIC, 2020; Whitman et al., 2019). Before the appropriate SLN(s) can be removed and analyzed, they must be properly identified.

The process utilized by the project implementation facility and elsewhere involves the injection of a radioisotope tracer into the SLN. The tracer is injected directly into the breast by

the surgeon and the women are later scanned under a gamma camera, also called a scintillation camera, which detects gamma rays emitted from the body via the nuclear isotope. Here lies the problem. The female breast is sensitive and highly innervated, many people cannot tolerate injections into much less sensitive parts of their bodies, thus many patients report this to be a very painful experience. At the facility implementation site, the committee head of The National Accreditation Program for Breast Centers (NAPBC) and physician who both performs the injections and related surgeries has been collecting data on her patients' pain ratings before and after the procedure. She has noted that despite the use of lidocaine prior to the isotope injection, many of her patients are reporting this part of the process as the most painful of all their procedures. The SLN injections take place on the day of their respective lumpectomies or mastectomies.

In accordance with the objectives and mission of the NAPBC, the aforementioned surgeon is dedicated to providing compassionate care and the improvement of quality outcomes, for women diagnosed with diseases of the breast, based on evidence-based standards (American College of Surgeons, 2020). Currently, this facility is conducting a multiarmed quality improvement study to determine the best EBP intervention(s) to alleviate pain during SLN injections. The aim of this arm of the study is to include a session of a guided imagery (GI) exercise prior to the radioisotope injection in attempt to mitigate the pain experience for the participants involved. Pain rating scores of the women who received guided imagery will be compared to existing data of the pain ratings of the women who did not use the GI tool.

Data from the Literature Supporting Need for the Project

Globally, breast cancer is the most common cancer in women consisting of 25.4% (2,088,849 new cases) of all cancers diagnosed in 2018, with the exclusion of nonmelanoma skin cancer (World Cancer Research Fund, 2020). Breast cancer is the second most common type of cancer diagnosed in U.S. females and the second most prominent cause of cancer

related death after lung cancer (American Cancer Society [ACS], 2018.; Centers for Disease Control and Prevention [CDC], 2020).

A diagnosis of breast cancer is lifechanging and can affect a woman's emotional, physical, and psychological wellbeing (Smit et al., 2019). The journey from diagnosis, treatment to recovery can be wrought with both physical and emotional suffering including increased anxiety and an alteration of self-image, identity, and femininity (Kneece, 2017; Smit et al., 2019). In their 2019 systematic review and meta-synthesis of qualitative studies regarding women's experiences of living with breast cancer, Smit et al. (2019) concluded that it was imperative for health care providers to be supportive and sensitive to improve patients' experiences throughout their breast cancer journeys.

National Data

In alignment with global statistics, breast cancer is the most common carcinoma diagnosis for females in the U.S. besides nonmelanoma skin cancer (ACS, 2018.; CDC, 2020). It is estimated that one out of eight women or 13% will be diagnosed with invasive breast cancer within their lifetime in the United States (ACS, 2018). In the year 2020 the incidence of breast cancer is predicted to increase by 276,480 new cases of invasive cancer and 48,530 new noninvasive or in situ cases (ACA, 2018). African American and Caucasian women develop breast cancer at the same rate, but black women are more likely to die from it than white women (CDC, 2020).

State Data

The project facility located in central Illinois serves patients from both Indiana and Illinois. The American Cancer Society (ACS) estimates that there will be 5,410 new female breast cancer cases in Indiana and 11,020 in Illinois in the year 2020 (ACS, 2018). According to data collected between 2012 and 2016, the Indiana incidence rate was 121.9 per 100,000 women and 131.9 per 100,000 in Illinois (ACS, 2018).

Data from the Clinical Agency Supporting Need for the Project

At the project facility site, 12,174 mammograms were performed in 2019, 1168 of these women were asked to return due to suspicious findings. 375 of these women, based on the imaging findings, underwent a diagnostic biopsy. This is not the same as a SLN biopsy. This biopsy is guided by ultrasound, mammography, or MRI to locate the tumor and retrieve a tissue sample to definitively diagnose it as benign or malignant. There were a total of 141 positive breast biopsies in 2019, meaning the tissue sample was malignant. Only seven women chose to continue with their care elsewhere, usually because they were transferring to a facility that performed nipple sparing mastectomies (Breast Navigator, personal communication, June 30, 2020). A total of 58 SLN radioisotope injections were performed (Breast Navigator, personal communication, June 30, 2020). So, a little less than half, 43.3% of the patients who tested positive for breast cancer and continued their treatment at this facility met the criteria SLN biopsies and received SLN injections.

When meeting with the physician who performs both the injections and the surgeries, she reported that this SLN injections are very painful for her patients, some state that it is the most painful procedure within the whole process. Even anesthetizing the site with lidocaine before the injections has not made a significant decrease in their postprocedural pain ratings according to this physician and key stakeholder (NAPBC facility surgeon, personal communication, June 4, 2020). Currently, this facility is conducting a quality improvement study to determine the best evidence-based intervention to reduce the pain experienced by the women who present for the SLN injections, so each patient's pain ratings are recorded.

Purpose of the Evidence-Based Practice Project

The purpose of this EBP project is to determine if the use of guided imagery (GI), a mind body, complementary therapeutic exercise, can alleviate the procedural pain experienced by breast cancer patients during the SLN injections. Because this situation is very brief and occurs at the beginning of a busy day for these participants, moderate sedation is not an option. The

guided imagery exercise will be introduced as an adjunct to the standard of care in hopes of making the patient's experience more tolerable.

Guided Imagery

Guided imagery is a powerful and simple relaxation technique that directs one's imagination to a place of peace and comfort to reduce anxiety, increase wellbeing, ease pain, and promote healing. The process involves listening to a speaker, often with sounds or music in the background, who prompts the listeners, step by step, to imagine that they are in a beautiful and peaceful location. The mind is kept busy imagining the warmth of the sun on the skin, the breeze blowing through the trees, and or the delights and sensations of the environment that they are concentrating on. It is an easy exercise that can be practiced anywhere. The words and images that the listener is thinking about direct his or her thoughts away from pain, stress and worry and instead alter the focus to healing and comfort.

Guided imagery promotes a state of relaxation and calm through the mind-body connection. Evidence from scientific studies has found that this mind-body connection can have beneficial effects on mental wellbeing, promotion of healing, perceptions of pain, heart rate, blood pressure and breathing patterns (Carlson et al., 2017). In fact, Guided imagery is recommended by the National Comprehensive Cancer Network (NCCN) to aid in reducing nausea and vomiting (NCCN, 2016).

PICOT Question

Specifically, this project will address the following PICOT question: Do women diagnosed with breast cancer, undergoing sentinel lymph node radioisotope injection, report less pain during the procedure when using guided imagery compared to women who do not utilize guided imagery over a 4-month implementation period?

Significance of the EBP Project

According to the American Nurses Association's position statement regarding pain, nurses have an ethical obligation to relieve both pain and suffering through individualized,

evidence-based interventions (ANA, 2018). Additionally, the ANA recognizes the necessity of multimodal and interprofessional strategies to achieve pain relief, which includes the advocation for policies that provide access to all effective pain management approaches (2018). The provision of guided imagery (GI), as a complementary pain relief modality, for breast cancer patients during their SLN injections adheres to the guidance provided by the ANA to provide optimal care for persons experiencing pain (2018).

The project facility site is accredited by the NAPBC and in accordance with its standards they strive to continually monitor and improve care including data collection on quality indicators for subspecialties involved throughout the breast cancer diagnosis and treatment continuum (American College of Surgeons, 2020). SLN injections are part of that continuum and current facility data measuring pain ratings for women undergoing this procedure suggests that the standard of care including subcutaneous lidocaine is not adequately controlling their pain.

Therefore, the implementation of a guided imagery intervention during the SLN injections provides a means to decrease patients pain ratings and improve their experience at this juncture of their breast cancer journey. An improvement in patient outcomes will be demonstrated by adequate pain control that improves the tolerability of an uncomfortable procedure.

CHAPTER 2

EBP MODEL AND REVIEW OF LITERATURE

Evidence-based Practice Model

Overview of EBP Model

The Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) model was designed to assist nurses with the process of both determining best practice based on the latest and highest quality evidence and expediently and properly putting those findings into practice (Dang & Dearholt, 2017). Essentially the model contains three main categories; practice question,

evidence and translation (PET), this three-step process contains 19 subcategories which provide a straightforward, step by step guide that can be followed at the very inception and throughout an EBP practice change project (Dang & Dearholt, 2017).

Steps contained within the practice question or (P) include recruitment of the interprofessional team, definition of the clinical problem, development and refinement of the EBP question, identification of stakeholders, determination of responsibilities for project leadership and the scheduling of pertinent team meetings (Dang & Darnholt, 2017). The next step of the process pertains to evidence (E) and entails conducting an internal and external search for evidence with subsequent appraisal of the level and quality of the findings. Next the strength and quality of the evidence findings are evaluated and synthesized (Dang & Darnholt, 2017). Recommendations for change are developed based on the level and strength of the results of the synthesis.

Translation (T) the final element consists of determination of the feasibility of the recommendations, creating a plan of action, securing support and resources to implement the action plan. Next implementation of the plan takes place followed by an evaluation of outcomes that are then reported to stakeholders. At this point, future steps are identified, and findings may be disseminated (Dang & Darnholt, 2017).

Application of EBP Model to DNP Project

After obtaining copyright permission to use the JHNEBP model for this project was obtained, it was used as a map and checklist for guidance throughout each step. Each aspect of the practice question portion outlined within the model was fulfilled, with some steps overlapping. The interprofessional team was identified early within the process with the help of the project and facility advisor. Identification and definition of the clinical problem, inadequately controlled pain during SLN radioscope injections, was based on personal communication from the NAPBC committee head and surgeon, internal data from an ongoing, multiarmed quality improvement study and input from the breast navigator.

The student, the breast navigator and the NAPBC surgeon comprise the bulk of the interprofessional team with the facility advisor's oversight. Leadership and project responsibilities and their sequence were clarified and outlined. Project responsibilities were further delineated and discussed at quarterly quality meetings and meetings arranged with the key stakeholders and IRB committee.

The internal data collected i.e., data regarding procedural pain during SLN injections provided the basis for defining the clinical problem. Data was also collected at the project facility regarding the number of patients diagnosed with breast cancer, treatment pathways and a tally of how many received SLN injections. A systematic search for evidence was conducted using five databases, handsearching and citation chasing. Ten studies were ultimately chosen. The strength and quality of the evidence was rated using the JHNEBP evidence appraisal tools (Dang & Darnholt, 2017). Based on the strength of the evidence supporting the efficacy of GI for pain mitigation, it was recommended as adjunctive intervention to address the clinical problem. A detailed explanation of the search and appraisal of evidence will be provided in the coming sections.

The DNP student met with the breast navigator to further discuss the feasibility, fit and logistics of the implementation of providing GI for this patient population. Next the student accompanied the breast navigator and observed the process and steps involved for SLN injections to better visualize a tenable plan of action. Further meetings were planned with the NABCP surgeon to secure support, and the project, protocol and consent were presented and approved by the IRB committee. An educational pamphlet was designed for the consenting participants, the appropriate means of providing the guided imagery session was rated and chosen and equipment was arranged to be available on the days of the SLN injections.

After developing and refining the action plan based on team input, the sequence and process was presented and approved by the interprofessional team and key stakeholders. Prior to Implementation of the plan, periodic meetings with team members were conducted to discuss

progress of the implementation as well as adjustments that were required. Outcomes were evaluated via statistical analysis using students *t*-testing and Pearson's *R* correlation and discussed with stakeholders. The identification of the next steps will most likely be decided after all arms of the study are completed. The NAPBC surgeon will next assess whether the utilization of a different nuclear isotope will reduce mean procedural pain scores compared to the data collected in this EBP project and previous arms of the quality improvement study.

Strengths and Limitations of EBP Model for DNP Project

The strengths of this model lie in its ease of use. The steps provide concrete and objective guidance that can realistically be achieved. Most of the steps are explicitly explained and provide a form that the team leader can fill out addressing all pertinent aspects. The sequence is also helpful to streamline the process and avoid pitfalls from skipping steps but requires flexibility. For instance, some aspects of fit and feasibility need to be considered much earlier within the process and should be considered throughout the plan's development. Also, identification of the problem could occur before an interprofessional team is recruited. The development of the EBP or PICOT questions requires at least a preliminary search and appraisal of evidence prior to providing the proposed intervention.

One must be able to support the use and efficacy of the intervention to key stakeholders and ancillary staff to gain their support. Additionally, in the translation section the plan is implemented but may need further evaluation and revision for improvement prior to the next step of outcome evaluation. To truly appreciate the usefulness of this model, one must make themselves fully cognizant of all the steps at the onset. Incidentally, the model was intended for use of nurses at the bedside and does not address the intricacies and requirements for gaining IRB approval and thus should be included in the translation steps if human subjects will be involved (Melnyk & Fineout-Overholt, 2018). Otherwise, the JHNEBP model's PET management guide was a helpful aid in guiding this project.

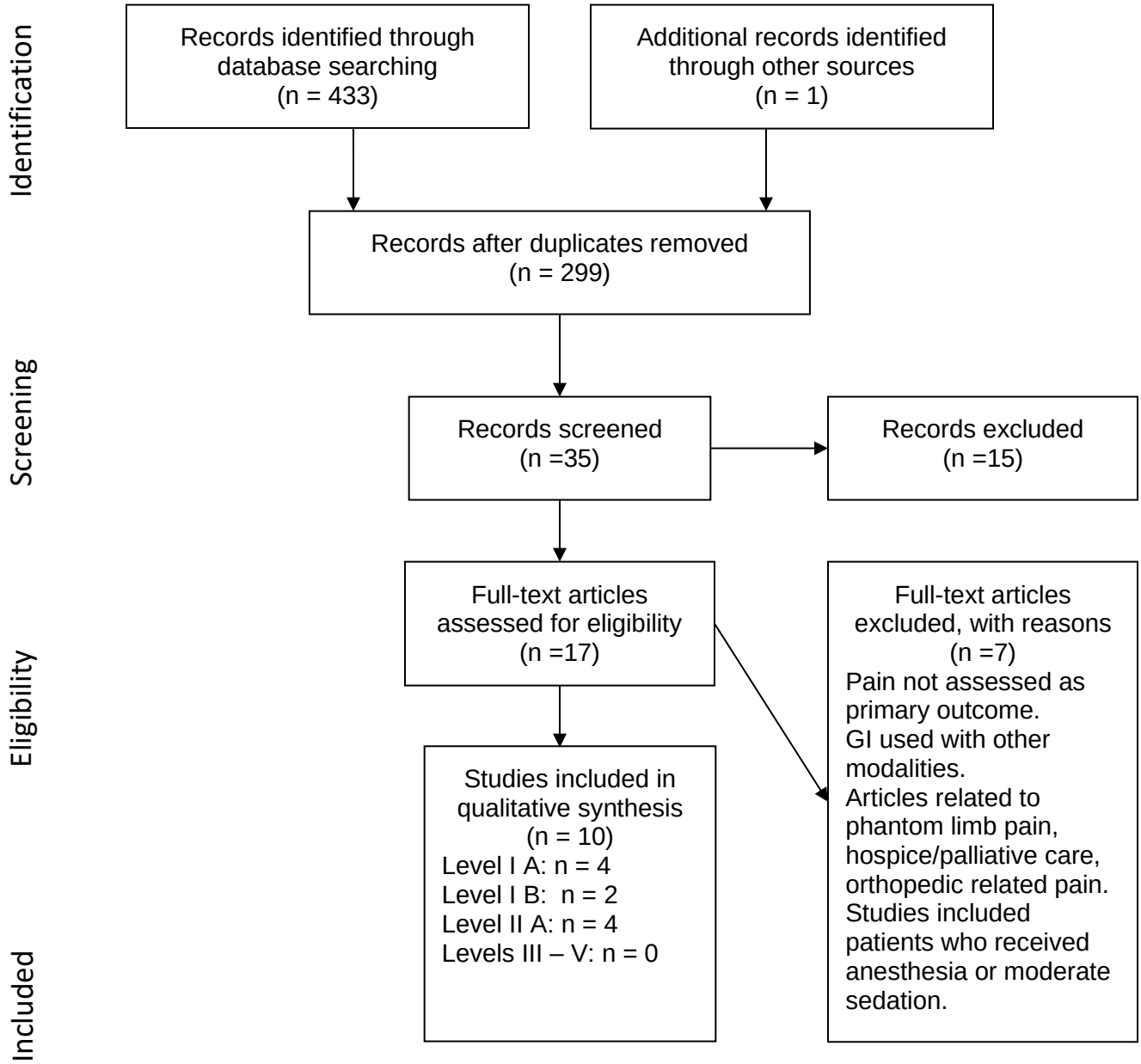
Literature Search

Sources Examined for Relevant Evidence

A systematic literature search was conducted utilizing the CINAHL, Cochrane Library, Medline, PsychInfo and the Joanna Briggs Institute EBP databases. Citation chasing and hand searching of the *Pain Management Nursing* journal were also conducted. Key words used included “guided imagery”, and pain or “breast cancer” or “breast neoplasm”. Appropriate MeSH, APA Thesaurus of Psychological Index Terms and CINAHL subject headings were applied, Limiters to hone the search included the dates between 2010-2020, English language, an adult only age group, and scholarly peer reviewed when available within the database. Inclusion criteria focused on articles related to acute and procedural pain, and breast cancer including randomized controlled trials, systematic reviews and meta-analyses, Articles relating to hospice or palliative care, phantom limb pain, diabetic neuropathy and orthopedic disorders or those that did not measure pain as a primary outcome were excluded.

The results obtained from CINAHL, with the search terms and limiters listed above yielded 79 results. After further investigation of the provided abstracts and consideration of inclusion and exclusion criteria, six articles were chosen for the evidence table. Within the Cochrane Library the yield was 201, three new pieces of evidence were chosen. Medline yielded 81 pertinent results with four duplications from the previous search, no additional studies were chosen. PsychInfo had a yield of 31 results and no additional studies were chosen. The JBI search produced a yield of 39 results, one new article was chosen. The hand search of the *Pain Management Nursing* journal yielded 10 applicable results, 2 of which were duplicate findings, no new pieces of evidence were chosen. Lastly, no new articles were chosen from citation chasing, mainly because the articles’ sources were outdated.

Figure 1.1
PRISMA 2009 Flow Diagram © 2009 (Moher, Liberati, Tetzlaff & Altman, 2009)



Levels of Evidence

The JHNEBP research evidence appraisal tools were used to level and appraise the evidence located through the literature search (Dang & Darnholt, 2017). Evidence levels range from level I through V and are designated categorically based on the types of studies conducted and whether they were founded on scientific evidence (experimental, nonexperimental, quasi-experimental) or experiential. For instance, the pinnacle of level I would be systematic reviews of RCTs with metanalysis, and the base of level V would include experiential evidence i.e., case reports or the opinion of nationally recognized experts (Dang & Darnholt, 2017).

The underlying search strategy hinged on locating the highest levels of evidence available on GI according to the previously described search terms and limiters. A secondary and challenging goal was to locate evidence that could be applied to this very unique procedural setting.

Appraisal of Relevant Evidence

Relevant evidence found from the systematic search strategy was critically appraised using the same tools available online from JHNEBP. The user is guided through a series of orderly yes or no questions to determine whether key factors were present and addressed within the work being analyzed. Depending on whether most of the questions were answered affirmatively, the user places the studies into one of three categories: A – high quality, B – good quality and C- low quality or major flaws. High quality studies are those with “consistent, generalizable results sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence” (Dang & Darnholt, 2017, appendix E, p. 5). Good quality studies include “reasonably consistent results; sufficient sample size for the study design; some control, and fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence” (Dang & Darnholt, 2017, appendix E, p. 5). Lastly, low quality studies or those

considered to have major flaws consist of “little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn” (Dang & Darnholt, 2017, appendix E, p. 5).

The synthesis review with meta-analysis conducted by Noergaard et al., 2019 was evaluated as low quality, not because it was a poor study, but because the authors found inconclusive evidence that GI reduced patients reports of pain intensity. This study was included because it was well conducted in every other aspect and did report that patients using GI for minimally invasive procedures had an average reduction in post-operative pain medication consumption between 21-86% (Noergarrd et al., 2019). Because this study was one of the only ones found that pertained to using GI for a minimally invasive procedure much like SNL injections it was included.

Level I Evidence

Álvarez-García & Yaban (2019) conducted a synthesis review and meta-analysis with the purpose of determining the effects of GI in reducing preoperative anxiety and postoperative pain in adults and children. A comprehensive description of their literature search was provided. The search included eight databases PubMed, CINAHL, WOS, Scopus, Cochrane, Lilacs, CUIDEN Plus, and the Council of Higher Education Database: selected internet sites including Google Scholar, Clinical-Trials.gov and Turning Research into Practice. Hand searches were conducted within six journals: Alternative Medicine Alert, BMC Complementary and Alternative Medicine, Complementary Therapies in Clinical Practice, Complementary Therapies in Medicine, the Journal of Alternative and Complementary Medicine, and the Journal of Evidence-Based Complementary and Alternative Medicine. A table was provided listing specific search terms for each database.

There were no limits placed on publication dates, thus everything published up until April of 2019 was considered. Languages were limited to English, Turkish or Spanish. Inclusion criteria were RCTs, including adults and children that used individualized preoperative GI as

the intervention and a comparison had to be made with conventional care. The outcomes had to include ratings of preoperative anxiety and acute postoperative pain. Studies that combined GI with other therapies, provided GI after surgery only or measured postoperative pain greater than a day after surgery were excluded. Out of 1,100 records reviewed, 21 studies were included for the synthesis review and eight studies provided enough information for utilization in two separate meta-analyses each including four studies a piece.

A table was provided with an analysis of the methodological quality of each included study. The Cochrane Collaboration tool and the Grading of Recommendations Assessment, Development and Evaluation system were tools utilized in quality assessment. The findings of the synthesis review were divided into four subcategories, only those related to adults were used for this project. The authors found that preoperative GI provided to adults is effective in reducing postoperative pain per the sign test ($p = 0.019$). Of the twelve trials, 10 showed that GI reduced pain postoperatively, two showed statistical significance and two trials did not report a positive effect from guided imagery. Preoperative anxiety was classified as trait and state anxiety. Six out of the eight trials showed a positive effect on state anxiety from GI, but only two were statistically significant, sign test ($p = 0.145$). On the other hand, nine out 10 trials showed that GI reduced trait anxiety, with four studies showing statistical significance, sign test ($p = 0.011$). Results from the two meta-analyses determined that GI intervention in the preoperative period is effective in reducing acute postoperative pain ($p = 0.035$) and effective at reducing preoperative trait anxiety ($p < 0.001$).

Specifics related to each study were provided in the appendix. Limitations were discussed, further research is required on preoperative state anxiety in adults and the exploration of dose specific GI sessions. All the studies provided a different protocol, some participants only received GI once preoperatively and other trials started the GI one week prior to surgery. The authors conclude that GI is a low-cost and easy intervention that nurses can

apply preoperatively to reduce anxiety and acute postoperative pain in adults and children. Appraisal of this piece of evidence according to JHNEBP rates Level I A.

Charalambous et al. (2016) in their RCT, aimed to determine whether GI in combination with progressive muscle relaxation (PMR) could be effective in mitigating a cluster of symptoms experienced by patients diagnosed with breast or prostate cancer undergoing chemotherapy. A symptom cluster is defined as "a condition where two or more symptoms that are related to each other occur simultaneously" (Charalambous et al., 2016, p.2). Symptoms included within the cluster include pain, fatigue, nausea, vomiting, retching. The authors hypothesized that the control group would experience lower reported levels of these symptoms thus improving their health care quality of life.

Statistical calculations were conducted to ensure an adequate sample size for this study design and rationale was provided. Participants were randomly assigned to the intervention and control groups. Total sample of those that completed the study included 104 in the intervention group and 104 in the control group. Inclusion criteria consisted of a clinical diagnosis of breast or prostate cancer; receiving chemotherapy; experience of fatigue, pain, nausea and vomiting, anxiety and or depression; able to follow instructions; good cognitive ability; and a willingness to participate. Participant demographics were well matched at baseline regarding gender, age, diagnosis, treatment and education. The participants were representative of all regions of Cyprus, the location of the interventions occurred in their homes or at a location of their choice.

The interventional group received supervised sessions of PMR and GI once weekly for four weeks, the sessions included 15 minutes of GI and daily unsupervised sessions. The control group received the standard of care. Pain was measured using a numeric pain scale spanning from 0 to 10. Other symptoms within the cluster were measured using the following tools: Cancer Fatigue Scale (CFS); the Revised Rhodes index of nausea, vomiting and retching (INVR); Zung self-rating anxiety scale SAS and the Beck Depression Inventory-II. Health related

quality of life was assessed using the EORTC QLQ-C30 module, developed specifically for those diagnosed with cancer.

The analyses of the findings were done with the IBM 21 SPSS software where Chi-square tests ($\chi 2$), independent *t*-test, Paired *t*-test and Linear Mixed Models (LMM) were calculated. Overall statistical significance was held at the two-sided 5% level ($p < 0.05$). Average pain levels for the intervention and control group were reported at baseline (mean 4.17, *SD* 1. 47 and 3.55, *SD* 1. 73 respectively). The intervention group experienced lower levels of Fatigue ($p < 0.0225$), Pain ($p = 0.0003$) and better HRQoL ($p < 0.0001$) compared to those in the control group. Similar positive effects were discovered regarding nausea, vomiting and retching, which was reported significantly less often among the intervention group [pre-post: 25.4(5.9)– 20.6 (5.6) compared to the control group (17.8(6.5)– 22.7(5.3) ($F = 58.50$ $p < 0.0001$). More patients in the control group (pre = 33-post = 47) were found to be moderately depressed compared to those in the intervention group (pre = 35-post = 15) ($X^2 = 5.93$; $p = 0.02$).

Ultimately, post measurements indicated that patients in the intervention group reported lower pain levels (mean 2.48, *SD* 1. 35) and the control group reported increased pain levels (mean 4.80, *SD* 1. 46). The efficacy of GI and PMR intervention in relieving pain was statistically significant within time ($F = 29.64$, $p < 0.0001$). These statistical data were concisely and accurately represented in the multiple tables contained within the article.

Limitations were discussed regarding the inability to perform a double blind RCT and the inability to determine whether the participants were able to complete the full protocol of the interventional sessions when conducted unsupervised or if they were practiced in a quiet environment without interruptions. The authors concluded that their RCT, considering its limitations provided evidence to support the provision of GI and PMR to mitigate symptom clusters, including pain, for patients diagnosed with breast and prostate cancer. This study was rates as level I, A according to the JHNEBP research evidence appraisal tools.

Giacobbi et al. (2015) conducted a systematic review of RCTs to determine the effects of GI on aspects of pain, function, anxiety, depression and general quality of life among patients diagnosed with arthritis or other rheumatoid conditions (AORD). A comprehensible and reproducible search was conducted within 10 databases including Academic Search Complete, Medline, PsycInfo, Scopus, SPORTDiscus, Cochrane Central Register of Controlled Clinical Trials, CINAHL, Physiotherapy Evidence Database, Web of Science, and ERIC. Citation chasing and hand searching was also employed. Keywords included ‘‘random,’’ ‘‘mental imagery,’’ ‘‘guided imagery,’’ ‘‘visualization,’’ and ‘‘relaxation’’; ‘‘randomly,’’ ‘‘randomized,’’ and ‘‘randomized’’ to increase possible retrieval. It is unclear why the researcher did not truncate random*.

Inclusion criteria and limiters were delineated : RCTs with a comparison group; adult participants aged 18 years and older; use of guided imagery as the sole or partial intervention strategy; focus on AORD; publications in English from January 1, 1960 to June 1, 2013; and results reported for pain, physical function, anxiety, depression, or quality of life. A total of 1,313 studies were identified and reviewed, seven met the inclusion criteria. The studies included 16 groups (nine intervention and seven control) representing 306 individuals, with eight men and 282 women randomly assigned to the various study arms. Tables were provided on search strategy process and study characteristics and findings.

The Cochrane Collaboration guidelines for coding risk of bias were used to appraise the seven studies included. Findings were reported qualitatively. Explanation of the measurement tools utilized within the RCTs was provided. The GI interventions employed ranged from one-time exposure to 16-week duration. The authors reported that statistically significant findings were reported in all the studies supporting GI for reductions in pain and medication usage with related increases in function and mobility. Results were presented within a table and discussed narratively at length, but statistical significance reported from the original studies was not further defined. Limitations were addressed regarding the decision to only include published studies,

the limitation to trials only reported in English and the possibility of self-reported outcomes (utilized within many of the studies) being subject to error. Further research to be conducted was identified as well-designed RCTs that better investigate and substantiate GI outcomes.

In conclusion, the authors find that GI is beneficial for patients with AORD, especially in relation to pain mitigation. Thus, it is recommended that practitioners implement GI in clinical settings. This study was rated as level I, A according to the JHNEBP research evidence appraisal tools.

Gonzalez et al. (2010) conducted a single-blind, RCT to assess the efficacy of GI for postoperative pain outcomes for patients undergoing same-day surgical procedures. A total of 44 patients, consented to participate. Twenty-two were randomly assigned to the intervention and control groups, respectively. Inclusion criteria included age 18 years or older, scheduled for head or neck outpatient surgery at an Ohio air force base medical center with an ability to read and understand English who consented to participate. Demographic variables were presented within a table. Outcomes measured included preoperative anxiety levels, analgesic consumption, postoperative pain, length of stay, and patient satisfaction.

Baseline levels of anxiety and pain were measured for both groups prior to the administration of sedation, using the Amsterdam Preoperative Anxiety and Information Scale (APAIS) and a vertical visual analog scale (VAS) for pain measurement. Prior to surgery, the intervention group listened to a 28-minute GI CD with headphones and the control group was offered 28 minutes of privacy. The validity of these instruments was discussed and supported.

One- and two-hour assessments were repeated for both groups postoperatively. Pain measurements between the 2 groups were compared statistically using the Mann-Whitney V test. The mean level of pain for the control group at 1 hour was 41.18 mm compared with the GI group at 28.68 mm (p = .057). The pain levels for the GI group at 2 hours were significantly lower (p = .041) than the control group, with means of 20,00 and 34.72 mm, respectively. The

GI group reported a significant decrease in mean anxiety levels from 25.32 mm to a mean repeat level of 11.86 mm (p = .002). The GI group's mean length of stay in the post anesthesia care unit (PACU) was 9 minutes shorter than the control group (p = 0.055). No significant difference in the consumption of pain medication or patient satisfactions scores with anesthesia were noted. Tables reporting on statistical findings were provided.

Limitations were discussed including the trend for preemptive anesthesia using high doses of narcotics for both groups early within the surgical procedure, and the practice of the PACU nursing staff providing oral analgesics as soon as the patients were able to tolerate liquids. Other limitations considered using a double-blind approach and the inability to exact better control on noise levels, changes in schedule delays or extraneous noises outside of busy real-world conditions at the time of the GI application. Another limitation considered the fact that not all the head and neck surgeries were the same, and future studies may be more inclusive if they were limited to just one type of surgical procedure.

Though the interventional and control group received the same number of narcotics, the GI group reported statistically significantly lower pain levels at the 2-hour measurement, compared with the control group. The authors concluded that GI can significantly reduce preoperative anxiety and postoperative pain in an ambulatory surgical setting. This study was rated as level I, A according to the JHNEBP research evidence appraisal tools.

Stoerkel et al. (2018) conducted a two-group, nonblinded, randomized controlled study to determine the effectiveness of a self-care toolkit (SCT) in alleviating distress and reducing surgical related symptoms for breast cancer patients. The SCT contained an MP3 player with recorded GI exercises promoting mind-body techniques and an acupressure designed anti-nausea wristband. Both study groups received what the researchers described as treatment as usual (TAU) with the interventional participants receiving the added SCT.

Eligibility criteria included females over the age of 18, newly diagnosed with nonmetastatic breast cancer who would be undergoing mastectomy or lumpectomy as their

initial treatment. Candidates that were excluded were those with severe hearing impairment, unable to listen to the GI audio files, women receiving neoadjuvant therapy (chemotherapy) and those that refused to participate. A total of 316 women were assessed for eligibility, 100 were admitted into the study according to the above criteria. Forty-nine women were randomly assigned to the intervention group (SCT) and 51 to the control group (TAU), 35 participants from each group completed the study. Narrative information was provided on patient demographics with a corresponding table.

Several outcomes were measured at baseline, preoperatively, postoperatively and at a two week follow up, all of which were depicted within a table. Anxiety, pain intensity and interference, fatigue, sleep disturbance, physical function, satisfaction with social roles and depression were measured with the NIH Patient-Reported Outcomes Measurement Information System (NIH PROMIS 57). Global health status and quality of life were measured using the EORTC QLQ-C30. NIH PROMIS 57 and the EORTC QLQ-C30 self -reporting surveys were completed electronically on a tablet via Wi-Fi. Anxiety, pain and nausea were also separately measured preoperatively and postoperatively via the GA-VAS, nausea VAS and the Defense and Veterans Pain Rating Scale (DVPRS) respectively. Inflammatory biomarkers were measured from serum ESR and CRP at baseline, preoperatively and at the two-week follow up. A Likert fashioned satisfaction survey was presented at the end of the study to measure overall satisfaction with GI. The validity and consistency of the measurement tools were explained and supported with evidence.

In reference to pain, the authors found that there was a statistically and clinically significant difference between the experience of pain interference reported by the SCT group compared to the TAU group. “The significant mean increase in Pain Interference from baseline to follow-up was 9.93 T-scale points in the TAU and 2.89 in the SCT group, reflecting pain interference in the TAU group that exceeded the MID range of 4.0–6.0” (Stoerkel et al., 2018, p. 923). Pain measured immediately postoperatively using the DVPRS, showed smaller increases

in the SCT group. The PROMIS 57 scores were significantly higher among the intervention group compared to control group: pain interference ($p = 0.005$), fatigue ($p = 0.023$) and social role satisfaction ($p = 0.021$). The intervention group showed reduced increases in postoperative pain ($p = 0.008$) and in postoperative serum ESR ($p = 0.0197$).

Limitations noted by the authors related to the optimal time to introduce the SCT. The provision of the toolkit at the time of diagnosis may have been an inopportune time considering the overwhelming nature of receiving a cancer diagnosis. As many as 79% of eligible candidates refused to participate mainly stating lack of time as a reason. The authors surmised that those that refused did not deem participating in the study as a priority for them at that juncture in their lives.

The authors concluded that GI exercises provided via the SCT are beneficial for patients undergoing surgical treatment for breast cancer. Study findings indicate less pain interference and better coping for the interventional group. This study was rated as level I, B according to the JHNEBP research evidence appraisal tools.

Zech et al. (2016) conducted a systematic review and meta-analysis of RCTs to determine the efficacy, acceptability, and safety of GI/hypnosis for mitigating symptoms experienced by patients diagnosed with fibromyalgia (FM). The authors performed their review and meta-analyses in accordance the PRISMA-statement (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) and the Cochrane Collaboration recommendations. The search strategy and process was well documented and depicted within a table. Four databases were searched including the Cochrane Library, Medline, PsychInfo, and SCOPUS. Additionally, the National Institute of Health's clinicaltrials.gov and citation chasing was employed.

Search terms were adjusted according to the vagaries and requirements of particular databases. The Medline search terms were documented as follows "{['Hypnosis' (Mesh) OR 'Imagery (Psychotherapy)'(Mesh)]} AND 'Fibromyalgia' (Mesh) AND {[clinical(Title/Abstract)

AND trial (Title/Abstract)] OR clinical trials (MeSH Terms) OR clinical trial (Publication Type) OR random* (Title/Abstract) OR random allocation (MeSH Terms) OR therapeutic use (MeSH Subheading)}." (Zech et al., 2016, p. 3). Seven RCTs including a total of 387 subjects were included. A diagram was provided depicting the number of studies chosen or eliminated at each level of the review process.

Inclusion criteria were stringent as the authors had previously published a systematic review in 2011 and wanted to update their process to accommodate changes in the process and recommendations for systematic reviews since that period. Eligible studies were randomized controlled trials or quasi randomized controlled trials which had to contain participants that were above 18 years of age. Interventions included GI/hypnosis as a primary intervention for pain and could be coupled with another psychological therapy if compared to the other psychotherapy alone. Studies that combined GI/hypnosis with the pharmacologic treatment, provided relaxation therapy only or contained participants previously diagnosed with a severe psychological disorder were excluded. Outcome measurement within the studies primarily a reduction in pain of ≥ 50%, improvement in QOL, psychological distress, acceptability of GI and safety.

Details of each study were provided narratively and in table format. Within the meta-analysis outcomes were analyzed and compared by utilization of a random effects model applying risk differences (*RD*) or standardized mean differences (*SMD*) with 95% confidence intervals (CI). The authors found a clinically relevant benefit for GI/hypnosis within the interventional groups on pain relief ≥50% [*RD* 0.18 (95% CI 0.02, 0.35), $p = 0.008$], pain relief ≥ 30% [RD 0.25 (95% CI 0.01, 0.05), $p = 0.02$], pain intensity [*SMD* 1 1.12 (95% CI – 1.97, - 0.28), p = 0.009], coping with pain [*SMD* – 0.32 (95% CI – 0.59, - 0.05), $p = 0.02$], and psychological distress [*SMD* - 0.40 (95% CI - 0.70, - 0.11), $p = 0.008$]. There were not significant differences for acceptability of GI/hypnosis compared to controls. Two studies showed that cognitive behavioral therapy (CBT) combined with GI was more effective than CBT

alone regarding the reduction of psychological distress [*SMD* -0.50 (95% CI - 0.91, - 0.09)]. Safety was not evaluated within any of the chosen studies.

Some of the limitations and areas for further research included the fact that 90% of the participants were Caucasian and female. Some studies did not specify duration of the disease, so they were unable to calculate a median value for that information. Though, studies including participants diagnosed with major psychological disorders were eliminated, there was no feasible way to determine whether individual studies included patients diagnosed with depressive disorders or anxiety were included, thus results may have differed had there been more control with this variable. When data was less than adequately reported or missing the authors calculated *SD*s by established imputation methods for two studies each.

The authors concluded that GI is moderately efficacious in mitigating pain and psychological distress and provides a cost-effective treatment modality that can easily be used by patients at home without the expense or time required for psychological therapy sessions. According to the JHNEBP appraisal tools this study is rated as a Level I, A.

Level II Evidence

Chen et al. (2015) conducted a two-group, pretest-posttest, quasi-experimental design with a RCT to evaluate the effect of GI and relaxation therapy on females diagnosed with breast cancer. Sixty-five breast cancer patients recruited from a private, Taiwanese medical center were enrolled in the study. Thirty-two participants were randomly assigned to the experimental group and 33 to the control group. Both groups received chemotherapy self-care education, but the experimental group also received relaxation GI training. The length of the study was from 2011 to 2012.

The training and intervention consisted of one hour of GI and relaxation training provided before chemotherapy and a compact disc (CD) for performing the exercise for 20 minutes daily ,at home, for 7 days after chemotherapy. Sample recruitment was based on a convenience sample among 165 eligible women who were randomly assigned to either group. Inclusion

criteria included age over 20 years, the ability to communicate in Chinese, and those receiving chemotherapy for the first time. From a power analysis and results from a pilot study, the researchers estimated that a statistically worthy sample size must consist of at least 30 participants within each group.

The hospital anxiety and depression scale (HADS) and the symptom distress scale (SDS) were administered to collect data and evaluate symptoms of distress, depression, and anxiety for the experimental and control groups. The instrument validity of these tools were discussed and analyzed. Demographic data including age, religion, education, marital status, cancer stage and previous chemotherapy were also collected, and the information was depicted in a table.

Statistical tests used to analyze the data included chi-square tests, Student's *t*- tests, paired *t*-tests, generalized estimating equation (GEE) analysis, and an independent sample t test and to calculate the Pearson product-moment correlations. *P* values < 0.05 were considered as significant. Kolmogorov–Smirnov testing was applied to determine whether a normal distribution existed among the sample.

When the results of the pretest-posttest were compared, patients in the control group reported significant increases in nausea, vomiting, appetite loss, constipation, abdominal distension and heartburn each with a *p* value < 0.05. SDS scores of the participants before chemotherapy were 1.33 in the interventional group and 1.44 in the control group. The experimental group reported a significant decrease in insomnia, pain, restlessness, inability to concentrate, and emotional numbness each measurement also with a *p* value < 0.05, decreased anxiety and depression had a *p* value < 0.00 pre and posttest.

Limitations were discussed and included a small sample size, short study duration, and participant inclusion being only hospitalized patients. Therefore, the authors suggest further research using a larger sample size that includes the measurement biometric indicators such as salivary cortisol levels and immunocytochemistry to better generalize findings and provide more

objective outcome measurements. Overall, the authors advocate that GI and relaxation interventions can assist providers in mitigating the adverse effects of chemotherapy to improve quality of life for this patient population. This study was rated as level II, B according to the JHNEBP research evidence appraisal tools.

Noergarrd et al. (2019) conducted a systematic review with meta-analysis of nine RCTs and one quasi-experimental study to evaluate the effectiveness of hypnotic analgesia in reducing pain, anxiety, procedure length and adverse events in patients undergoing minimally invasive procedures. A comprehensive search was undertaken to identify published and unpublished studies. Seven databases were searched: Medline, CINAHL, the Cochrane and JBI Libraries, Scopus, Swemed+ and PsycINFO. Identified keywords and index terms listed: hypnosis, “hypnotic analgesia”, “self-hypnosis”, “self-hypnotic relaxation”; nonpharmacological analgesia; acute pain; procedural pain, invasive procedure.

Searches were carried out in databases from inceptions through July 2018. Grey literature was searched in the following databases and websites: Mednar, ProQuest Dissertations and Theses (for international dissertations and theses), Google Scholar, Trip database, National Institute of Health's (NIH) Clinical Trials Databases, American Society of Clinical Hypnosis (ASCH), The American Board of Medical Hypnosis (ABMH, The American Society of Clinical and Experimental Hypnosis (SCEH) and International Society of Hypnosis (ISH).

Inclusion criteria included quantitative randomized or nonrandomized controlled trials, studies conducted on patients 18 and older for any type of minimally invasive procedure under conscious sedation, interventions described as hypnotic analgesia or guided imagery, control groups were required to include standard of care or usual pharmacologic analgesia, measurement of outcomes including pain intensity, anxiety, pain medication consumption, adverse events or length of procedure. Articles that discussed the use of GI during open surgery, burn treatment, labor or those including children or adolescents were excluded.

According to the above criteria a total of 10 studies were chosen consisting of 1,365 participants. Evidence was critically appraised using A standardized instrument for critical appraisal from Joanna Brigg Institute. The meta-analysis of statistics assessment and review Instrument (JBI-MAStARI) was used for extraction and calculation of quantitative data. A diagram of both eliminated and included studies was provided as well as an evidence table depicting details and pertinent information for all included articles.

In the five studies that measured the amount of analgesia/sedation as an outcome, medication consumption in the GI groups was significantly less than in the control groups. A meta-analysis was not conducted, because one of the studies did not provide a standard deviation. Therefore, an average pain consumption difference was calculated, and the consumption of pain medication was reduced among the GI groups by 21-86%. Studies measuring anxiety as an outcome, used varying measurement tools, but it was found that in six out of 10 studies no significant difference in anxiety ratings was found between the two groups. Adverse events reported varied between 0%–80% in the intervention group and between 1%–96% in the control group. Which could vary depending on how adverse events are reported and defined as well as the length and type of minimally invasive procedure. Ultimately, the authors determined that the utilization of GI during minimally invasive procedures does not increase adverse events and is thus safe to implement.

Pain intensity was not found to be significantly decreased for the intervention group among the 10 studies. However, the authors posit that “because the consumption of analgesics was significantly reduced in several studies without a significant overall change of the patients' perception of pain intensity, one could ascribe the effect of hypnosis more to the management of the pain than to affecting the intensity of pain” (Noergaard et al., 2019, p. 4218).

Limitations and strengths were discussed. Among some of the limitations included were the selection of only published work, studies written only in English, Danish or Swedish, a study population that was mainly female, western European and Caucasian and the inclusion of a

quasi-experimental study within the synthesis. The authors suggest that further research is needed to evaluate participants' expectations of and receptiveness to hypnosis or GI and what the optimal duration of treatment is most effective during a procedure.

The overall conclusion is that evidence supports GI or hypnotic analgesia in conjunction with usual care among patients undergoing minimally invasive procedures. The intervention did not have a significant effect on pain intensity but did significantly reduce pain medication consumption among the GI group, which supports its efficacy and promotes safer patient care. This study was rated as level II, A according to the JHNEBP research evidence appraisal tools.

Peerdeman et al. (2016) performed a systematic review and meta-analysis of 27 experimental and quasi-experimental studies consisting of a total of 1256 patients. The purpose of their study was to evaluate the effectiveness of interventions that induce expectations (namely verbal suggestion, conditioning and mental imagery) on the relief of pain. The following databases were searched since inception through June 19, 2015: PubMed, PsycINFO, EMBASE, Cochrane CENTRAL, and the Cochrane Methodology Register. Citation chasing from available reference lists was also employed. A total of 15955 studies were located, 30 met inclusion criteria the synthesis, 27 provided sufficient data for quantitative analysis. The authors listed the following key words: meta-analysis, systematic review, expectation, expectancy, placebo effect, verbal suggestion, conditioning, imagery, pain, analgesia, and patients.

Inclusion criteria: studies were included if they assessed expectation inductions as described above on pain relief in a clinical setting. The induction interventions were limited to a brief time frame and had to be compared to a control group receiving no similar treatment, treatment as usual or no treatment. Additionally, pain outcomes had to be measured using a numeric pain rating scale. Only full-length research studies in English were included. A detailed search strategy was produced both narratively and pictorially for each level of the review. Two reviewers independently assessed each included piece for risk of bias, using the Cochrane risk of bias tool. The characteristics of each study were provided within a table.

"The overall effect of the expectation inductions corresponded with an average pain reduction of 1.16 points on a scale of 0-10 (95% CI 0.77 – 1.54). Verbal suggestion reduced pain with 1.39 points (95% CI 0.85 – 1.93), conditioning with 1.03 points (95% CI 0.30 – 1.76), and imagery with 0.62 points (95% CI 0.10 - 1.15)" (Peederman et al., 2016, p. 12). The authors noted that the remaining three studies, lacking sufficient information for quantitative analysis, concurred with the pooled effects of the studies included within the meta-analysis. Sub-analysis comparing acute procedural to chronic clinical pain indicated a medium pooled effect on acute procedural pain (k = 12, g = 0.67, 95% CI 0.36 – 0.97, I 2 = 74%) compared to a small, pooled effect on chronic pain (k = 6, g = 0.33, 95% CI 0.04 – 0.62, I 2 = 70%).

Limitations focused on what the authors found missing from the included studies and how future research may address these issues. For instance, they found that the inductive interventions addressed short term effects of pain and suggested that further research should be done to determine whether inductive expectation exercises have a long-lasting clinical impact. Other areas in need of further exploration would include better defining the specifics of verbal suggestion and imagery and whether combining relaxation, verbal suggestion and GI would be more effective together than separately. The examination of mediating and moderating factors such as patient expectations, characteristics, previous pain experiences and treatment histories may also be helpful in predicting success. Lastly, the authors believed it would be important to investigate negative expectations regarding adverse effects instead of focusing on enhancing or inducing positive expectations.

The authors concluded that brief expectation interventions, especially verbal suggestion, are effective in relieving acute procedural pain. These findings support the importance of how the clinician provides information regarding analgesic treatments, by not merely explaining the pain associated with a procedure but also giving equal attention and emphasis to the positive expected outcomes from a pain mitigating intervention. According to the JHNEBP research evidence appraisal tools, this study is Level II A.

Serra et al. (2012) conducted a Quasi-experimental study: pre and posttest design /interrupted time-series study to evaluate the effect of GI on patients undergoing radiation for breast cancer. A convenience sample of 66 women being treated at a cancer care center in New York consented to participate. Demographic and clinical data regarding the sample group were provided within a table. A description of statistical analysis of the findings and estimation of a proper samples size was included. A minimum of 65 patients was needed to detect a pre/post difference of the same magnitude in comparison to a previous study, with power of 80% and alpha of 0.05. Statistical testing was completed using SAS®, version 9.1, statistical significance was set at 0.05.

As this was a quasi-experimental study, outcomes were not measured in comparison to a control group. The intervention was provided by radiation oncology nurse during the first three to five days of radiation treatment and a CD was provided for home practice. The GI exercise was offered to the patients within the radiation suite and averaged around 20 minutes. Additional time was allotted as necessary per patient request. During the radiation sessions objective measurements indicative of a person's stress, pain and anxiety levels including thermal biofeedback, blood pressure, respiratory rate and pulse were assessed prior to and after the GI session. Subjective data were assessed at baseline and at the completion of their radiation treatments, using the EQ-5D, and instrument that measures current health status based on five domains including pain, mobility, self-care, anxiety and depression.

The authors found significant decreases in systolic and diastolic blood pressure, pulse rate, and respirations between GI sessions 1 and 2. Distress thermometer results indicated: decreases in global distress ($p = 0.04$), sadness ($p = 0.04$), worry ($p = 0.06$) and nervousness ($p = 0.05$). EQ 5D scores showed that as pain increased as expected (related to subcutaneous and superficial skin irritation d/t repeated phases of radiation) patients were able to report lower levels of depression and anxiety ($p = 0.01$). In conclusion, the authors found that GI can improve overall care and patient experiences with radiation supported by both subjective and

objective measurements. Findings showed a medium to large effect on the reduction of acute procedural pain. This study was rated as level II, B according to the JHNEBP research evidence appraisal tools.

Construction of Evidence-based Practice

Synthesis of Critically Appraised Literature

Evidence within each of the studies supports GI as being beneficial, in some form, for the mitigation, experience, perception and management of pain. Pain is a very subjective experience with different meanings for different people. Pain tolerances differ among individuals. Many of the studies measured pain as an outcome via different instruments and thus the effects of GI on pain differ. No study suggested that GI could eliminate pain entirely, but that its use could help people better deal with it. It is suggested that psychological distress related to breast cancer diagnosis can alter pain perception and paradoxically increased pain is associated with higher levels of psychological distress i.e., depression, anxiety, and fatigue (Charalambous et al., 2019; Charalambous et al., 2016; Stoerkel et al., 2018).

Breast Cancer

The efficacy of GI for the mitigation of pain and reduction of overall distress was supported for breast cancer patients within various treatment tracts (Charalambous et al., 2019; Chen et al., 2015; Serra et al., 2012; Stoerkel et al. 2018). For instance, breast cancer patients receiving chemotherapy treatments who utilized GI reported lower pain levels whereas those in the control group either reported increased pain levels or no change in pain from baseline to the completion of the intervention (Charalambous et al., 2019; Chen et al., 2015).

For patients receiving radiation therapy where pain is expected to increase with progressive treatments due to superficial tissue injury, the intensity of pain increased as the sessions progressed. Yet despite this, other positive effects indicative of better reactions to pain were detected in the interventional group such as lowered blood pressure, respirations and

pulse rates, global distress, anxiety and depression in comparison to their baseline measurements and their second session of GI (Serra et al., 2012).

Similarly, women who were diagnosed with nonmetastatic breast cancer and scheduled for surgical procedures such as lumpectomy or mastectomy without chemotherapy or radiation benefited from a GI self-care tool kit. The outcomes reported for the GI intervention group showed a significant reduction in pain interference, decreased pain perception and postoperative pain compared to the control group (Stoerkel et al., 2018).

Ambulatory Surgery Settings

Each of the pieces of evidence related to ambulatory surgical and procedural pain support and recommend GI as an evidence-based, inexpensive, and easy to implement adjunctive therapy for pain management. Evidence supports the use of GI for reducing postoperative pain scores, alleviating acute procedural pain and contributing to a reduced consumption of narcotics (Álvarez-García & Yaban, 2020; Gonzalez et al., 2010; Peerdeman et al., 2016; Noergaard et al., 2019).

Pain is intertwined with and influenced by psychological factors such as anxiety (Charalambous et al., 2019). GI is a mind-body exercise that influences physiologic and emotional responses (Carlson et al., 2017). Therefore, the effects of GI were shown to synergistically reduce preoperative anxiety and postoperative pain for same day surgeries and minimally invasive procedures (Álvarez-García & Yaban, 2020; Gonzalez et al., 2010). Verbal suggestion, conditioning and mental imagery were also found to produce medium to large effects on acute procedural pain (Peerdeman et al., 2016).

The meta-analysis conducted by Noergaard et al. (2019) reported that the consumption of pain medication was reduced from between 21 to 86% among patients who received GI compared to the control groups, but only a few studies reported a statistically significant reduction in pain intensity. As with the Serra et al. (2016) study measuring the effects of GI on breast cancer patients receiving radiation, the Noergaard et al. (2019) meta-analysis displays

GI's ability to help patients better tolerate painful experiences. In both instances, the study participants had improved outcomes compared to the those who received the standard of care without GI. Pain was not eliminated, but GI beneficially contributed to patients' pain perceptions and coping abilities.

Chronic Conditions

GI has been shown to be significantly effective in improving pain and QOL in patients with conditions such as fibromyalgia, arthritis, and other rheumatoid conditions (Giacobbi et al., 2015; Zech et al., 2016). Within these patient populations, GI again has been found to be an efficacious therapeutic tool for the treatment of pain and improvement of psychological wellbeing. In specific reference to pain, all seven of the studies included in the systematic review of RCTs conducted by Giacobbi et al. (2016) provided evidence supporting the effectiveness of GI. More specifically, Zech et al. (2016) in their meta-analysis, found significant findings of pain reduction of ≥ 50% within 6 of their studies, a decrease in pain intensity ratings and an increased ability to cope with pain among other positive benefits of GI.

Though neither of these studies address acute procedural pain, they both evidentially endorse GI as a cost-effective strategy for pain mitigation. These studies provided substantial evidence in support of the efficacy of GI and its positive effect on holistically improving patient outcomes. Studies conducted by Gonzalez et al. (2010) and Noergaard et al. (2019) using GI as an adjunctive therapy for pain, provided evidence that patients who received pain medications and GI had better outcomes than those who received pain medications alone. In conjunction with those findings, Zech et al. (2016) also reported patients who received cognitive behavioral therapy (CBT) had better pain outcomes when GI was added compared to patients who only received CBT. Regardless of whether GI is used alone or in addition to other standard treatments for pain, its addition has repeatedly produced better pain outcomes among varied patient populations, situations and diagnoses.

Best Practice Model Recommendation

The standard of care for patients undergoing SLN radioisotope injections, at the project facility site, does not include any pain alleviation interventions. Women present to the procedural setting and receive their intradermal injections. The use of lidocaine to anesthetize the injection sites was trialed prior to this EBP project. Facility data analysis indicated no statistically significant difference between mean pain scores of the lidocaine group compared to the women who received no lidocaine anesthetization. Mean pain scores of lidocaine group were 3.727, *SD* = 1.737, compared to the mean scores of the non-lidocaine group 3.462, *SD* = 2.961. Equal variances not assumed (*t* = -.273, *p* = 0.788). The use of moderate sedation or narcotic pain medications is neither a feasible nor safe option for the brief time required for this procedure. The patients must leave the procedural site for a minimum of 45 minutes, unsupervised, before optimal time for the nuclear scan has been achieved. Additionally, these patients receive these injections on the date of their mastectomies or lumpectomies so the timeframe for the day's events is tightly structured.

The evidence reviewed, regarding the efficacy of GI for relieving pain and preoperative anxiety, supports its use as a viable, intervention for this patient population. GI is cost-effective, relatively easy to implement and can serve as a useful tool for the entire breast cancer treatment process. GI represents an evidence-based therapy that supports holistic, integrative care for patients diagnosed with breast cancer (Carlson et al., 2017).

CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

The medical center's institutional review board granted permission to implement the project as of 8/31/2020. Consenting patients presenting to the nuclear radiology lab for their SLN injections were provided with a 5-minute guided imagery session called 5 Minute Escapes: Meditations created by Olsen Applications Ltd., © 2016, version 1.4.1, last update June 2020

available on IOS via disposable headphones. Permission to use this application was granted via email from the creators. The sessions were conducted immediately before the arrival of the surgeon, who is also the NAPBC committee head, performing said injections. When participants were still listening to the GI when she arrived, she had agreed to let them finish their intervention. Prior to their arrival date, the SNL patients received an educational brochure, followed by a phone call from the DNP student. At the time of the phone call, patients who were interested were familiarized with the free application, so they could practice at home if so desired. Patients had also received the educational brochure from the NAPBC committee head surgeon, but whether they utilized GI prior to the date of their procedure was entirely voluntary.

In garnering stakeholder support and IRB approval, it was agreed that participants should not be obligated to utilize GI at home to avoid further burdening them during a stressful time within their lives. This sentiment was also supported by the findings of the Stoerkel et al. (2019) who found that 79% of eligible participants refused to participate noting a lack of time as a contributing factor.

Participants and Setting

Participants included all the breast surgeon's female patients scheduled for SLN injections. Exclusion criteria consisted of male gender, an inability to speak English or severe sensory or cognitive impairment that prevented potential participants from being able to understand or hear voice, music or background sounds during the meditation. The breast navigator was another integral participant involved in the study, as she was present for and assisted with each procedure. The physical setting for the intervention was the nuclear medicine suite, within a tertiary medical center located in Central Illinois where patients from Indiana and Illinois are served. Department management and personnel were briefed on the intervention and were agreeable to the study. As the project continued, staff members were updated on the progress and mechanisms of the study. Participants received introductory educational material

at the NAPBC surgeon's office at the time of their appointments with subsequent telephone calls performed on-site by the DNP student.

Pre-Intervention Group Characteristics

All participants were female, each were diagnosed with breast cancer with intent to treat. This convenience sample consisted of each patient that the NAPBC surgeon scheduled for an SLN injection after IRB approval had been obtained. No participants refused and all met inclusion criteria. The ages of the women ranged from 45 to 75 years of age, with the mean age being 62.7 (n = 6). Two out of the six participants were African American and the remaining four were Caucasian. Half were married, with one single and two divorced. Only one within the group was currently employed. Data available from the comparison group was limited to pain scores and age. The ages of the women from this group ranged from 47 to 80 years of age, with a mean age of 61.3. Marital status, employment or race was not available for this group.

Intervention

The treatment group received the GI educational brochure, followed by a phone call from DNP student. All participants agreed to participate, their commitment was voluntary and measured in addition to their pain score ratings after the injections. The participants were encouraged to utilize GI at home to acclimate themselves to the process, but this portion of the intervention activity was self-motivated and strictly voluntary. Each participant was provided with project leader's contact information, via the facility site to answer and ongoing questions after the initial conversation. Informal consent was determined during the phone conversation and consent was again obtained prior to the sentinel node injections. The location of the intervention occurred on-site within the nuclear medicine department, with minimal interference with scheduled workflow. Consent was obtained and after patients changed into their gowns and were prepped for the injections. The project leader provided the patients with disposable ear buds and initiated the five-minute GI meditation exercise from the application via a tablet

available from the medical center. After, the meditation was finished the surgeon proceeded with the interventions where pain ratings were recorded.

Comparison

Participants' pain ratings were measured before and after the procedure and recorded using the Visual Analog Scale for Pain (VAS). Initial pain ratings were recorded prior to the guided imagery exercise. Post injection pain scores from the GI project were compared to previously collected data from other arms of the SLN injection quality improvement study lead by facility advisor and NABPC committee head, where patients did not receive GI. The other arms of the study compared the pre- and post-pain ratings, via the VAS of women who received local anesthesia with lidocaine just prior to the radioisotope injection and those that received the radioisotope injection alone. There was not a statistical difference between these two groups.

The process of identifying the SLNs through radioisotope involves injecting tissue near or into the densely enervated areola of the breast. According to anecdotal findings and data collected by the NAPBC committee head surgeon, women report this procedure to be considerably painful. Comparisons and analysis of the data between the intervention and comparison groups was used in determining whether the provision of a five-minute session of GI as a complementary alternative medicine was effective in mitigating reports of pain.

Outcomes

Participants' pain ratings were measured before and after the procedure and recorded using the Visual Analog Scale for Pain (VAS). VAS is a pain rating scale that has been found to have high construct validity, is sensitive to changes in pain and easy for patients to use (Begum & Hussain, 2019; Karcioglu et al., 2018; Thong et al., 2018). Initial pain ratings were recorded prior to the guided imagery exercise. Post procedure pain scores of the intervention group were analyzed for differences compared to the post procedure pain scores of the comparison group who did not receive GI. Results were statistically evaluated utilizing student's *t*-test.

Time

The projected timeline for successful completion was estimated to be within five months duration to recruit 15-20 women. This number was based on the most recently available quarterly data of the number of women presenting to project facility site for SLN injections. Numbers historically increased during the month of October. The project was implemented as soon as consenting participants were scheduled by the participating surgeon. Initiation of the project intervention, based on available participants, began in mid-November through late February of 2021. Weekly correspondence continued via text, email and in person communication with the breast coordinator. All tasks to complete planning were previously accomplished. Meetings with the NAPBC committee head, breast cancer navigator, manager of radiologic services and the nuclear medicine technologists were completed. The protocol for the implementation was presented to the above and approved by the IRB. The recruitment of participants was dependent and limited by the NAPBC surgeon's schedule. Participant numbers were anticipated to surge during October's National Breast Cancer Awareness month but were less than anticipated due to the COVID 19 pandemic. None the less, the project leader had met all requirements and was prepared well in advance. The pain rating tools, the GI application, educational brochure, disposable ear buds, informed consent had also been presented to IRB and approved.

Protection of Human Subjects

Certification from the Collaborative Institutional Training Initiative (CITI Program) was completed by project leader and presented as a prerequisite for IRB approval. There are no perceivable risks of harm to providing patients information on the benefits and utilization of GI. The amount of time they choose to allocate to practicing GI on their own is completely voluntary. The reinforcement that participation was voluntary was stressed to minimize undue burden placed on patients who may be overwhelmed and distressed regarding their diagnoses. It was also imperative to approach the patients with dignity, compassion, and individualized

consideration. Beyond, the ultimate objective of this arm of the study, the project leader and implementation group strove to provide this population of patients with a means of comfort and relief that they could benefit from throughout their breast cancer treatment and recovery timeline.

Consents and data collected remained in a locked cabinet at the project facility site. Statistical data recorded on a spreadsheet were contained on a password, encrypted server. No personal patient information was taken from the premises under any conditions. Phone calls to patients were conducted on site. Demographic information of participants who consented to participate remained within the EPIC system at project facility. Participant data were identified with a number rather than any personally identifiable health information. Names of patients, phone numbers and dates of birth did not leave the facility. Data were stored at the medical center to be kept for a total 5 years after completion of the final arm of the study. Prospective participants did not fall in the category of vulnerable populations according to CITI definitions.

CHAPTER 4

FINDINGS

The objective of this EPB project was to implement a complementary alternative modality to mitigate pain perceptions for women diagnosed with breast cancer undergoing SLN injections within a procedural setting. Post procedure pain scores were rated using a VAS and compared to the scores of women who endured the procedure without the GI session. The impetus for the project was in response to anecdotal findings from the participating general surgeon who had noted that her patients were reporting this component of their breast cancer treatment experiences to be the most painful.

The current protocol does not allow for sedation or pain medication to be administered prior to the SLN injections due to the brief nature of the encounter. The women receive the isotope injections within the nuclear medicine suite and are required to wait a predetermined

time of 45 minutes with their families prior receiving their nuclear scans. This portion of their day precludes their scheduled surgeries. There was a significant difference between the mean pain scores of the GI intervention group and the comparison group. Unfortunately, the analysis did not indicate that the intervention group experienced lower pain ratings. A detailed analysis of the EBP intervention data outcomes will be provided within the following paragraphs.

Participants

A total number of 6 participants were included within the intervention group. These women were recruited via the NABPC general surgeon's office from the participating tertiary medical center located in Central Illinois. All six participants met eligibility criteria and consented to be in the study. However, none of the six utilized GI prior to the date of their procedure as this was not compulsory. This portion of the implementation was agreed upon by the key stakeholders to minimize the burden placed on those that agreed to participate in the study. All six did receive both a phone call from the project leader explaining GI and the purpose of the project as well as an educational pamphlet that was prepared for them. This pamphlet was provided by the surgeon and was included with *The Breast Cancer Treatment Handbook* (Kneece, 2017) which each of her patients received.

As noted in chapter three, page 12, all participants were female, each were diagnosed with breast cancer with intent to treat. This convenience sample consisted of each patient that the NAPBC surgeon scheduled for an SLN injection after IRB approval had been obtained. The dates of the interventions began November 17, 2020 and were completed on February 11, 2021. No participants refused and all met inclusion criteria. The ages of the women ranged from 45 to 75 years of age, with the mean age being 62.7 (n = 6). African American participants consisted of 33.3 % of the participants and Caucasians consisted of 66.7%. Married participants comprised 50% of the intervention group, with 17% being single and 33% divorced. Of the participants 83.3% were unemployed or retired, only 17% were employed [Table 4.3]. Data

available from the comparison group was limited to pain scores and age. The ages of the women from the comparison group ranged from 47 to 80 years of age, with a mean age of 66.0. Marital status, employment or race was not available for this group, as data was collected prior to this current intervention.

Changes in Outcomes

Statistical Testing and Significance

Statistical analysis was conducted using IBM SPSS statistics (Version 25) predictive analytics software. Two testing methods including an independent student *t-test* and Pearson's *r* for correlation were used for outcome analysis. Independent student *t-tests* were conducted to compare the mean pain scores of the intervention group, who received the five-minute GI session to the mean pain scores of the comparison group who received no GI implementation. Independent *t-tests* were conducted to compare the mean ages of the intervention group compared to the comparison group. Pearson's *r* correlation was utilized to determine if a correlation existed between reported pain scores and the participants' ages. The project leader wanted to detect whether a patient's age was related to their pain perceptions.

Findings

An independent *t- test* was conducted to compare variables for the GI intervention group and the no GI comparison group. The mean pain score for the GI group was 6.67 (*SD* = 1.86) [Table 4.2]. The mean pain score for the comparison group was 3.46 (*SD* = 2.96) [Table 4.2]. The statistical outcome between the GI group and comparison group was not significant in determining that the GI group reported less perceived pain ($t = 2.864$, $p = 0.012$). Equal variances could not be assumed because the comparison group ($n = 13$) was more than twice as large as the interventional GI group (n = 6). It cannot be ruled out that a type II error occurred within the analysis of this project: As the sample size was too small and potential variability too large to determine if there was a significant difference between the two groups.

A Pearson's *r* correlation was conducted to explore whether there was a relationship between perceived pain ratings and participants ages. A weak correlation, nonsignificant was found (r (2) = .221, $p > 0.05$). There was not a statistically significant difference in the ages of the intervention group and the comparison group using independent *t-testing* (t = -.480, p = .605). The mean age of the GI intervention group was 63.3 (SD = 10.63). The mean age of the comparison group who did not receive GI was 66.0 (SD = 11.51) [Table 4.1].

Table 4.1

Demographic Characteristics between groups

Characteristics	**GI group**	**No Gi group**
Mean age	63.3	66.0

Table 4.2

Independent t-test for pain scores

	N	**Mean**	***SD***
GI	6	6.67	1.86
NO GI	13	3.46	2.96

(t = 2.864, *p* = 0.012, *df* = 14.98) Equal Variances Not Assumed

Table 4.3

Demographic characteristics of Intervention group

Characteristics				
Race	Age	Marital Status	Employment Status	Pain Score VAS
AA	70	Married	Unemployed	7
AA	45	Single	Unemployed	6
C	59	Married	Employed	5
C	65	Divorced	Retired	5
C	62	Divorced	Unemployed	10
C	76	Married	Retired	7

C Caucasian, AA* African American*

CHAPTER 5

DISCUSSION

The goal of this EBP project was to determine if the implementation of GI, as a complementary alternative therapy, would be successful in mitigating pain perceptions among women presenting for SLN injections. Findings from this project were intended to answer the PICOT question: Do women diagnosed with breast cancer, undergoing sentinel lymph node radioisotope injection (P), report less pain during the procedure (O) when using guided imagery (I) compared to women who do not utilize guided imagery (C) over a 4-month implementation period (T)? The time component of this PICOT question could not be arbitrarily determined prior to onset of implementation because participant recruitment was dependent upon the number of patients presenting to the participating surgeons clinic related to abnormal mammography findings and subsequent diagnostic biopsy. The recruitment and implementation occurred simultaneously as patients populated the procedural setting schedule.

In the following paragraphs further discussion will be provided on the explanation of the findings, strengths and limitations to the study. After, these components are elucidated their implications on future practice, research, EBP model application and education will be discussed.

Explanation of Findings

Without consideration of the limitations of the study, the statistically substantiated findings suggest that the answer to the PICOT question is no. Women presenting for SLN injections who received a 5-minute session of GI did not report less procedural pain compared to women who received no GI therapy. A total of six women presented to the designated surgeons clinic hours from the time that IRB approval was obtained on August 31, 2020 to February 2021. All six were contacted and none declined to participate. The total sample size of the GI intervention group was $n = 6$, the comparison group $n = 13$. The primary outcome

measured was procedural pain scores rated on a VAS tool for women who received the GI intervention. These scores were then compared to procedural pain scores, previously recorded prior to the implementation of the EBP project, of 13 women during a period spanning from August of 2019 to February of 2020.

Independent samples *t*- testing was used to compare differences between groups. There was a significant difference between the intervention and comparison group (t (2)= 2.864, p = 0.012). However, the mean pain scores of the GI group (n = 6, *M* = 6.67, *SD*= 1.86) were not significantly less than the non-GI group (n = 13, *M* = 3.46, *SD* = 2.96). No correlations were found among reported pain scores and patient age. Further analysis on demographic factors could not be conducted due to the availability of data recorded from the comparison groups.

These findings were consistent with the systematic review with metanalysis conducted by Noergarrd et al. (2019) examining the effectiveness of GI in the management of pain in minimally invasive procedures. In their study, they measured pain medication consumption between intervention and comparison groups and found a significant reduction of opioid consumption among the intervention group, with no increased adverse effects. However, among their analysis few of the studies reported significant reductions in reports of pain intensity. Serra et al. (2012) reported similar findings in their quasi-experimental study measuring the effects of GI on women presenting for radiation therapy. They used both objective and subjective measurements to measure pain. As the radiation sessions progressed when tissue becomes more inflamed and sensitive, the women in the GI intervention group had considerably lower scores on objective measurements of pain tolerance as opposed to pain scores. Significant decreases in systolic and diastolic blood pressure, pulse rate, and respirations were found between radiation sessions 1 and 2 among the GI group (Serra et al., 2012).

Gonzalez et al. (2010) also collected data on pain control and narcotic consumption postoperatively in an ambulatory setting. They concluded that preoperative GI was effective in

reducing anxiety and consequently resulted in a significant reduction of postoperative pain scores, narcotic consumption and PACU discharge times.

These studies represent the effectiveness of GI in reactions to pain based on objective measurements rather than a strictly subjective VAS pain scale scores. VAS pain scores are measured numerically and have evidence-based validity and reliability (Begum & Hussain, 2019). However, there are many influences on the perception of pain and scores can vary based on patient expectations, moderating factors, characteristics, treatment histories and previous pain experiences (Peerdeman et al., 2019). The main goal of this study was to reduce procedural pain scores of women undergoing SLN injections, but a secondary goal was to provide a means to make the experience more tolerable.

In the studies within the literature review, related to chronic pain, GI provided an effective therapy to assist patients in coping with pain (Giacobbi et al., 2015; Zech et al., 2016). Chen et al. (2015) measured the expanded effects of GI for breast cancer patients undergoing chemotherapy finding a positive relationship in overall symptom distress, including pain, depression, insomnia, and anxiety. Pain perception is individualized and influenced by factors outside the scope and constraints of this project.

Demographic data for the comparison group were limited to age only, all participants were female. A greater sample size was anticipated because October is Breast Cancer Awareness Month. Historically numbers of women presenting for mammograpy and consequent SLN injections spike throughout October and November (NAPBC breast surgeon, personal communication, September 14, 2020). However, this was not the case for 2020, where 8,900 women presented for mammograpy screening compared to 12,174 in 2019 (Facility breast coordinator, personal communication, February 26, 2021). The repercussions of the COVID 19 pandemic may have influenced the number of people willing to visit healthcare settings for routine screenings due to quarantine restrictions, limitations to nonemergent hospital encounters and patient fear of contracting the virus.

Strengths and Limitations of the DNP Project

Strengths

The implementation of this EPB project intervention incurred no additional costs to the facility, minimally interfered with departmental flow, was feasible to implement and could easily be replicated. The sample size was small but, bias was minimized because all potential participants consented to participate, and none were excluded. In adherence to the JHNEBP implementation model (Dang & Dearholt, 2017), each of the recommended steps were addressed. This guide was very helpful in anticipating the expectations and sequence of events to gain support for the implementation of this project. Key factors included gaining support and approval of key stakeholders. This was accomplished through consultation and continual sharing of information with the NAPBC surgeon, the breast navigator and the nuclear medicine team. The JHNEBP model was also an influential guidance tool for presentation of the proposed project to the quality improvement team and the facility IRB. The action planning tool was very helpful in navigating this EBP implementation and emphasized how change to protocol would influence workflow and processes. Negotiation and careful consideration of workflow constraints were thoroughly explored and evaluated to cause minimal interruption. Another essential consideration was minimizing participant burden. Patients who are dealing with a diagnosis of breast cancer can be overwhelmed by the stress related to a cancer diagnosis (Carlson et al., 2017; Smit et al., 2019; Stoerkel et al., 2018). Therefore, it was agreed that there would be no obligation for participants to utilize GI prior to there scheduled procedures.

Studies from Álvarez-García & Yaban (2019), Gonzalez et al. (2010) and Stoerkel et al. (2018) found that GI was efficacious in the absence of prior familiarization. In the Stoerkel et al. (2018) study they discussed how presenting an at home GI intervention to newly diagnosed cancer patients was inopportune timing in relation to the overwhelming nature of receiving a cancer diagnosis. In fact, within their study 79% of potential participants refused to join due to perceived time constraints (Stoerkel et al., 2018). Participants for this EBP project were

provided with educational pamphlets defining GI and its efficacy with examples of free applications that they could access at home. Education was further reinforced during the phone contacts conducted by the project leader. Participants were encouraged to familiarize themselves with GI prior to their procedures on a voluntary basis. This was in adherence to the implementation plan approved by the IRB and key stakeholders.

In summary, GI serves as a cost effective and holistic approach to pain management. Providing the participants in this EBP project with five minutes of time to relax and listen to GI was well received and did not interfere with the flow of daily activities within this institution. Though not formally measured, 4 out of 6 participants found the GI exercise to be beneficial and were grateful that this alternative therapy was provided for them. At that time, a demonstration was provided on how to use the application and an additional educational pamphlet was provided for those who did not remember receiving one from the surgeon. Limitations of the project will be discussed below.

Limitations

A key limitation to this study was the unanticipated small sample size. Recruitment of this convenience sample of participants was dependent on how many patients diagnosed with breast cancer presented to the NAPBC surgeon within the time frame between attainment of IRB approval and project component deadlines. Facility data indicated that fewer women had presented for mammography screening in 2020 compared to previous years. From August of 2019 to July of 2020 there were a total of 24 SLN injection procedures performed. From August 2020 to February 2021 only six patients who were candidates for SLN injections presented. The first case after IRB approval on August 31, 2020 did not occur until mid-November.

Another limitation was limited access to the project facility related to COVID 19 restrictions. Ideally, it would have been better for the project leader to be present at the time of the participants initial appointments in the surgeon's clinic. This would have allowed for more meaningful, face to face, patient centered communication. At this time, the patients could have

been provided with a sample presentation of GI and instructed on how to use and access applications. Instead, this took place over the phone and some of the patients did not remember receiving the GI educational pamphlet from the surgeon or had not looked at it prior to the phone call. When planning the project implementation, the key stakeholders thought that it would be best if the project leader waited until a week or so after participant appointments to allow them to come to terms with their cancer diagnoses and proposed treatment plans. Incidental findings among the participant group indicated that most of the women enjoyed the GI exercise and found it relaxing, despite no significant reductions in pain score ratings. It would have been beneficial for them to use GI as a resource throughout their breast cancer journeys beyond just the SLN procedural encounter.

To minimize threats to internal validity the same VAS tool that was used for the comparison group was used for the GI participants. However, the project leader was not present when the pain scores of the comparison group were recorded as this took place before EBP project implementation. So, it cannot be determined whether the tool was used uniformly for the comparison group. There was also a lack of demographic data available for the comparison group as well. The NAPBC surgeon had previously been recording pain scores for her SLN patients as part of a quality improvement project. This data was limited to patient age, the date of the procedure and pain scores. The analysis of demographic differences between groups that may have contributed to pain perceptions was limited to age.

Additionally, the JHNEBP implementation model is helpful for anticipating barriers to implementation but does not provide viable solutions when barriers are encountered. For instance, to gain stakeholder support negotiation and compromise were necessary. The project leader was a guest at this facility, therefore had a lack of control of intervention implementation. Constraints were placed on the length of the GI session provided and when it was performed. A maximum of 5 minutes was permitted for the GI intervention to avoid disruption to departmental or physician scheduling. Step 16 of the JHNEBP PET Management Guide addresses evaluating

outcomes during the translation phase (Dang & Dearholt, 2017). While evaluating the translation process, the project leader felt that the GI would be most useful if it were applied during the injections instead of before. This was thwarted because the physician preferred to speak to her patients while she was injecting them. Due to the small number of available participants, major changes in the implementation process would not have been feasible. Had the length or timing of the GI session been altered, the rigor of the study design would have been compromised.

Lastly, the nature of this project was very specific. The body of evidence did not provide specific examples of methods to eliminate pain during SLN breast injections. Therefore, the findings from the highest levels of evidence for the efficacy of GI for pain were extrapolated from similar but not identical situations and patient populations. Identification of the problem and the desire to improve the experiences of women diagnosed with breast cancer was straightforward. However, it was challenging to find the best EBP standards for a very particular, unexplored circumstance.

Implications for the Future

The findings from this EBP project do not support GI as an effective therapy for the reduction of pain scores during SLN injections. This study was limited by a small sample size and larger studies may produce different results. However, future exploration of GI for this patient population should be explored. Considerations to be studied are optimal length and timing of GI sessions. Important questions include: Do women report lower pain scores when they are listening to GI while the injections are taking place? Are GI meditations lasting more than 5 minutes more efficacious?

Practice

The application of a complimentary alternative therapy like GI is beneficial for patients in coping with chronic and acute pain (Alvarez-Garcia & Yaban, 2020; Charalambous et al., 2016; Chen et al., 2015; Giacobbi et al., 2015; Gonzalez et al., 2010; Hamlin & Robertson, 2017; Noeregaard et al., 2019; Peederman et al., 2016; Serra et al., Stoerkel et al., 2108; Zech et al.,

2017). This EBP project implementation process can be used as an example of how to incorporate a strategy such as GI easily and cost-effectively into care plans for patients undergoing minimally invasive procedures.

GI provides a holistic approach to improving patient experiences when other pain mitigation therapies are not feasible. The statistical findings from this project's analysis did not support GI as effective in lowering VAS pain ratings during SLN injections. However, clinical findings indicate that patients were receptive to participating and trying a therapy that was new to them. No potential candidates refused to participate, and the majority (66.7%) were grateful for the personalized extra comfort measure offered. It is important to be openminded to offering evidenced-based, complementary alternative therapies either as part of the standard of care or when other therapies are ineffective.

EBP Model

The JHNEBP implementation model was a useful framework to guide the planning process for this EBP project. It provides a series of checklists that prompt the project leader on major components and considerations that should be addressed prior to translating evidence into practice. A detailed explanation of how this model was followed is provided in chapter 2. This model does contain areas that must be addressed in getting support and or approval for the implementation of an EBP intervention. Important elements of this model that are imperative to contemplate are gaining stakeholder support and minimizing workflow interference. These were the biggest challenges for this project and influenced the implementation process.

The JHNEBP model does not offer solutions when resistance or barriers are encountered. Neither does it address the expectations of organizational IRBs. Also, the user should review all the steps in advance prior to proceeding because some steps need to be considered early within the process. For instance, a thorough literature search identifying the best available practice to improve the clinical problem should be started at the inception, because this data will be fundamental in gaining support for the chosen interventional strategy.

Research

It is difficult to predict whether a larger sample size would have produced different results. To generalize findings, further research is needed using larger numbers of participants. Limitations within the synthesis of evidence also noted that a lack of data existed regarding whether acceptance and previous familiarity with GI influences its efficacy. Forthcoming studies should also investigate the optimal length for GI sessions and whether pain is more effectively alleviated when the intervention is provided at the time of the injections rather than before. This was not permitted during this EBP project.

Education

Patients within this project were provided with an educational pamphlet about what GI is and how to access it. This was followed by a phone call from the team leader further explaining the purpose of the project and answering any questions. In the planning process, two of the key stakeholders expressed concern that patients would be too stressed and overwhelmed to be contacted about the project the day of their office visits when the plan of care and cancer diagnosis were discussed. During the follow up phone calls, some of the patients had not even remembered receiving the educational pamphlet or had not looked at it. Stakeholder input is important for successful project implementation. Patients must be receptive to learning for it to be effective.

After listening to the GI meditation prior to their injections, participants were more interested in using it at home. When the project leader was able to see them in person and show them how to use GI, they wanted more information and were interested in learning. This is an incidental finding within this project that may be helpful for others who would like to introduce GI to their patients. Providing a brief demonstration sampling of GI may be more effective than written or verbal instruction for those who are unfamiliar with it. Education on GI for stakeholders and IRB members should also be incorporated into the implementation plan for better understanding and acceptance.

Conclusion

One of the treatment standards for patients diagnosed with breast cancer involves SLN identification via intradermal injection into the breast tissue. This procedure is brief but painful so exploration of modalities to make the procedure more tolerable was warranted. The participating facility is accredited by the NAPBC whose standards include the improvement of treatment and care provided to breast cancer patients. The goal of this EBP project was to determine if the delivery of a 5-minute GI session could relieve procedural pain in women presenting for SLN injections. Mean pain scores for women who received GI were compared to a group who received the standard of care which included no pain reduction measures. This study provides an example of how changes in protocol that incorporate GI can be easily implemented with minimal interruption in workflow.

Participant recruitment was hampered by the COVID 19 pandemic, the sample size was limited to six participants. Statistical findings from this study do not support GI as an evidence-based complementary alternative therapy for pain mitigation. However, the intervention was still beneficial in the provision of patient-centered, holistic care. Participants were receptive and appreciative that this personalized meditation was provided for them. The majority (66.7%) of the patients found the GI exercise to be relaxing and comforting and expressed openness to using GI in their continued breast cancer journeys. Further research with larger sample sizes is needed to determine optimal timing and length of GI sessions to ascertain whether adjustments could produce decreased pain scores. Though statistically significant results were not found in this project to support GI, it is a safe, cost-effective therapy that should be further explored for use during other minimally invasive procedures where sedation and pain medication are not practical.

REFERENCES

Álvarez-García, C., & Yaban, Z. (2020). The effects of preoperative guided imagery interventions on preoperative anxiety and postoperative pain: A meta-analysis. *Complementary Therapies in Clinical Practice*, 38, 101077. https://doi.org/10.1016/j.ctcp.2019.101077

American Cancer Society. (2020). *Breast cancer facts & figures*. Retrieved July 10, 2020, from https://www.cancer.org/research/cancer-facts-statistics/breast-cancer-facts-figures.html

American College of Surgeons. (2020). *About the national accreditation program for breast centers*. Retrieved July 1, 2020, from https://www.facs.org/quality-programs/napbc/about

American College of Surgeons. (2020). *National accreditation program for breast centers.* Retrieved July 1, 2020, from https://www.facs.org/quality-programs/napbc

American Nurses Association. (2018). ANA position statement: The ethical responsibility to manage pain and the suffering it causes. *OJIN; The Online Journal of Issues in Nursing*, 24(1). https://doi.org/10.3912/OJIN.Vol24No01PoSCol01

BREASTCANCER.ORG. (2020, June 25). *U.S. breast cancer statistics* | breastcancer.org. Breastcancer.org. https://www.breastcancer.org/symptoms/understand_bc/statistics

Begum, R., & Hussain, M. A. (2019). Validity and reliability of visual analogue scale (VAS) for pain measurement. *Journal of Medical Case Reports and Reviews*, 2(11), 394–402. https://doi.org/https://jmcrr.info/index.php/jmcrr/article/view/113/95

Carlson, L. E., Zelinski, E., Toivonen, K., Flynn, M., Qureshi, M., Piedalue, K.-A., & Grant, R. (2017). Mind-body therapies in cancer: What is the latest evidence? *Current Oncology Reports,* 19(10). https://doi.org/10.1007/s11912-017-0626-1

Centers for Disease Control and Prevention. (2020). *Breast cancer statistics*. Retrieved July 10, 2020, from https://www.cdc.gov/cancer/breast/statistics/index.htm.

Charalambous, A., Giannakopoulou, M., Bozas, E., & Paikousis, L. (2019a). Parallel and serial mediation analysis between pain, anxiety, depression, fatigue and nausea, vomiting and

retching within a randomised controlled trial in patients with breast and prostate cancer. BMJ Open, 9(1), e026809. https://doi.org/10.1136/bmjopen-2018-026809

Charalambous, A., Giannakopoulou, M., Bozas, E., Marcou, Y., Kitsios, P., & Paikousis, L. (2016). Guided imagery and progressive muscle relaxation as a cluster of symptoms management intervention in patients receiving chemotherapy: A randomized control trial. *PLOS ONE*, 11(6), e0156911. https://doi.org/10.1371/journal.pone.0156911

Chen, S.-F., Wang, H.-H., Yang, H.-Y., & Chung, U.-L. (2015). Effect of relaxation with guided imagery on the physical and psychological symptoms of breast cancer patients undergoing chemotherapy. *Iranian Red Crescent Medical Journal*, 17(11). https://doi.org/10.5812/ircmj.31277

Dang, D., & Dearholt, S. (2017). *Johns Hopkins nursing evidence-based practice: model and guidelines*. (3rd ed.). Sigma Theta Tau International.

Giacobbi, P. R., Stabler, M. E., Stewart, J., Jaeschke, A.-M., Siebert, J. L., & Kelley, G. A. (2015). Guided imagery for arthritis and other rheumatic diseases: A systematic review of randomized controlled trials. *Pain Management Nursing*, 16(5), 792–803. https://doi.org/10.1016/j.pmn.2015.01.003

Giuliano, A. E., Ballman, K. V., McCall, L., Beitsch, P. D., Brennan, M. B., Kelemen, P. R., Ollila, D. W., Hansen, N. M., Whitworth, P. W., Blumencranz, P. W., Leitch, A., Saha, S., Hunt, K. K., & Morrow, M. (2017). Effect of axillary dissection vs no axillary dissection on 10-year overall survival among women with invasive breast cancer and sentinel node metastasis. *JAMA*, 318(10), 918. https://doi.org/10.1001/jama.2017.11470

Gonzalez, E. A., Ledesma, R. J., McAllister, D. J., Perry, S. M., Dyer, C. A., & Maye, J. P. (2010). Effects of guided imagery on postoperative outcomes in patients undergoing same-day surgical procedures: A randomized controlled trial. *AANA Journal*, 78(3), 181–188.

Guided imagery. (2020). TheFreeDictionary.com. Retrieved July 20, 2020, from https://medical-dictionary.thefreedictionary.com/guided imagery.

Hamlin, A. S., & Robertson, T. (2017). Pain and complementary therapies. *Critical Care Nursing Clinics of North America*, 29(4), 449–460. https://doi.org/10.1016/j.cnc.2017.08.005

Karcioglu, O., Topacoglu, H., Dikme, O., & Dikme, O. (2018). A systematic review of the pain scales in adults: Which to use? *The American Journal of Emergency Medicine*, 36(4), 707–714. https://doi.org/10.1016/j.ajem.2018.01.008

Kneece, J.C. (2017). *Breast cancer treatment handbook, 9th edition (2017)* (9th ed.). Educare Publishing .

Melnyk, B. M., & Fineout-Overholt, E. (2018). *Evidence-based practice in nursing & healthcare: A guide to best practice* (4th ed.). Wolters Kluwer.

Moher, D., Liberati, A., Tetzlaff, J., & Altman, D. G. (2009). Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. *PLoS Medicine*, 6(7), e1000097. https://doi.org/10.1371/journal.pmed.1000097

National Comprehensive Cancer Network. (2016). *NCCN Guidelines for patients* (Version 1.2016) [Supportive care book series]. https://www.nccn.org/patients/guidelines/content/PDF/nausea-patient.pdf

Noergaard, M., Håkonsen, S., Bjerrum, M., & Pedersen, P. U. (2019). The effectiveness of hypnotic analgesia in the management of procedural pain in minimally invasive procedures: A systematic review and meta-analysis. *Journal of Clinical Nursing*, 28(23-24), 4207–4224. https://doi.org/10.1111/jocn.15025

Peerdeman, K. J., van Laarhoven, A. I., Keij, S. M., Vase, L., Rovers, M. M., Peters, M. L., & Evers, A. W. (2016). Relieving patients' pain with expectation interventions. *PAIN*, 157(6), 1179–1191. https://doi.org/10.1097/j.pain.0000000000000540

National Cancer Institute. (2020). *Sentinel lymph node biopsy*. Retrieved July 9, 2020, from https://www.cancer.gov/about-cancer/diagnosis-staging/staging/sentinel-node-biopsy-fact-sheet

Serra, D., Parris, C., Carper, E., Homel, P., Fleishman, S. B., Harrison, L. B., & Chadha, M. (2012). Outcomes of guided imagery in patients receiving radiation therapy for breast cancer. *Clinical Journal of Oncology Nursing*, 16(6), 617–623. https://doi.org/10.1188/12.cjon.617-623

Smit, A., Coetzee, B., Roomaney, R., Bradshaw, M., & Swartz, L. (2019). Women's stories of living with breast cancer: A systematic review and meta-synthesis of qualitative evidence. *Social Science & Medicine*, 222, 231–245. https://doi.org/10.1016/j.socscimed.2019.01.020

Stoerkel, E., Bellanti, D., Paat, C., Peacock, K., Aden, J., Setlik, R., Walter, J., & Inman, A. (2018). Effectiveness of a self-care toolkit for surgical breast cancer patients in a military treatment facility. *The Journal of Alternative and Complementary Medicine*, 24(9-10), 916–925. https://doi.org/10.1089/acm.2018.0069

Thong, I. K., Jensen, M. P., Miró, J., & Tan, G. (2018). The validity of pain intensity measures: What do the nrs, vas, vrs, and fps-r measure? *Scandinavian Journal of Pain*, 18(1), 99–107. https://doi.org/10.1515/sjpain-2018-0012

Whitman, G., AlHalawani, R., Karbasian, N., & Krishnamurthy, R. (2019). Sentinel lymph node evaluation: What the radiologist needs to know. *Diagnostics*, 9(1), 12. https://doi.org/10.3390/diagnostics9010012

World Cancer Research Fund International. (n.d.). *Breast cancer statistics*. American Institute for Cancer Research. Retrieved July 1, 2020, from https://www.wcrf.org/dietandcancer/cancer-trends/breast-cancer-statistics

World Cancer Research Fund. (n.d.). *Worldwide cancer data*. Retrieved July 10, 2020, from https://www.wcrf.org/dietandcancer/cancer-trends/worldwide-cancer-data

Zech, N., Hansen, E., Bernardy, K., & Häuser, W. (2016). Efficacy, acceptability and safety of guided imagery/hypnosis in fibromyalgia - a systematic review and meta-analysis of randomized controlled trials. *European Journal of Pain*, 21(2), 217–227. https://doi.org/10.1002/ejp.933

BIOGRAPHICAL MATERIAL

Miss Kirk began her pursuit of higher education by completing her Bachelor of Science degree in health Care Planning and Administration from the University of Illinois, Champaign-Urbana in 1996. She went on to achieve an associate nursing degree from Purdue University Northwest, graduating as president of her nursing class in December of 1998. She started her nursing career in April of 1999 and has worked at a Northwest Indiana hospital since that time with positions that were predominately focused on cardiology, including the cardiac catheterization lab and non-invasive cardiology departments. She went on to obtain her Bachelor of Science in nursing in 2012 from Purdue University Northwest. Miss Kirk is currently enrolled as a full-time student in Valparaiso University's Doctor of Nursing Practice program with an expected graduation date of May 2021. She is student member of the American Association of Nurse Practitioners and Theta Epsilon Chapter of Sigma Theta Tau. Miss Kirk aspires to obtain employment with the Veteran's Administration after graduation. Her interest in improving outcomes for cancer patients and desire to provide care for U.S. veterans is directly related to her father's service during the Viet Nam war where he subsequently has survived two types of cancer diagnoses directly related to Agent Orange exposure.

ACRONYM LIST

ANA: American Nurses Association

GI: Guided Imagery

CDC: Centers for Disease Control

DNP: Doctor of Nursing Practice

EBP: Evidence Based Practice

IRB: Institutional Review Board

JHNEBP: Johns Hopkins Nursing Evidence-Based Practice

NAPBC: The National Accreditation Program for Breast Centers

NCCN: National Comprehensive Cancer Network

PICOT: Population, Intervention, Comparison, Outcome and Time

QOL: Quality of Life

RCT: Randomized Controlled Trial

SLN: Sentinel Lymph Node

VAS: Visual Analogue Scale

APPENDIX A

Evidence Table for GI

Citation (APA)	Purpose	Design	Sample	Measurement/ Outcomes	Results/Findings	Level/ Quality
Álvarez-García, C., & Yaban, Z. (2020). The effects of preoperative guided imagery interventions on preoperative anxiety and postoperative pain: A meta-analysis. *Complementary Therapies in Clinical Practice*, 38, 101077. https://doi.org/10.1016/j.ctcp.2019.101077 Retrieved from CINAHL.	To assess the efficacy of GI to reduce preoperative anxiety and postoperative pain.	Systematic review and meta-analysis	21 RCTs for systematic review 8 RCTs for meta-analysis Total number of study participants not included	Preoperative anxiety in adults (state and trait anxiety) Postoperative pain ratings in adults. When meta-analysis was conducted within the 8 studies meeting criteria for such, generalization of data findings was conducted using a random effects model.	Meta-analysis : GI had a moderate effect in reducing preoperative anxiety in adults. (n = 333; d = 0.64; 95% CI = 0.97, -0.3), $p < 0.001$ GI in the preoperative period was effective in reducing pain postoperatively in adults (n =318, d = -0.24, CI = -0.46, - 0.02) p = 0.035 Systematic review- sign test shows preoperative anxiety can be reduced in adults P =0.011 and subsequent postoperative pain p = 0.019	Level I A

Citation (APA)	Purpose	Design	Sample	Measurement/ Outcomes	Results/Findings	Level/ Quality
Charalambous, A., Giannakopoulou, M., Bozas, E., Marcou, Y., Kitsios, P., & Paikousis, L. (2016). Guided imagery and progressive muscle relaxation as a cluster of symptoms management intervention in patients receiving chemotherapy: A randomized control trial. *PLOS ONE*, 11(6), e0156911. https://doi.org/10.1371/journal.pone.015691. Retrieved from CINAHL.	To assess the effectiveness of GI and muscle relaxation on a cluster of symptoms including pain, nausea, fatigue, nausea, vomiting, anxiety and retching in patients diagnosed with breast and prostate cancers.	A randomized controlled parallel design trial with 2 groups.	208 total patients, 104 in the intervention group 104 in the control group	Health Related Quality of Life (HRQoL) Pain numeric pain scale The Cancer Fatigue Scale (CFS) The Revised Rhodes index of nausea and vomiting (INVR) SAS -self rating anxiety scale And the Beck Depression Inventor II or BD- II These factors were measured in both groups pre- and post-intervention.	Relevant findings related to pain: participants in the control group reported decreased pain (mean 2.48, *SD* 1.35 whereas those in the control group reported increased pain at the end of the study period (mean 4.80, *SD* 1.46). Statistical significance of the intervention (F =29.64, p < 0.0001)	Level I A.

Citation (APA)	Purpose	Design	Sample	Measurement/ Outcomes	Results/Findings	Level/ Quality
Chen, S.-F., Wang, H.-H., Yang, H.-Y., & Chung, U.-L. (2015). Effect of relaxation with guided imagery on the physical and psychological symptoms of breast cancer patients undergoing chemotherapy. *Iranian Red Crescent Medical Journal,* 17(11). https://doi.org/10.5812/ircmj.31277 Retrieved from Cochrane Library	To assess the efficacy of GI and relaxation on patients diagnosed with breast cancer.	A quasi-experimental study with a randomized controlled trial.	65 total participants. 32 were randomly assigned to the experimental group and 33 were assigned to the control group.	HADS (hospital anxiety and depression scale) and SDS (Sheehan disability scale) ratings were measured prior to the initial administration of chemotherapy and 10 days after.	Relevant findings related to pain: the experimental group showed decreases in pain ratings pain (*SD* -0.28 ± 0.58, $p < 0.05$). Control group reported significant increases in nausea, vomiting, appetite loss, constipation, abdominal distension and heartburn each with a *p* value < 0.05. Intervention group reported a significant decrease in insomnia, pain, restlessness, inability to concentrate, and numbness each measurement also with a *p* value < 0.05, decreased anxiety and depression, *p* value < 0.00 pre and posttest.	Level II A

Citation (APA)	Purpose	Design	Sample	Measurement/ Outcomes	Results/Findings	Level/ Quality
Giacobbi, P. R., Stabler, M. E., Stewart, J., Jaeschke, A.-M., Siebert, J. L., & Kelley, G. A. (2015). Guided imagery for arthritis and other rheumatic diseases: A systematic review of randomized controlled trials. *Pain Management Nursing,* 16(5), 792–803. https://doi.org/10.1016/j.pmn.2015.01.003. Retrieved from CINAHL.	To determine if GI is effective in reducing pain, and depression as well as increasing functionality, and quality of life for patients diagnosed with arthritis and other rheumatic diseases.	A systematic review of RCTs.	Seven studies including 306 total participants 8 of which were men and the remaining 282 were female.	Outcomes from the various studies were measured using the following tools: AIMS 2, VAS (numeric pain rating scales), Anxiety (STAI-T) or ATQ 30, McGill's pain questionnaire, fibromyalgia impact questionnaire, and the arthritis self-efficacy questionnaire.	Each of the 7 studies reported significant statistical findings supporting GI as an effective intervention for pain relief. Increased QOL scores.	Level I B

Citation (APA)	Purpose	Design	Sample	Measurement/ Outcomes	Results/Findings	Level/ Quality
Gonzalez, E. A., Ledesma, R. J., McAllister, D. J., Perry, S. M., Dyer, C. A., & Maye, J. P. (2010). Effects of guided imagery on postoperative outcomes in patients undergoing same-day surgical procedures: A randomized controlled trial. *AANA Journal*, 78(3), 181–188. Retrieved from CINAHL.	Assessment of the efficacy of GI for postoperative pain outcomes for patients undergoing same-day surgical procedures.	RCT, single blind study	44 total participants; 26 men and 18 women.	Wilcoxon signed rank test was used to statistically analyze preoperative and postoperative anxiety level scores measured using the APAIS tool for the experimental and control groups. Individual intra and postoperative narcotic use was recorded. Pain ratings for each group were measured 1 and 2 hours postoperatively using the VAS numeric scale, statistical analysis was performed using the Mann Whitley U test. PACU mean length of stay scores were recorded.	Findings relevant to pain: Control group mean level of pain at 1 hour was 41.18 mm, GI experimental group was 28.68 mm (p = .057). GI group : 2 hours post-op were significantly lower than control group (p = .041), mean scores of 20,00 and 34.72 mm, respectively.	Level I A

Citation (APA)	Purpose	Design	Sample	Measurement/ Outcomes	Results/Findings	Level/ Quality
Noergaard, M., Håkonsen, S., Bjerrum, M., & Pedersen, P. U. (2019). The effectiveness of hypnotic analgesia in the management of procedural pain in minimally invasive procedures: A systematic review and meta-analysis. *Journal of Clinical Nursing*, 28(23-24), 4207–4224. https://doi.org/10.1111/jocn.15025 Retrieved from the Joanna Briggs Institute EBP database	To evaluate the efficacy of hypnotic analgesia, an alternative term for GI in the Medline MeSH terms, for minimally invasive procedural pain.	Systematic review and meta-analysis.	Ten studies including a total of 1,365 participants. Nine RCTs and one quasi-experimental study.	Patient reported procedural pain ratings. Nine out of ten studies utilized the VAS pain scale ratings and on used the Subjective Units of Discomfort Scale. Other measures included: adverse events, pain medication consumption and procedure length.	Outcomes related to patient reported pain: few studies showed statistically significant pain intensity and anxiety ratings. Yet, a reduction of pain medication consumption was found ranging from 21 to 86% among a meta-analysis of the 1,365 participants.	Level II A

Citation (APA)	Purpose	Design	Sample	Measurement/ Outcomes	Results/Findings	Level/ Quality
Peerdeman, K. J., van Laarhoven, A. I., Keij, S. M., Vase, L., Rovers, M. M., Peters, M. L., & Evers, A. W. (2016). Relieving patients' pain with expectation interventions. *PAIN,* 157(6), 1179–1191. https://doi.org/10.1097/j.pain.0000000000000540 Retrieved from CINAHL.	To determine the efficacy of interventions including: brief verbal suggestion, conditioning, or imagery on pain compared to no treatment or control treatment.	Systematic review and Meta-analysis	27 experimental and quasi-experimental studies consisting of a total of 1256 patients.	Pain was measured using a visual analogue scale, or something similar where pain could be rated numerically.	Overall effect of the interventions on patients' pain relief was observed to be medium (g = 0.61, I^2 = 73%), verbal suggestion (k = 18, g = 0.75), conditioning (always paired with verbal suggestion, k = 3, g = 0.65), and imagery (k = 6, g = 0.27)	Level II A

Citation (APA)	Purpose	Design	Sample	Measurement/ Outcomes	Results/Findings	Level/ Quality
Serra, D., Parris, C., Carper, E., Homel, P., Fleishman, S. B., Harrison, L. B., & Chadha, M. (2012). Outcomes of guided imagery in patients receiving radiation therapy for breast cancer. *Clinical Journal of Oncology Nursing*, 16(6), 617–623. https://doi.org/10.1188/12.cjon.617-623 Retrieved from CINAHL.	This study was conducted to evaluate the effects of GI on women undergoing radiation for breast cancer.	Quasi-experimental study: pre and posttest design /interrupted time-series study	66 female patients undergoing radiation for breast cancer. No control group	EQ 5D – a multi attribute utility instrument used to assess health care quality of life scores were taken before and after the participants treatment. Distress thermometer ratings. Biometrics – pulse, blood pressure, respirations and thermal biofeedback pre- and post-intervention.	Significant decreases in systolic and diastolic blood pressure, pulse rate, and respiration were noted between sessions 1 and 2. Distress thermometer results: decreases in global distress (p = 0.04), sadness (p = 0.04), worry (p = 0.06) and nervousness (p = 0.05). EQ 5D scores showed that as pain increased as expected (related to skin irritation d/t radiation) patients were able to report lower levels of depression and anxiety (p = 0.01).	Level II A

Citation (APA)	Purpose	Design	Sample	Measurement/ Outcomes	Results/Findings	Level/ Quality
Stoerkel, E., Bellanti, D., Paat, C., Peacock, K., Aden, J., Setlik, R., Walter, J., & Inman, A. (2018). Effectiveness of a self-care toolkit for surgical breast cancer patients in a military treatment facility. The Journal of Alternative and Complementary Medicine, 24(9-10), 916–925. https://doi.org/10.1089/acm.2018.0069 Retrieved from Cochrane Library	To determine the effects of a self-care toolkit (which included GI exercises) for breast cancer patients undergoing surgical treatment.	RCT	100 female participants 49 randomly assigned to intervention group self-care toolkit and 51 assigned to standard of care	Anxiety, pain intensity, pain interference, sleep disturbance and fatigue measured via PROMIS 57 scores, pain was rated using the Defense and Veterans Pain Rating Scale (DVPRS) And inflammatory blood markers ESR and CRP.	PROMIS 57 scores were significantly higher among the intervention group compared to control group : pain interference($p = 0.005$), fatigue ($p = 0.023$) and social role satisfaction ($p = 0.021$). Intervention group showed reduced increases in postoperative pain ($p = 0.008$) and in postoperative ESR ($p = 0.0197$).	Level I B

Citation (APA)	Purpose	Design	Sample	Measurement/ Outcomes	Results/Findings	Level/ Quality
Zech, N., Hansen, E., Bernardy, K., & Häuser, W. (2016). Efficacy, acceptability and safety of guided imagery/hypnosis in fibromyalgia - a systematic review and meta-analysis of randomized controlled trials. European Journal of Pain, 21(2), 217–227. https://doi.org/10.1002/ejp.933 Retrieved from CINAHL	to determine the efficacy, acceptability, and safety of GI/hypnosis for mitigating symptoms experienced by patients diagnosed with fibromyalgia (FM).	Synthesis review of RCTs with meta-analysis	7 RCTs with a combined total of 387 participants.	Primary outcomes : ≥ 50% pain relief, Fibromyalgia Impact Questionnaire (FIQ) improvement of ≥ 20%, psychological distress, disability, acceptability of GI, and safety.	Pain relief ≥50% [RD 0.18 (95% CI 0.02, 0.35), *p* = 0.008], pain relief ≥ 30% [RD 0.25 (95% CI 0.01, 0.05), *p* = 0.02], pain intensity [*SMD* 1 1.12 (95% CI – 1.97, - 0.28), *p* = 0.009], coping with pain [*SMD* – 0.32 (95% CI – 0.59, - 0.05), *p* = 0.02], and psychological distress [*SMD* - 0.40 (95% CI - 0.70, - 0.11), *p* = 0.008]. No studies evaluated safety of the intervention.	Level I A

APPENDIX A

Proof of Permission to use GI application.

BK **Brandy Kirk <brandy.kirk@valpo.edu>**
2/7/2021 3:45 AM

To: Olson Apps Support

Thank you, I will do that.

On Sun, Feb 7, 2021 at 3:44 AM Olson Apps Support <help@olsonapps.co.uk> wrote:

> Hello,
>
> Yes, by all means use the name of the app. This sounds a really interesting project. Please could you send a copy of the final document once you have finished?
>
> Kind regards
> James
>
> > On 6 Feb 2021, at 21:54, Brandy Alicia Kirk <brandy.kirk@valpo.edu> wrote:
> >
> > To whom it may concern,
> >
> > I am doing a doctoral project for my nurse practitioner program at Valparaiso University in Valparaiso, IN USA. I am providing patients undergoing breast biopsies with 5 minutes of guided imagery and then subsequently comparing their pain ratings to patients who did not receive guided imagery.
> > I wanted to mention which application that I used in my project. May I do this if I put the copyright date next to the title?
> >
> > Thank you,
> > Brandy A. Kirk BSN, RN
> >
> > Sent from Mail for Windows 10

APPENDIX B

Educational Pamphlet Text

Guided Imagery Study

[redacted] with a graduate student enrolled in Valparaiso University College of Nursing and Health Professions are conducting a study to enhance and improve breast cancer patient outcomes based on evidence-based standards in adherence with the National Accreditation Program for Breast Centers objectives. The purpose of the study is to provide a holistic therapy to use in addition to the current standards of care to help you through your breast cancer journey. This specific part of the study is aimed at reducing possible anxiety and pain that may be experienced during your sentinel lymph node (SNL) injection procedure. Our combined goal is to provide you with a better experience. Prior to your SNL injection, that takes place in the nuclear medicine department, the study leader will provide you with an opportunity to relax and listen to a guided imagery instructional for five minutes prior to your procedure with Dr. [redacted]. We will be asking you to rate your pain before and after the procedure. Prior to the procedural date, you will receive a phone call from the study leader Brandy Kirk BSN, RN, a doctoral student from Valparaiso University to answer questions and further explain the study details, should you decide to participate. The practice of guided imagery has many positive benefits, and we hope that, it can provide you with some comfort and relief both before and beyond the date of your procedures.

What is guided imagery?

Guided imagery is a powerful and simple relaxation technique that directs your imagination to a place of peace and comfort to reduce anxiety, increase wellbeing, ease pain, and promote healing. The process involves listening to a speaker, often with sounds or music in the background, who prompts you, step by step, to imagine that you are in a beautiful and peaceful location. Your mind is kept busy imagining the warmth of the sun on your skin, the breeze blowing through the trees, and or the delights and sensations of the environment that you are

concentrating on. It is an easy exercise that anyone can practice, anywhere. You just need a few minutes in quiet place to listen to the speaker and your mind will do the rest.

How does guided imagery work?

The words and images that you are listening to and thinking about direct your brain away from pain, stress and worry and focus your thoughts on healing and comfort through the power of your mind. You can practice this exercise for as few as five minutes or up to 20 minutes. You can try it at night before you go to sleep or whenever is convenient for you. However, you are not obligated to use the meditations to be included within the study.

What are the benefits of guided imagery?

Guided imagery promotes a state of relaxation and calm through the mind-body connection. Evidence from scientific studies has found that this mind-body connection can have beneficial effects on mental wellbeing, promotion of healing, perceptions of pain, heart rate, blood pressure and breathing patterns (Carlson et al., 2017). In fact, Guided imagery is recommended by the National Comprehensive Cancer Network (NCCN) to aid in reducing nausea and vomiting (NCCN, 2016).

How can I use guided imagery?

There are many apps, videos, and CDs that provide access to guided imagery techniques. One option called *5 Minute Escapes: Meditations* is an application created by Olsen Applications Ltd., version 1.4.1, last updated June 2020, which can be downloaded on your tablet, personal computer or smart phone. This application provides three **free** guided imagery exercises each lasting around five minutes. It is available on Android, IOS (Apple) or Google Play. The free exercises are available under the Tropical Island, Japanese Garden or Private Yacht options. If you would like full access to all available exercises the cost is currently $7.99, which would be a personal responsibility and not provided by [redacted]. The full access version allows you to listen for longer sessions and access some of the other backgrounds but is not required. Personal data usage charges for streaming would also apply if not connected to Wi-Fi.

The next option that is also free and easy to use would be locating guided imagery videos on YouTube. We recommend the *5 MINUTE Calming Meditation (With Guiding Voice) - 2017 Updated Version* , produced by The Honest Guys. You can just type in "5-minute calming meditation with guiding voice." There are several available exercises with different time frames, designed by these creators. So, if you like, you can explore other choices they offer. Regardless, of which way you choose to access guided imagery instructions, if you find them enjoyable, we would like you to try to participate three times per week at your convenience.

Useful websites to learn more:

https://ww5.komen.org/BreastCancer/Guided-Imagery.html

https://www.allinahealth.org/healthysetgo/thrive/the-health-benefits-of-guided-imagery