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Implementation of aromatherapy, a non-pharmacological intervention, to reduce anxiety during
the preoperative period

Amanda J. Honig, Mia G. Galassi, & Olufemi O. Ogungbe

Uniformed Services University

Daniel K. Inouye Graduate School of Nursing

Naval Medical Center San Diego

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LT Amanda J. Honig

Daniel K. Inouye Graduate School of Nursing
Uniformed Services University



LT Mia G. Galassi

Daniel K. Inouye Graduate School of Nursing
Uniformed Services University



LCDR Olufemi O. Ogungbe

Daniel K. Inouye Graduate School of Nursing
Uniformed Services University

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Abstract

Phase II Site: Naval Medical Center San Diego

Project Title: Implementation of aromatherapy, a non-pharmacological intervention, to reduce anxiety during the preoperative period.

Authors: Honig, A. J., Galassi, M. G., & Ogungbe, O. O.

Background or Problem/Issue: Anxiety experienced during the preoperative period can lead to increases in pain, nausea, and length of stay, ultimately decreasing patient satisfaction and increasing cost. Currently, NMCS D lacks a non-pharmacological intervention or process to help reduce preoperative anxiety. There is often a significant amount of waiting prior to surgery that could be optimized by implementing a non-pharmacological measure (aromatherapy via “STILL” soothing scents) to potentially reduce anxiety in patients preoperatively.

Clinical Question or Purpose: Does the implementation of aromatherapy before surgery reduce preoperative anxiety in adult surgical patients undergoing elective surgery?

Project Design: This evidence-based project was a quality improvement initiative that utilized pre- and post-state anxiety evaluations to determine the effect of aromatherapy on preoperative anxiety among adults undergoing elective surgery.

Analysis of the Results: Pre- and post-aromatherapy State Trait Anxiety Inventory for Adults (STAIAD) Short Form Y-1 questionnaires indicated that exposure to aromatherapy significantly reduced preoperative anxiety. Participants above the median age exhibited the most profound decrease in anxiety regardless of gender. Qualitative survey responses indicated that 96% of patients would use preoperative aromatherapy in the future and 91% experienced increased satisfaction with their perioperative care.

Organizational Impact/Implications for Practice: Heightened physiological response to increased anxiety leads to increased perioperative nausea and vomiting, higher pain scores, and susceptibility to prolonged recovery from surgery. Implementing aromatherapy can reduce anxiety, thereby attenuating these complications and preventing additional accrued cost. Furthermore, this evidence-based project has the added benefit of increasing overall patient satisfaction of the perioperative process.

Introduction

Worldwide, 54-98% of adults experience increased anxiety and stress preoperatively (Jaruzel, Gregoski, Mueller, Faircloth, & Kelechi, 2018; Ni et al., 2013). An increased state of anxiety preoperatively, or a hyperarousal state, amplifies both psychologic and physiologic responses. Psychological response can amplify underlying conditions, such as post-traumatic stress disorder, thereby potentiating a higher degree of emergence delirium postoperatively (Bopp, Spence, & Burkard, 2013). Moreover, the heightened stress response results in adverse physiologic responses such as increased incidence of postoperative nausea and vomiting, increased pain sensitivity, increased anesthetic requirement, unwanted hemodynamic responses, and an overall increase in perioperative morbidity (Bopp et al., 2013). These adverse effects result in untoward patient outcomes, prolonged hospitalization, and an increase in medical costs (Jaruzel et al., 2018). As a solution, evidence-based nonpharmacological interventions support implementation for aromatherapy to reduce preoperative anxiety and subsequently optimizing patient outcomes and medical costs (Wotman et al., 2017).

Significance of the Problem

Given the direct correlation of patient outcomes on the military's mission readiness, controlling preoperative anxiety is a priority (The Defense Health Agency [DHA], 2017). Currently, Naval Medical Center San Diego (NMCSD) has pharmacological interventions to mitigate preoperative anxiety. Although pharmacological treatments are effective, they carry side effects of central nervous system depression that may be intolerable for some patients and can interfere with the informed consent process (Wotman et al., 2017). Therefore, midazolam is routinely reserved for administration immediately prior to transport to the operating room once an anesthesia provider assumes vigilant care. To address the remaining preoperative wait period,

nonpharmacological therapies offer a safe alternative intervention that is capable of reducing preoperative anxiety and anesthetic requirements, improving patient outcomes, and ultimately decreasing medical costs (Wotman et al., 2017). One alternative nonpharmacologic therapy gaining popularity and supported by evidence to decrease anxiety is aromatherapy (Braden, Reichow, & Halm, 2009; Ni et al., 2013).

Relevance to Military Nursing

The military must maintain a deployable-ready force. According to the Department of Defense (DoD), a ready medical force is defined as having the medical capability to support deployed operations and a medically ready force is defined as a military force that is medically fit to deploy (The Defense Health Agency [DHA], 2017). This nonnegotiable status demands that the Military Health System (MHS) adopt traits of a high-reliability organization (HRO). This involves an astute preoccupation with failure and commitment to transparency in order to proactively optimize patient outcomes and readiness through value-based metrics (Wadsen, 2017). Thus, the Quadruple Aim Performance Process was established to provide a strategic framework geared towards an integrated system of readiness and health (DHA, 2017). To accomplish this mission, the MHS must anticipate the unique needs of service members and their families in addition to supporting healthcare providers delivering individualized care. A critical review of the current perioperative process reveals that greater than 50% of beneficiaries experience increased anxiety during the preoperative time frame (Bopp, Spence, & Burkard, 2013). A heightened stress response leads to increased adverse effects and delayed recovery, both of which negatively impact the patient and the provider. The opportunity exists to transform the preoperative wait period through the use of the evidence-based approach of aromatherapy, which targets the olfactory nerve and limbic system to reduce anxiety (Wotman et al., 2017).

Reducing anxiety and any of its other untoward complications could positively influence readiness.

System or Clinical Question

Does the implementation of aromatherapy reduce preoperative anxiety in adult patients undergoing elective surgery?

Literature Review of Solutions

To explore the clinical application of aromatherapy, a PICOT question was developed to guide the literature search for the benefits of aromatherapy on preoperative anxiety: Does the implementation of aromatherapy before surgery reduce preoperative anxiety in adult patients undergoing elective surgery?

The following databases were used to search the literature: PubMed, Embase, and CINAHL. The keywords utilized included aromatherapy, essential oils, essential oil, lavender, bergamot, citrus, anxiety, stress, and preoperative. Lavender, bergamot, and citrus were explicitly used in the key terms because their chemical components are capable of anxiolysis. However, to ensure the research would guide the evidence-based solution, all essential oils were included in the search and reviewed to guarantee inclusion of a wide range of articles yielding the best evidence. Limits were placed for non-English articles and narrative review. Due to lack of literature for pediatrics and desire for inhaled aromatherapy intervention by itself, exclusion criteria included pediatrics and studies utilizing multiple nonpharmacological interventions.

The above parameters yielded fifty-eight articles. Twenty-five were duplicates, leaving thirty-three for further evaluation. Another twenty-one were excluded due to: having a non-specific preoperative timeframe (5), being informational or nonexperimental papers (5), using aromatherapy in conjunction with other therapies (4), replacing preoperative medications (2),

including surgical procedures outside NMCSO scope (1), and due to lack of access to the full-text available even after interlibrary loan request (4). A full-text review was completed in which another five articles were eliminated. They were excluded due to: use of chemical components not included in the proposed aromatherapy clip to be trialed at NMCSO (2), observational or pilot study design (2), and incorporation of multiple complementary alternative medicine (CAM) therapies (1). At the conclusion of our search, a PRISMA Flow Chart (Figure 1) was developed to depict the phases of our literature review. After screening and review, seven studies remained for critical appraisal (Figure 2) using the John Hopkins Nursing Evidence-Based Practice (JHNEBP) Evidence Grading Tool. Each article was appraised by all team members. Any conflicts among raters were resolved by discussion. The appraisal process led to the following categorization of the seven reviewed articles: three Level I randomized control trials of grade B quality, one Level I prospective experimental pretest posttest design study, two Level II quasi-experimental studies of grade B quality, and one Level II prospective controlled pilot study of grade B quality.

The literature on inhalational aromatherapy illustrated multifactorial benefits on preoperative anxiety seeded in physiologic effects, high therapeutic index, ease of implementation, and low cost.

Specific physiologic benefits stem from the chemical components of aromatherapy, such as linalool and linalyl acetate, which produce a sedating effect. Immediately on inhalation, these molecules activate the olfactory nerve leading to depolarization of the lateral olfactory striae projecting to the amygdala. Within the limbic system, the subsequent release of neurotransmitters norepinephrine, serotonin, and dopamine modulate the emotional, behavioral, and memory response (Fayazi, Babashahi, & Rezaei, 2011). Ultimately, an increased gaba-

aminobutyric acid (GABA) effect in the limbic system is responsible for the sedating quality and anxiety reduction (Wotman et al., 2017). One study found that even without an intact olfactory sense, patients still reaped the therapeutic physiologic benefits (Braden, Reichow, & Halm, 2009). The literature did not clarify if anatomical or mechanical obstruction of the nares hindered the effectiveness of aromatherapy, however, we made the executive decision to exclude patients with known nasal obstruction to minimize confounding variables.

Despite slight variations in aromatherapy oil used, study design and population of interest between the seven articles reviewed, all had a similar purpose of evaluating inhaled aromatherapy's ability to reduce anxiety preoperatively. Specific aromatherapy components used among the articles were lavender, bergamot, citrus, or a combination of these oils, which became relevant when evaluating which aromatherapy scents to implement at NMCSD. Variations in aromatherapy exposure time frame fluctuated throughout each article ranging from five minutes to at least thirty minutes of inhalation exposure. The State Trait Anxiety Inventory for Adults (STAIAD), a 4-point Likert scale, was the evaluation tool consistently used as a pre-test, post-test measurement of anxiety level. A change in state anxiety score by 5 was used as the magnitude of difference, or effect size, to determine statistically and clinically significant results in each study. Appropriate statistical analysis was performed in each article and results consistently yielded a statistically significant decrease in state anxiety scores after aromatherapy exposure regardless of exposure time, surgical procedure, or gender. Aromatherapy exposure time frames varied from five minutes to greater than thirty minutes prior to surgery, however, each study consistently obtained a baseline STAIAD questionnaire prior to exposure followed by a post-exposure STAIAD questionnaire. The differences in exposure time did not cause fluctuation in results - statistically significant reductions in STAIAD scores were obtained

regardless of the time interval between pre-test, post-test STAIAD questionnaires. Therefore, our project plan was guided by two phases as opposed to specific, rigid time frames that would place unnecessary restriction on the aromatherapy exposure interval. Results regarding vital signs were not conclusive or specific enough to measure a true change in anxiety level. Based on these collective findings, the literature supported our decision to use an aromatherapy adjunct comprised of lavender, bergamot, and citrus in the preoperative setting and illustrated the validity and reliability of the STAIAD Short Form Y-1 questionnaire in detecting changes in preoperative anxiety after aromatherapy exposure.

In addition to the physiologic effectiveness of aromatherapy, it is also safe, patient-centered, and fiscally sound. From a sustainability standpoint, these three factors are critical for acceptance from the patients receiving the aromatherapy, the staff implementing the intervention, and the administrators providing financial support. The product that will be implemented consists of an individualized, clip-on diffuser that is less than seven dollars per clip, contains three evidence-based scents, lasts three weeks, and does not require a provider-driven order set for implementation (“Soothing Scents,” 2019). Lavender, bergamot, and citrus are included in this diffuser clip and each was substantiated as an effective anxiolytic in our literature review. Aromatherapy delivered through this standardized diffuser clip was attached to the side of each patient’s face mask by the Doctor of Nursing Practice (DNP) student which increased the internal validity of our DNP project. While the intent was to focus on anxiety reduction preoperatively, this solution had the potential to improve patient satisfaction and promote a positive perioperative patient experience as a whole. Therefore, in addition to the quantitative data collected via the STAIAD Short Form Y-1, the team collected qualitative data by adding two subjective survey questions during the post-exposure phase: (1) In the future, would the

participant use aromatherapy during the preoperative period, and, (2) Did the use of preoperative aromatherapy improve the patient's satisfaction with their surgical experience?

Focus Areas

This project had four focus areas. First, multiple literature searches were performed to identify aromatherapy as the non-pharmacological intervention that reduced preoperative anxiety, required the least amount of staff burden, and demonstrated efficacy despite sensory deficits. Second, adult ambulatory elective surgery patients were identified during their surgical check-in to complete an initial STAIAD Short Form Y-1 questionnaire to establish their baseline state anxiety prior to their procedure. Third, the patient was provided an aromatherapy clip, educated on the clip function, and a STAIAD Short Form Y-1 questionnaire was handed to the participant to fill out, in the preoperative holding area before any anxiolytic intervention was performed. Lastly, we will publish this manuscript, after we have disseminated the results to the stakeholders.

Organizing Framework

Evidence-based practice (EBP) is the conscientious use of current best evidence in making decisions about patient care (Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000). Our team used the Iowa model (Figure 3) to guide the systematic implementation of the best evidence based clinical practice to promote quality care. The Iowa Model provided a framework to ensure the safe implementation of aromatherapy to elective surgical patients in order to decrease preoperative anxiety. The Iowa model focuses on identifying problem triggers, evaluating the literature for evidence-based solutions, and translating evidence into clinical practice (Titler et al, 2001). There are seven steps to utilizing the Iowa model: (1) topic selection,

(2) team formation, (3) evidence retrieval, (4) grading evidence (5) developing an EBP standard, (6) implementing EBP, and (7) evaluation (Doody & Doody, 2011).

Project Design

General Approach

This evidence-based project was a quality improvement initiative that utilized pre- and post-state anxiety evaluations to determine the effect of aromatherapy on preoperative anxiety among adults undergoing elective surgery. We provided each elective surgery adult patient with an aromatherapy clip to inhale throughout their preoperative journey. Pediatric patients were excluded due to a lack of literature evaluating the effect of aromatherapy in this population. Patients with evidence of nasal obstruction were also excluded to eliminate potential confounding variables that may interfere with aromatherapy's effect on anxiety. Each patient completed a STAIAD Short Form Y-1 questionnaire as a means of determining pre- and post-implementation state anxiety. Sustainability of aromatherapy is supported by the results of this DNP project, which have been disseminated via multiple platforms to key stakeholders to determine adoption into practice.

Setting and Population

NMCSD is a 272-bed multi-specialty hospital and ambulatory complex that offers general medical and surgical treatments (18 operating rooms) in both the inpatient and outpatient settings to approximately 250,000 eligible for care (Navy Medical Center San Diego [NMCSD], 2018). Daily operations include 4,000 outpatient Medical/Dental visits, 50 operating room cases, 170 emergency department visits, 10 babies delivered, and 45 new patients admitted. Located in San Diego, California, it is staffed with approximately 6,500 personnel (approximately 1,200 Officers, 2,000 Enlisted, 2,100 Civilian Government Service, and 300 civilian contractors).

NMCSD is part of a regional military health care system that includes seven branch clinics as part of the TRICARE West region (NMCSD, 2018). Additional resources and services available at NMCSD are emergency, family practice medicine, dental clinic, intensive care, and pharmacy. This program provided preoperative aromatherapy to the adult patient population scheduled for elective surgery.

Procedural Steps

Topic selection and team formation. Following in line with the IOWA model, our team identified that NMCSD lacked a non-pharmacological approach to mitigating preoperative anxiety in adult surgical patients. Additionally, the preoperative wait period provided an opportunity for implementation of an autonomous anxiolytic intervention that the patient or bedside staff could initiate without interfering with workflow or disrupting the consent process. Identifying a problem with a subsequent opportunity to improve patient experience without additional demand on the staff provided the foundation for our team to initiate a literature review for solutions.

Evidence retrieval and grading. As detailed in the literature review for solutions, our team perused multiple reputable databases for evidence-based literature on aromatherapy as a non-pharmacological approach to reduce preoperative anxiety. After application of inclusion and exclusion criteria, our team critically appraised the strength of the evidence using the JHNEBP Evidence Rating Scale in addition to summarizing appraisal findings in an evidence table (Figure 2). Seven peer reviewed, evidence-based articles were included in our final review. These articles from the literature review provided sufficient evidence to support the use of aromatherapy to decrease preoperative anxiety.

Development, implementation, and evaluation of evidence-based practice standard.

In order to initiate and evaluate the efficacy of aromatherapy in preoperative anxiety reduction, our team of three Student Registered Nurse Anesthetists (SRNAs) headed three milestones: (a) procurement of the aromatherapy clip and copyright permissions for the use of the STAIAD Short Form Y-1 questionnaire, (b) administration of the aromatherapy clip with the pre- and post-STAIAD Short Form Y-1 questionnaires, and (c) analysis and dissemination of the data collected to support adoption in practice.

Procurement of aromatherapy and copyright permissions for STAIAD Short Form Y-1 questionnaire. To ensure standardization of the aromatherapy program, we identified a company, Soothing Scents, that offered to provide our patient population of interest with compact aromatherapy diffuser clips comprised of three evidence-based components - lavender, bergamot, and citrus ("Soothing Scents," 2019). Based on the literature, power analysis yielding a sample size of ninety patients with an alpha level of 0.05 and a beta level of 0.2 was sufficient to determine statistical significance of our results utilizing paired t-test (Eslami, Ebrahimi, Hosseinkhani, Khazaei, & Darvishi, 2018; Genc & Saritas, 2019). Therefore, this initial offering provided our team the means to deliver aromatherapy to a sufficient sample size to determine significance and aided in our recommendation for sustainment of aromatherapy within our department. Acquiring the STAIAD Short Form Y-1 questionnaire required a financial commitment to obtain copyright allowance from Mind Garden, Inc. - therefore, our team sought out funding through the TriService Nursing Research Program (TSNRP) and obtained IRB approval through Naval Medical Center San Diego. Due to copyright constraints, Mind Garden, Inc. explicitly states that the entire instrument cannot be included into any publication or

appendices; only four sample items specified by Mind Garden may be included to satisfy the requirements of an academic committee (Figure 4).

Administration of aromatherapy with pre and post STAI Form Y-1 questionnaire. Our team developed a procedural timeline for implementation which comprised of two key phases: (P1) check-in at the ambulatory surgical desk and (P2) arrival in the preoperative holding area prior to administration of midazolam. During phase one (P1), the patient checked into the ambulatory surgical check-in desk. Here, one of our team members assigned each individual a project code number to exclude personal identifiable information and administer the first STAIAD Short Form Y-1 questionnaire to obtain a baseline state anxiety assessment. After completion, the patient received the aromatherapy clip and was provided with a standardized instructions for use. Phase two (P2) began upon arrival to the preoperative holding area. At that time, a DNP project member asked the patient to fill out the second STAIAD Short Form Y-1 questionnaire in addition to the two qualitative survey questions prior to receiving midazolam and being transported into the operating room. This allowed for quantitative and qualitative evaluation of the effects of aromatherapy. The team member collected all the questionnaires for data analysis and the patient was allowed to keep the aromatherapy clip.

Analysis and dissemination of findings. The plan for data analysis, execution of data analysis, and dissemination of findings are detailed under their respective headings.

Data Analysis Plan

After synthesis and critical appraisal of the seven articles, a data analysis plan was developed to mirror the methods in which the literature successfully measured a reduction in

anxiety. This plan was shared with the statistician at NMCSO who assisted in executing the appropriate statistical tests to analyze the results. Data collection occurred over a three-month time frame from April 2020 to June 2020.

The independent variable, aromatherapy, served as a nominal level process measurement in which the aromatherapy clip was provided to adult patients upon check-in at the ambulatory surgery front desk. The dependent variable, state anxiety level, was the outcome measurement which was determined with the STAIAD Short Form Y-1 questionnaire. The STAIAD Short Form Y-1 questionnaire, or state anxiety scale, is a self-rated, 4-point Likert scale that assesses the presence and severity of state anxiety in ten questions. State anxiety refers to current symptoms of anxiety related to the present situation to evaluate how respondents feel “right now, at this moment” (Spielberger, 2015). Capturing state anxiety as opposed to trait anxiety is key to ensure appropriate measurement of situational anxiety. Trait anxiety is predominately part of the patient’s psyche and therefore not the data point of interest for our project. For this reason, our team intentionally utilized TSNRP funding to obtain the right to use the STAIAD Short Form Y-1 that is specific to state anxiety. The state anxiety scale has been more extensively used in psychological research than any other anxiety measure over the past two decades, with a median reliability coefficient of 0.92 (Spielberger, 2015). The sensitivity and validity of the state anxiety scale to environmental stress has been repeatedly demonstrated in research on emotional reactions to surgery (Chapman & Cox, 1977; Jelicic & Bonke, 1991). This interval level scale ranges quantitative values from twenty to eighty, where a score of twenty represents low state anxiety and eighty represents high state anxiety. Quantitative data allowed for the use of parametric statistics due to the normal distribution of the data. Therefore, a paired t-test was used to compare mean state anxiety scores before (P1) and after use of the aromatherapy clip (P2).

Based on the literature, a mean reduction in the patient's state anxiety score by five points supported sustainment of this intervention at NMCSO (Eslami et al., 2018; Fayazi, Babashahi, & Rezaei, 2011; Genc & Saritas, 2019).

Lastly, the data analysis plan included nonparametric one sample proportion testing to address qualitative data collected via nominal variables of "yes" or "no" to two subjective questions regarding future use of aromatherapy and patient satisfaction.

Potential Barriers

Potential barriers to the implementation of this EBP initiative included potential dissatisfaction of stakeholders, inability to sustain financial support, and the unpredictable onset of coronavirus (COVID-19). Stakeholders include the patients, preoperative staff, and facility leadership. There was potential for all three parties to perceive our intervention as an interruption of the preoperative workflow routine. To mitigate this barrier, we identified key leadership stakeholders - the Perioperative Department Head, the Anesthesia Department Head, and the Commanding Officer, and scheduled a formal meeting with each to present our EBP project aim. We requested and confirmed support and addressed any concerns or questions. To ensure efficiency and prevent disruption of workflow, our team of three SRNAs maintained responsibility for the administration and data collection throughout the project implementation to eliminate additional demand on the staff.

While this DNP project acquired enough aromatherapy clips for successful initiation for our desired sample size, there remained a concern of how to achieve financial support for sustainability of aromatherapy. The project results, detailed under their respective heading, support the use of aromatherapy to reduce preoperative anxiety. The literature illustrates that reduced preoperative anxiety can reduce subsequent complications of nausea and vomiting, pain,

and prolonged length of stay (Braden, Reichow, & Halm, 2009; Jaruzel et al., 2018). Therefore, our DNP project carries potential to assist with reduction in these postoperative complications. To initiate an informed decision process, our business case analysis was shared with key leadership stakeholders to illustrate the cost-benefit in reducing preoperative anxiety and the associated reduction in postoperative nausea and vomiting, pain, and length of stay. Therefore, the decision to sustain aromatherapy will be based on the Perioperative Department's ability to include aromatherapy in the budget.

Lastly, with COVID-19 came enhanced safety precautions including mandatory mask wearing for all preoperative patients. A return to the literature assisted in adaptation of the project execution by determining how various medical-grade masks effected aromatherapy delivery. Comparison of manufacturer standards for the medical-grade masks used by patients at NMCS D revealed a submicron particle filtration efficiency of 95% against 0.1 to 0.3 micron particles (Food and Drug Administration, 2020). The aromatherapy diffuser particles are 1 to 3 microns in size, which presented a barrier to the initial plan to clip the individual diffuser to each patient's gown ("Soothing Scents," 2019). Soothing Scents, the aromatherapy supplier, had advertised clipping the diffuser to a patient's nasal cannula. This approximated the same exposure distance as experienced with the diffuser clipped to a patient's mask, facing inward. Therefore, after confirmation of safety with Soothing Scents, the decision was made to standardize placement of each patient's aromatherapy diffuser to their respective face mask to ensure adequate exposure.

HIPAA Concerns and Ethical Considerations

Health Insurance Portability and Accountability Act (HIPAA) concerns regarding the implementation of this project were mitigated by not collecting any Personally Identifiable

Information (PII). Due to the collection of pre- and post-aromatherapy exposure questionnaires for each participant, a project code number was assigned to each individual to track the two state anxiety scores. Only gender, surgical procedure, and age of each participant with respective results was recorded. All project information was stored on a restricted password-protected common access card (CAC) share-drive allowing only EBP team member access. Our team consulted with the research cell at NMCS D regarding Privacy Board Review and filed all appropriate documentation for approval per NMCS D policies.

Project Results

The initial sample size included 100 patients ages 18 to 87 who were provided the STAIAD Short Form Y-1 questionnaire before and after exposure to aromatherapy. Each patient was asked two additional qualitative questions, inquiring if they would use aromatherapy preoperatively in the future and if the use of aromatherapy increased their satisfaction with their perioperative experience. The project team omitted one participant's responses due to a failure to complete all portions of the questionnaire, leaving a final sample size of 99 subjects.

Quantitative data collected included raw scores of each individual's pre- and post-state anxiety answers derived from the STAIAD Short Form Y-1 questionnaire. These raw scores were interpreted utilizing their corresponding scoring key within the STAI Manual to correlate with a final score ranging from twenty to eighty; the higher the final score, the higher the level of anxiety. To compare pre- and post-state responses, paired t-tests were utilized. There was a statistically and clinically significant difference in state anxiety score after aromatherapy exposure, with a mean state change of 17.42 points ($p < 0.001$). This exceeded the effect size benchmark derived from the evidence, which defined a significant change in state score as 5 points.

To explore the relationship between mean state change and age or gender, independent sample t-tests were also implemented. Although this step was not detailed in the data analysis plan, this post-hoc decision was deemed necessary to determine if any specific demographic influenced the overall findings. It was determined that while the mean state change was statistically significant across all ages, it did differ by age subgroup. The breakdown of participants in the various age groups were as follows: Ages 18-30 consisted of 36 participants, 31-45 age group had a total of 29 participants, and lastly, the 45 and older category included 35 participants. The age subgroups less than the median (ages 18-37) were more likely to have state changes below the median, whereas the age subgroup above the median (ages 37-87) were more likely to have state changes above the median. In regard to gender, there was a total of 49 females and 51 males who participated, however there was no difference in mean state changes between males and females.

Qualitative data was collected from binary “yes” or “no” responses to two subjective questions. A one sample proportion test revealed that 96% of patients, regardless of age, would use aromatherapy again in the preoperative setting to relieve anxiety. Additionally, 91% of patients, regardless of age, reported increased satisfaction with their perioperative experience after aromatherapy exposure. Those whose state change was below the median were more likely to report that aromatherapy did not increase their satisfaction.

Analysis of the Results

Based on the results from various statistical analyses, we concluded that preoperative aromatherapy is a valuable non-pharmacological adjunct to offer adult surgical patients. This finding is on par with the results currently published in the literature. Our results provided insight

into which specific demographic may benefit the most which directly benefits the end user and elaborates on the findings available in the literature.

Current research has produced results confirming that aromatherapy benefits users regardless of gender, however, there has been a lack of attention paid to the potential for variation in benefit amongst different ages. Our data illustrates that regardless of gender, older patients experienced a more profound reduction in anxiety after aromatherapy exposure. This offers clinicians reassurance that aromatherapy may provide the greatest benefit to a population that is vulnerable to side effects of pharmacological agents.

Overall, the majority of patients reported an increased satisfaction in their perioperative experience and were interested in using aromatherapy in the future. The few that did not experience increased satisfaction also exhibited mean state change below the median, suggesting that patients with less situational anxiety may not find value added by being offered adjuncts for anxiety management.

Organizational Impact and Implications to Practice and Policy

Current literature in conjunction with the above findings support the recommendation that NMCS D implement aromatherapy for adult elective surgical patients during the preoperative phase. The positive impact on the organization involves participation in high reliability organizational aims, recapturing out of network beneficiaries, and patient-centered care without additional staff burden. All of these implications result in fiscal benefit for the organization and streamline efforts to improve patient outcomes and satisfaction without sacrificing the resiliency of the workforce.

Aromatherapy aligns with high reliability organization goals and the 2017 National Defense Authorization Act. High reliability organizations use quantitative metrics to anticipate

areas for improvement and deliver valued-based care aimed at zero preventable complications (Wasden, 2017). Our project results provide quantitative and qualitative measures to support the implementation of aromatherapy to reduce preoperative anxiety, which is complicit in the development of preventable complications.

By potentially reducing preventable complications, the overall cost of an individual's surgery and recovery period is reduced by half (Ellison, 2019; Healy, Mullard, & Campbell, 2016). Aromatherapy's ability to decrease preoperative anxiety may facilitate reduction of postoperative nausea and vomiting, pain, and overall costs associated with adverse responses (Spackman et al., 2014). An average between 54-98% ambulatory surgical patients experience preoperative anxiety (Chapman & Cox, 1977; Jaruzel et al., 2018). To exemplify this impact, this equates to 11,100 patients at NMCS D who could benefit from preoperative aromatherapy. The average cost of an inpatient hospital stay in a United States government hospital is approximately two thousand dollars per day (Doyle, Lennox, & Bell, 2013; Ellison, 2019). If merely half of these patients subsequently experienced decreased care requirements related to antiemetics, analgesics, and prolonged hospital stays, this would equate to an annual net savings of ten million dollars (Kellermann, 2017; Wasden, 2017).

Proactive prevention that is cost-conscious not only enhances profit margin by 5.8% – it improves the outcomes and experience for TRICARE beneficiaries (Healy & Mullard, 2016). Standardizing a genuine, comfortable atmosphere for our service members and their families increases the likelihood that they will desire to stay within the MHS for procedures, thereby limiting out of network costs. Increasing patient satisfaction has been shown to keep patients in the network and reduce out of network cost (Doyle, Lennox, & Bell, 2013; Kellermann, 2017). Estimated out of network costs are five thousand dollars per patient. If 50% of

beneficiaries seek surgical treatment out of network, that equates to a total fiscal deficit of twenty-five million dollars annually. With the use of aromatherapy, we have the opportunity to re-capture these patients by increasing patient satisfaction and preventing unnecessary out of network costs.

A critical aspect of sustainability is not merely proving that an intervention benefits the patient - the workforce delivering the intervention must buy-in as well as the executives providing the financial support. Aromatherapy implementation does not increase staff burden and remains a cost-effective intervention in comparison to other non-pharmacological options because it does not require extensive training or axillary equipment beyond the individual, single use diffuser. Due to the fact that the diffuser lasts an additional three weeks, the cost per day is valued at twenty-one cents ("Soothing Scents," 2019). The patient is afforded a sense of control during a phase of unfamiliarity and vulnerability while the workforce is empowered by providing autonomous, value-added interventions.

Future Directions for Research and Practice

Future directions for research and practice includes dissemination of these outcomes locally at NMCS D to include key stakeholders. This presentation will illustrate the benefits aromatherapy will provide to beneficiaries and discuss implementing a permanent aromatherapy program at NMCS D. The major barrier for sustainment of this program is cost. It would be a new program that has not been accounted for in the hospital's fiscal budget, and therefore would require approval from leadership, which is a lengthy process. We have therefore appointed an aromatherapy champion who is well versed in the project and is committed to advocate for the project implementation for the next four years. Due to the high therapeutic index and autonomous nature of aromatherapy implementation, there is potential for expanding

aromatherapy availability to other areas of inpatient and outpatient care as a holistic approach to anxiolysis.

To help gain support and traction for the program we will further present our findings as an oral presentation at the Uniformed Services University (USU) and as a poster presentation at the USU Research Week. Lastly, we will be presenting at the 2021 annual American Association of Nurse Anesthetists (AANA) conference and attempt to publish our EBP results in a reputable, peer-reviewed journal.

Conclusion

This project's principal focus was to illustrate the effect of aromatherapy as a non-pharmacological intervention to reduce anxiety in the preoperative period of surgery. A statistically significant decrease in anxiety among the participants was reported with the use of aromatherapy along with an increase in their satisfaction with the perioperative process. These findings are congruous with currently published literature. Coupled with the cost benefits detailed in this manuscript, we confidently recommend NMCS implement aromatherapy to adult elective surgical patients during the preoperative phase.

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Appendices

Appendix A: CITI Certifications



Completion Date 28-Aug-2018
Expiration Date 27-Aug-2021
Record ID 28310739

This is to certify that:

amanda honig

Has completed the following CITI Program course:

OU5D P&R Human Research (Curriculum Group)
Biomedical Investigators and Research Study Team (Course Learner Group)
1 - Biomedical Investigators (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w08673382-c520-461e-b417-369a81be9b37-28310739



Completion Date 25-Aug-2018
Expiration Date 24-Aug-2021
Record ID 28287084

This is to certify that:

Mia Galassi

Has completed the following CITI Program course:

OU5D P&R Human Research (Curriculum Group)
Biomedical Investigators and Research Study Team (Course Learner Group)
1 - Biomedical Investigators (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w917ccf16-1eef-461f-a0a8-707e2df42f73-28287084



Completion Date 24-Aug-2018
Expiration Date 23-Aug-2021
Record ID 28297621

This is to certify that:

Olufemi Ogungbe

Has completed the following CITI Program course:

OU5D P&R Human Research (Curriculum Group)
Biomedical Investigators and Research Study Team (Course Learner Group)
1 - Biomedical Investigators (Stage)

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w9826382e-a228-4a01-8031-cd867c543b54-28297621

Appendix B: USU Form 3202N**OFFICE OF RESEARCH**

4301 JONES BRIDGE ROAD

BETHESDA, MARYLAND 20814

PHONE: (301) 295-3303; FAX: (301) 295-6771

NOTICE OF PROJECT APPROVAL

Change Number: Original

VPR Site Number: GSN-61-11154
Principal Investigator: Galassi, Mia
Department: Graduate School of Nursing
Project Type: Student
Project Title: Implementation of aromatherapy, a non-pharmacological intervention, to reduce anxiety during the preoperative period at Naval Medical Center San Diego
Project Period: 3/16/2020 to 3/16/2021

Assurance and Progress Report Information:

<u>Name</u>	<u>Sup</u>	<u>Approval Type</u>	<u>Status</u>	<u>Approved On</u>	<u>Forms Received</u>
Progress Report	0			To be Submitted	N/A

Remarks:

This Notice Of Project Approval has been reviewed and approved. Please remember that you must submit a final Progress Report (Form 3210) upon completion of this project.

Questions regarding this approval should be directed to the following person in the Office of Research:
Sharon McIver, (301) 295-9814.



Toya V. Randolph, Ph.D., MSPH Date
Acting Vice President for Research
Uniformed Services University of the Health Sciences

cc: File
Radford, Kennett
Taylor, Laura

Appendix C: MTF IR/PI Letter of Determination**CID DETERMINATION****(CID USE ONLY)**

More information is required to complete review, specifically:

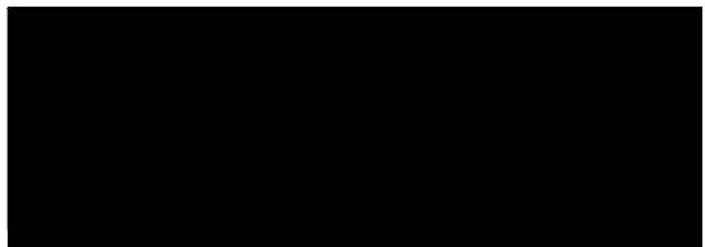
☒ **This is a Performance Improvement/ EBP/ Quality Assurance project.**

NOTES:

☐ **This appears to be a human subject research project and warrants full submission to the IRB**

NOTES:

Reviewer Signature and
Date:



Appendix D: PAO Clearance

BUMEDINST 5721.3D

NAVY MEDICINE CLEARANCE OF AUTHORED WORKS FORM						
DATE FORM COMPLETED: 1/26/2021						
Authors	Rank/CIV/CTR	Command/ Organization	Institutional affiliation	Role in a research or work	E-Mail Address	Phone Number
Honig, Amanda J. LT		DSS 00259-ANESTHESIOLOGY-64AN00		Nurse		757-648-0228
Galassi, Mia G. LT						
Ogungbe, Olufemi O. LT						
Does this work require expedited review? ☒ YES ☐ NO						
If yes, please explain ("note expedited review is not guaranteed"):						
Title of work:				Implementation of aromatherapy, a non-pharmacological intervention, to reduce anxiety during the preoperative period at Naval Medical Center San Diego Aromatherapy DNP Abstract.docx		
Format: This automated work is a(n): Abstract, Poster, Presentation				(1) A abstract to be submitted for USU Research Days; (2) Poster to be presented during USU Research Day events; (3) Oral podium presentation of summary of the Final Report; (4) Approval to upload final report to the "USU Archives"		
Select your parent command:						
☐ Research and Development Enterprise (R&D) ☒ Military Treatment Facility ☐ NMETLC ☐ BUMED Headquarters ☐ Other						
List publication(s) or forum(s) you plan to submit to (up to 3):						
Expected date of publication: 2021-01-21				Name of conference or event: AANA Annual Congress USU Research Week		
Conference or event date: 2021-04-01				Intended audience: Medical Professionals		

NAV/MED 5721/2 (02-2017)

Local Command						
Authority	Name	Phone Number	E-mail Address	Approve Y/N	Signature	Date
OPSEC Officer	MATTHEW.STJOHN			Y		2021-01-22
Command Ethics Counselor						
Public Affairs	VERNISHIA.VAUGHN			Y		2021-01-26

Appendix E: Forms Used in Data Collection

Figure 1: PRISMA Flow Diagram

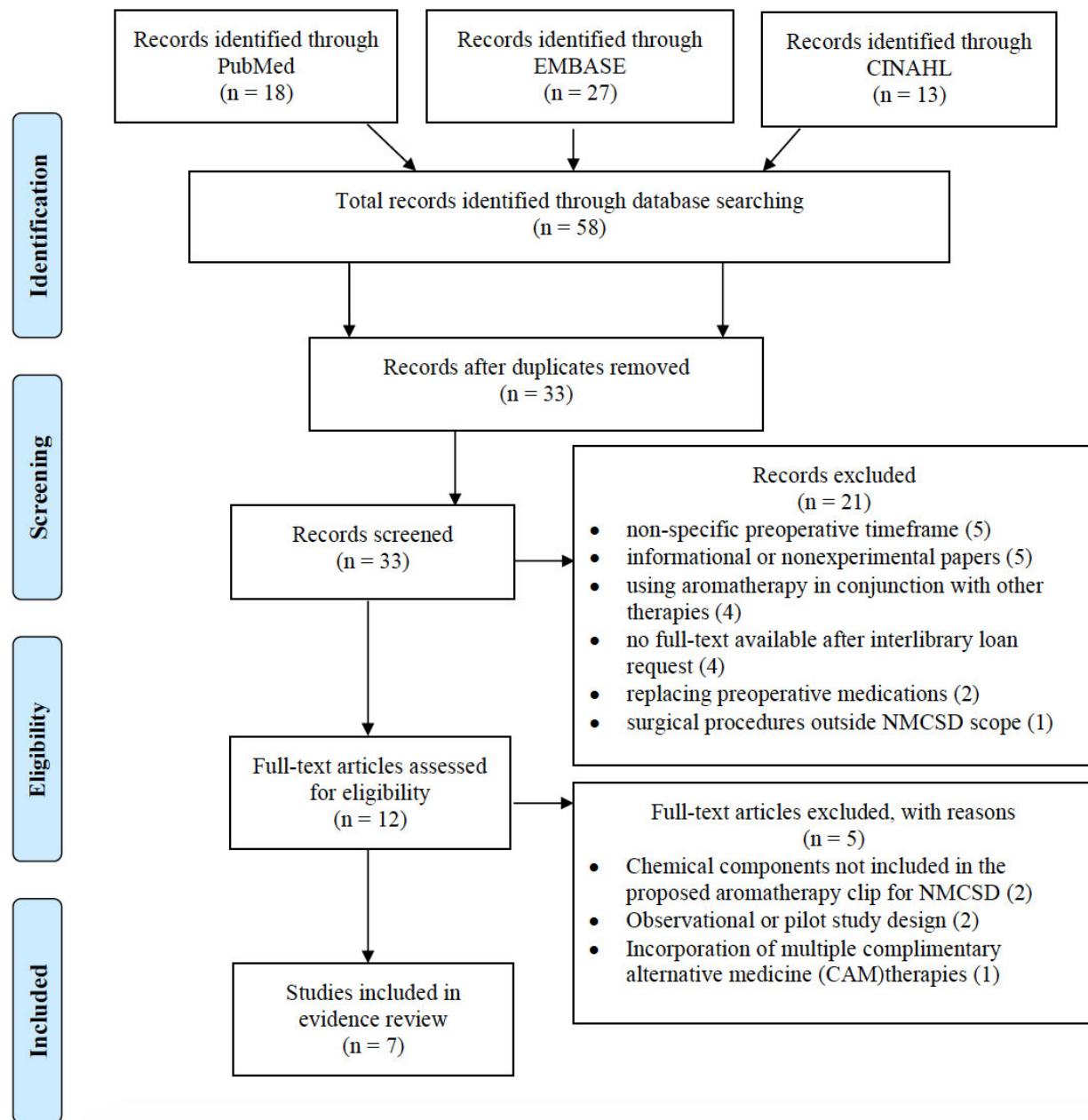


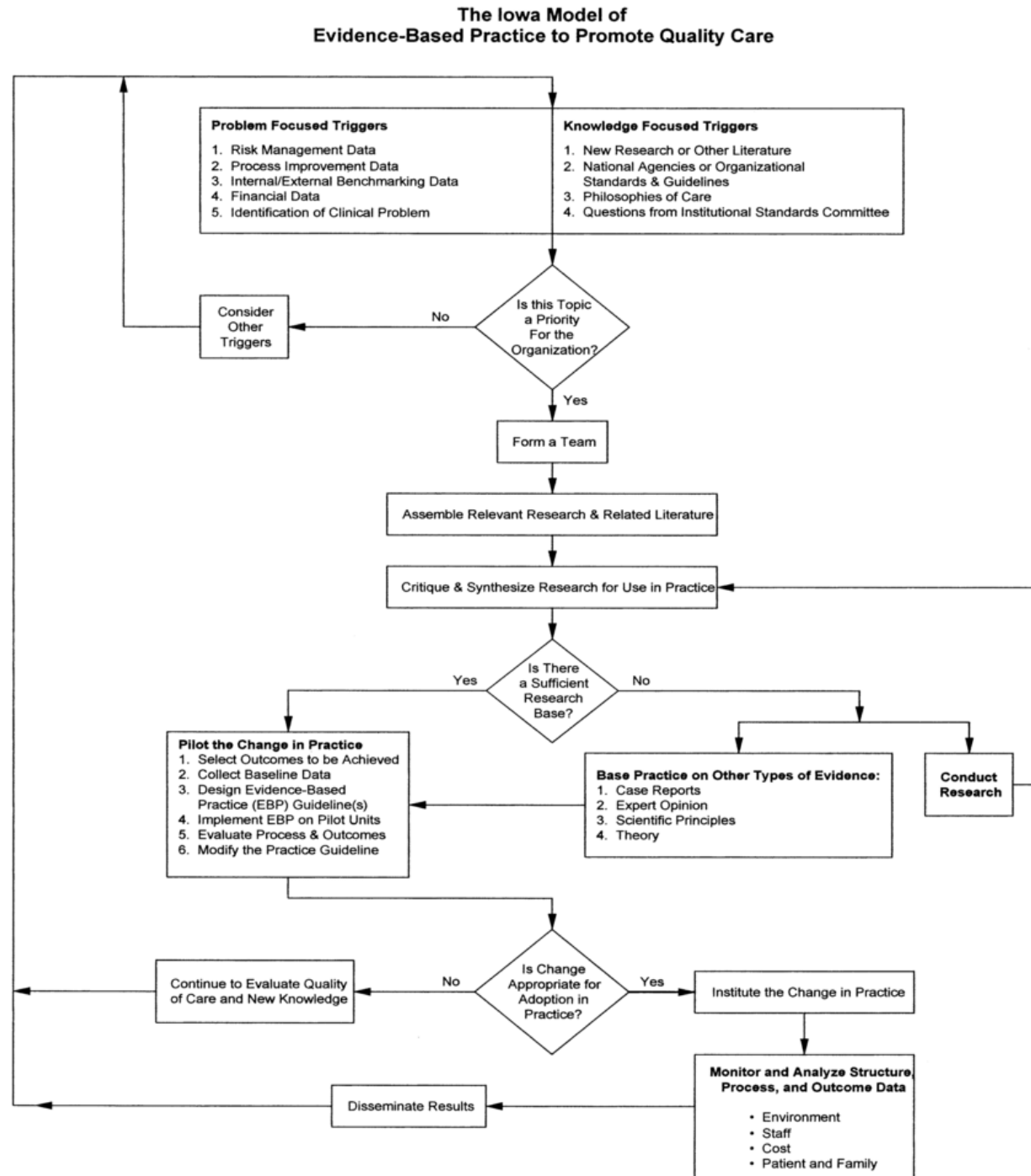
Figure 2: Evidence Table

Author(s), Year, Study Type, & Purpose	Independent Variable(s) & Sample Size	Dependent Variable(s) & Measurement Tool	Statistical Test(s)	Results	Study Quality (JHNEBP)
Braden et al. (2009) Prospective experimental pretest-posttest design Purpose to investigate whether EO lavandin is more effective than standard of care in reducing preoperative anxiety in general surgery patient population; also explored if lavandin decreased preoperative anxiety to a greater extent in females vs. males	3 Groups, n = 150 via power analysis: 1. Standard care, n = 50 2. Experimental: standard + 1 drop lavandin on cotton ball secured to gown), n = 50 3. Sham: standard + 1 drop odorless oil on cotton ball secured to gown, n = 50 LOM: Nominal	Anxiety level via visual analogue scale, measured on admission and at transfer to operating room LOM: Interval, 100-mm vertical visual analogue scale, least to worst anxiety experienced	ANOVA & Kruskal-Wallis: compare descriptive differences between 3 groups Analysis of covariance: correlations determined between variables hypothesized to impact anxiety at time of transfer (alpha level 0.10: baseline anxiety, pain, & use of preoperative medications); ANCOVA determined group assignment highly significant in relation to anxiety at OR transfer T-test: determine gender variations in anxiety reduction	ANOVA & Kruskal-Wallis: no differences in descriptive data comprising 3 groups, except: control group - less baseline anxiety; sham group - higher baseline pain ANCOVA: statistically significant decrease in anxiety level in experimental group at time of OR transfer across a diverse surgical population T-test: No statistically significance difference in anxiety reduction between males & females	Level I-B
Eslami et al. (2018) Randomized Control Trial Purpose: compare effects of aromatherapy using lavender and citrus extracts on state anxiety level of pts undergoing laparoscopic cholecystectomy	3 Groups, n = 90 via power analysis: 1. Lavender*, n = 30 2. Citrus*, n = 30 3. Control: odorless oil*, n = 30 *All: exposed to 20 min inhalation of 2 drops on tissue held 20-cm away LOM: Nominal	State anxiety score via STAI before & after exposure LOM: Interval, 20-80 scale	Chi-square: compare descriptive differences Smirnov test: established normality of distribution of quantitative data → parametric statistics Paired t-test: pre/post anxiety score within same group ANOVA & Tukey: compared state anxiety means of 3 groups	Chi-square: no differences Paired t-test: Statistically significant reduction in STAI scores in both the lavender and citrus groups (p<0.001); no difference in control group STAI scores (p=0.04) ANOVA & Tukey: Lavender & citrus reduced anxiety (p<0.01) to same extent (p=0.98); control increased anxiety (p<0.01)	Level I-B

Author(s), Year, Study Type, & Purpose	Independent Variable(s) & Sample Size	Dependent Variable(s) & Measurement Tool	Statistical Test(s)	Results	Study Quality (JHNEBP)
Fayazi et al. (2011) Quasi-experimental clinical trial Purpose: determine if inhaled aromatherapy decreases preoperative anxiety in pt's undergoing thoracic and abdominal surgery	2 Groups, n = 72 1. Experimental: inhaled lavender aromatherapy 2. Control: inhaled water on handkerchief LOM: Nominal	State anxiety score via STAI before & after exposure Vital signs (HR/BP) before & after exposure LOM: both interval	Chi-square: compare descriptive differences T--test: compare STAI scores and vital signs between 2 independent groups	Chi-square: no differences T-test: Statistically significant decrease in STAI score in experimental group compared to control; statistically significant decrease in systolic blood pressure in experimental group compared to control	Level II-B
Franco et al. (2016) Randomized Control Trial Purpose: determine if lavender fleur oil (LFO) aromatherapy will reduce anxiety when administered to women before undergoing breast surgery	2 Groups, n = 93 1. Experimental: Inhalation of lavender oil over 10 mins 2. Control: unscented oil over 10 min LOM: nominal	State anxiety level via STAI before & after exposure Vital signs (HR/BP) before & after exposure LOM: both interval	Paired t-test: compare STAI scores and vital signs before & after exposure in each group	Paired t-test: experimental group experienced a statistically significant ($p=0.001$) decrease in STAI score; no difference in control group STAI ($P=0.003$); no difference in vital signs in either group	Level I-B
Genc et al. (2019) Quasi-experimental study, pretest-posttest design with a control group Purpose: determine the effects of lavender oil on the levels of anxiety in patients with benign prostatic hypertrophy before surgery	2 Groups, n = 110 via power analysis 1. Experimental: 5 drops lavender oil on gauze pad, inhaled at least 5-min 2. Control: standard care LOM: nominal	State anxiety level via STAI before & 20-min after exposure Vital signs (HR/BP/RR/spO2) before & after exposure LOM: both interval	Chi-squared test: determine differences between the 2 groups T-test: comparison of anxiety scores & vitals between the 2 groups before & after treatment	Chi-squared test: no differences in descriptive data between groups T-test: no difference between pretest state anxiety; differences in posttest state anxiety statistically significant - experimental group illustrated statistically significant decrease in state anxiety level compared to control; no difference seen in pretest vitals between groups; statistically significant posttest improvement in spO2 & RR in experimental group, yet clinical significance questionable (spO2 93% & RR 21 pretest vs spO2 94% & RR 20 posttest in experimental group)	Level II-B

Author(s), Year, Study Type, & Purpose	Independent Variable(s) & Sample Size	Dependent Variable(s) & Measurement Tool	Statistical Test(s)	Results	Study Quality (JHNEBP)
Ni et al. (2013) Randomized Control Trial Purpose: determine if aromatherapy with bergamot essential oil could reduce preoperative anxiety in patients awaiting ambulatory surgery	2 Groups, n = 109: 1. Experimental: bergamot aromatherapy, n = 53 2. Control: water vapor, n = 56 After stratification based on prior surgical experience: 1. No experience, n = 34: experimental n = 23, control n = 11 2. Experience, n = 75: experimental n = 30, control n = 45 LOM: nominal	State anxiety level via STAI before & after exposure Vital signs (HR/BP) before & after exposure LOM: interval	Fisher's exact: determine if a difference in descriptive data existed between the two groups Mann-Whitney: determine differences between the 2 groups of non-normally distributed data Wilcoxon signed ranks: determine changes from baseline within each group of non-normally distributed data T-test: determine difference between the 2 groups of normally distributed data	Fisher's exact: all baseline characteristics were comparable between 2 groups except for surgical experience; more pts with surgical experience were randomly assigned to control group → <i>associations between anxiety scores and vitals parameters and aromatherapy were stratified by surgical experience (assuming prior experience may influence effect of treatment)</i> Mann-Whitney: -No experience - statistically significant reduction in STAI & vitals observed in the experimental group compared to no difference observed in the control group -Experience - statistically significant reduction in STAI only observed in the experimental group compared to no difference observed in the control group Wilcoxon signed ranks: -No experience - statistically significant reduction in STAI & vitals from baseline in experimental group; no differences within control group -Experience - statistically significant reduction in STAI & vitals from baseline in experimental & control group T-test: no difference in baseline or post-treatment STAI or vitals between those with & without surgical experience	Level I-B
Wotman et al. (2017) Prospective, controlled pilot study Purpose: evaluate efficacy of lavender aromatherapy in reducing preoperative anxiety in ambulatory surgery patients undergoing procedures in general otolaryngology	2 Groups, n = 100: 1. Experimental: lavender aromatab, opened to minimum scent, placed on gown over abdominal region, at least 30-min exposure 2. Control: standard care LOM: nominal	Anxiety level via visual analogue scale, measured upon arrival to preop area & before transfer to operating room LOM: interval, 10-cm horizontal line between 0 - 10, anchored by verbal descriptions of no, moderate, & high anxiety	Chi-squared test: compare descriptive differences between groups Welch's two-sample t-test: determine differences in anxiety change score (departure anxiety minus arrival anxiety score) between the 2 groups	Chi-squared test: no differences between the 2 groups descriptive data Welch's two-sample t-test: mean anxiety reduction statistically greater in experimental group than control group; clinical significance questioned as the numerical decrease was only a value of 1.07 Aromatherapy participants answered 3 additional questions r/t their experience: 77% felt calmer with aromatherapy, 92% found lavender scent pleasant, & 86% did not use aromatherapy on a regular basis	Level II-B

Figure 3: The Iowa Model



◊ = a decision point

Figure 4: STAIAD Short Form Y-1 Exemplar

For use by Amanda Honig only. Received from Mind Garden, Inc. on December 19, 2019



www.mindgarden.com

To Whom It May Concern,

The above-named person has made a license purchase from Mind Garden, Inc. and has permission to administer the following copyrighted instrument up to that quantity purchased:

State-Trait Anxiety Inventory for Adults

The four sample items only from this instrument as specified below may be included in your thesis or dissertation. Any other use must receive prior written permission from Mind Garden. The entire instrument may not be included or reproduced at any time in any other published material. Please understand that disclosing more than we have authorized will compromise the integrity and value of the test.

Citation of the instrument must include the applicable copyright statement listed below.

Sample Items:

I feel at ease
I feel upset
I lack self-confidence
I am a steady person

Copyright © 1968, 1977 by Charles D. Spielberger. All rights reserved in all media.
Published by Mind Garden, Inc. www.mindgarden.com

Sincerely,

Robert Most
Mind Garden, Inc.
www.mindgarden.com

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

Appendix F: DNP Project Completion Verification

**DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form**

The DNP Project titled: Implementation of aromatherapy, a non-pharmacological intervention, to
reduce anxiety during the preoperative period

was completed at Naval Medical Center San Diego by the following student(s):

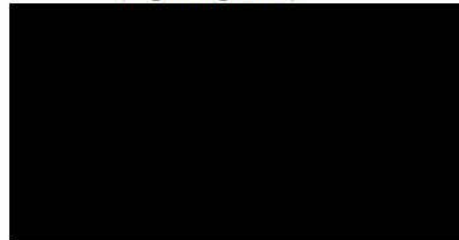
(Student Name)

LT Amanda J. Honig

LT Mia G. Galassi

LCDR Olufemi O. Ogungbe

(Digital Signature)



The DNP Practice Project Team verifies that the following components of the DNP project, accomplished by the above students, is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation:

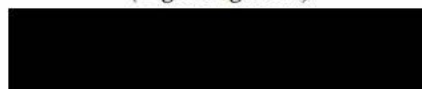
- Presentation of DNP project to the leadership/stakeholders at the Phase II Site,
- Abstract/Impact Statement (*Appendix F*), and
- DNP Project written report (*Appendix E*).

Verified by:

(type name)

CDR Danielle Cuevas

(Digital Signature)



Senior Mentor

Team Mentor

Team Mentor

CDR Tiffany Uranga



Team Mentor
& Phase II Site Director

For RNA Students only - add the following additional signature for final verification of project completion:

CDR Ken Radford

RNA Project Director (type name)



(Digital Signature)