RUTGERS
School of Nursing

DOCTOR OF NURSING PRACTICE (DNP) PROGRAM

A DNP PROJECT

EVALUATING THE EFFECT OF LAVENDAR OIL ON ANXIETY LEVELS IN ADULT PRE-OPERATIVE PATIENTS

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DATE: January 14, 2019

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Abstract

Purpose: To determine the effectiveness of administration of lavender oil and its impact on pre-operative anxiety levels in adult pre-operative patients.

Methodology: A quality improvement project was conducted in a same day surgery unit in an acute-care hospital over the course of a month and involved a convenience sample of 45 patients. The State Anxiety Inventory for Adults (STAI) tool was administered to subjects before and after intervention with lavender oil to determine baseline anxiety scores and post-intervention anxiety scores. Anxiety scores were then analyzed to determine effect.

Results: Analytical statistics revealed that lavender oil had a statistically significant effect in decreasing pre-operative anxiety levels in adult pre-operative patients (Z = -5.065, p = 0.001).

Implications for practice: Lavender oil can reduce pre-operative anxiety levels in adult pre-operative patients. Lavender oil's ease of administration, low cost, and low adverse effect profile make it a viable alternative to traditional medicine as a therapeutic anxiolytic agent for pre-operative anxiety. In this way, lavender oil is a feasible option to reduce the amount of sedatives and analgesics used, thereby leading to reduced cost and decrease in the incidence of any negative adverse effects that are associated with the use of such drugs. Opportunity for improvement would be change in policy, and development of a system to continually measure and evaluate outcomes for the improvement of patient care. In this way, evidence-based practice may be used to achieve better patient outcomes.

Keywords: lavender, lavender oil, anxiety, pre-procedure

Evaluating the Effect of Lavender Oil on Anxiety Levels in Adult Pre-Operative Patients

Pre-operative anxiety is a common problem faced by many patients prior to a planned procedure. This emotional state can negatively impact patient outcomes and decrease patient satisfaction (Wotman et al., 2017). There is a growing need for alternative methods to help reduce pre-operative anxiety with minimal adverse effect to the patient. Lavender is an essential oil with a simple and low risk profile that can be used as a therapeutic agent to decrease pre-operative anxiety levels (Franco et al., 2016; Wotman et al., 2017). This project explored the impact of lavender oil administration on pre-operative anxiety levels in adult pre-operative patients.

Background and Significance

Pre-operative anxiety is a common problem faced by many patients prior to a planned procedure, with a prevalence rate of as much as 80% in adult pre-operative patients (Fayazi, Babashahi, & Rezaei, 2011). Wilson et al.'s (2016) study found that pre-operative anxiety can be associated with physiologic responses such as nausea, sweating, elevated temperature, hypertension, and tachycardia, which can result in consequent need for more anesthesia during procedure, and places patients at higher risk for increased postoperative pain, resulting in higher consumption of analgesia. In this way, pre-operative anxiety can increase the need for sedatives and analgesia, as well as potentially exacerbate pain, which is already widely known to be a significant health problem, and has an annual estimated cost to society of at least $560-635 billion (Institute of Medicine [IOM], 2011; Wotman et al., 2017).

Pre-operative anxiety has also been associated with decreased patient satisfaction, reduced ability to comprehend information prior to surgery, and reduced ability to fight infection, which can ultimately lead to prolonged postoperative wound healing (Wotman et al.,

2017). This all translates to longer hospital stays and poor health outcomes (Wilson et al., 2016). In this way, pre-operative anxiety is an issue that can no longer be avoided due to its associated negative impact to healthcare.

Traditionally, pharmacologic measures, such as sedatives, anxiolytics, and opioids have been utilized to help decrease pre-operative anxiety. However, these agents have been associated with multiple adverse effects, including restlessness, fatigue, and confusion, which can ultimately affect the patient's capacity to participate in their care (Wotman et al., 2017). Furthermore, these medications can adversely interact with anesthetic agents administered during procedure and can potentially lead to drowsiness and respiratory depression, further prolonging recovery and resulting in delay with patient discharge (Wilson et al., 2016). In this way, there has been a growing need for alternative methods to help reduce pre-operative anxiety with minimal adverse effect to the patient. The World Health Organization (WHO) (2013) recognizes and has begun to accept the positive contribution that alternative medicine can make to the health and well-being of patients, as well as its overall impact on the practice of traditional medicine. Aromatherapy is a form of complementary medicine that has grown in popularity and may offer an alternative approach to traditional medicine to help decrease pre-operative anxiety (Franco et al., 2016; Karaman et al., 2016).

Lavender oil, in particular, is an essential oil that has been used in aromatherapy as an anxiolytic therapeutic agent (Franco et al., 2016). It has been used since ancient times in Greece and Rome and many studies have shown its positive effect in reduction of anxiety, including pre-operative anxiety (Braden, Reichow, & Halm, 2009; Fayazi et al., 2011; Franco et al., 2016; Hosseini, Heydari, Vakili, Moghadam, & Tazyky, 2016; Karaman et al., 2016; Perry, Terry,

Watson, & Ernst, 2012; Trambert, Kowalski, Wu, Mehta, & Friedman, 2017; Wotman et al., 2017).

Lavender oil also has many attributes that make it beneficial to use prior to surgery. These include its ease of administration, low cost, and low adverse effect profile (Wotman et al., 2017). These attributes also make lavender oil a viable option to reduce the amount of sedatives and analgesics used, thereby leading to reduced cost and decrease in the incidence of any negative adverse effects associated with use of these agents prior to procedure (Braden et al., 2009; Franco et al., 2016). In this way, lavender oil, with its simple and low risk profile, can be used as a therapeutic agent to decrease pre-operative anxiety levels (Wotman et al., 2017). This project explored the impact of lavender oil administration on pre-operative anxiety levels in adult pre-operative patients.

Needs Assessment

SWOT analysis was used in order to determine the needs assessment of the project site. SWOT stands for the strengths, weaknesses, opportunities, and threats that may be present in an organization, and served as a tool to assess the current situation (Moran, Burson, & Conrad, 2017). The project took place in a same day surgery unit in a hospital in northern New Jersey. Strengths for the project site included the fact that lavender oil is already part of the standard of care and is used in conjunction with traditional pharmacologic measures to help reduce pre-operative anxiety in patients. The weakness identified at the project site was that there was no formal measure of the effect of lavender oil in decreasing pre-operative anxiety. Opportunity for growth stemmed from the growing recognition of the advantages of alternative medicine. As previously stated, the WHO (2013) recognizes and has begun to accept the positive contribution that alternative medicine can make to the health and well-being of patients, as well as its overall

impact on the practice of traditional medicine. The use of lavender oil as aromatherapy is a form of complementary medicine that has grown in popularity and may offer an alternative approach to traditional medicine to help decrease pre-operative anxiety (Franco et al., 2016; Karaman et al., 2016). Threats to the system may include lack of support from stakeholders regarding the use of complementary medicine, such as aromatherapy, and/or the removal of funding for the use of lavender essential oils.

There was a need to determine the effectiveness of current practice of the use of lavender oil in decreasing pre-operative anxiety levels. Introduction of a tool to measure anxiety prior to and after the administration of lavender oil would help to determine the effect of lavender oil in decreasing anxiety levels in adult pre-operative patients. Lavender is an essential oil with a simple and low risk profile that can be used as a therapeutic agent to decrease pre-operative anxiety levels (Wotman et al., 2017). Therefore, a quality improvement project was conducted to explore the impact of lavender oil administration on pre-operative anxiety levels in adult pre-operative patients.

Problem Statement

The pervasive problem of pre-operative anxiety and the negative implications associated with it warrant need for evaluation and alternative methods to reduce this state of psychological distress with minimal adverse effect to the patient.

Clinical Question

The clinical question that guided this project was “In adult pre-operative patients, will the administration of lavender oil lead to decreased STAI scores?”

Aims and Objectives

Since lavender oil is already part of the standard of care at the project site, the overall aim of the project was to collect data for practical purposes in order to determine the effectiveness of the current practice of administration of lavender oil and its impact on pre-operative anxiety levels in adult pre-operative patients. The objectives of this project included:

- measurement of pre-operative anxiety levels prior to and after the administration of lavender oil to determine effect
- increase awareness of the nursing staff in the same day surgery unit regarding the effect of lavender oil on pre-operative anxiety as evidenced by a presentation of findings after the project has been completed

Review of Literature

A literature search for all English-language studies on lavender oil and pre-operative anxiety was performed on search engines, including PubMed, Medline, and CINAHL. Keywords included: "*lavender*" or "*lavender oil*" and "*anxiety*," combined with the word "*pre-procedure*." The search yielded 439 studies. Date delimitations were 2008 to the present. Inclusion criteria were original research studies or systematic reviews in peer-reviewed journals that examined lavender and pre-operative anxiety in adult patients (18 years and older). After applying date delimitations and the inclusion criteria as outlined, there were 226 studies remaining.

Exclusion criteria included animal studies, as well as studies involving children, since this would not add any meaningful information and the focus of the project is on adult humans. Exclusion criteria were also studies that focused on lavender as a chemical compound or herb, studies in which lavender was used as an oral medication, topical cream, or massage, and studies

in which lavender was used in non-surgical or non-procedural settings. After applying exclusion criteria, there were nine studies that remained. Of these, eight were research studies and one was a non-research study. A complete PRISMA diagram can be found in Appendix A. A complete table of evidence is included in Appendix B.

Lavender oil has been used since ancient times in Greece and Rome and many studies have shown its positive effect in reduction of anxiety, including pre-operative anxiety (Braden et al., 2009; Fayazi et al., 2011; Franco et al., 2016; Hosseini et al., 2016; Karaman et al., 2016; Perry et al., 2012; Trambert et al., 2017; Wotman et al., 2017). An example of this can be seen in Fayazi et al.'s (2011) experimental study on the use of lavender in the reduction of pre-operative anxiety. Their study explored the effect of inhaled lavandula oil on the anxiety level of patients in the pre-operative period (Fayazi et al., 2011). The State Anxiety Inventory for Adults (STAI), which has been used in more than 1,000 peer reviewed studies and is considered the "gold standard" in the assessment of state anxiety (a transient situation) and trait anxiety (a baseline anxious personality), was used to measure levels of anxiety (Franco et al., 2016). STAI scores were then compared between the control group, which received a placebo inhalation, and the experimental group, which received lavandula aromatherapy. Results of the study showed a significant drop in mean anxiety levels after intervention with the inhaled lavandula oil in comparison to the control group. This is supported by the independent t-test results from the study which revealed statistically significant difference between control and experimental groups after intervention ($p=0.001$) (Fayazi et al., 2011). Braden et al.'s (2009) prospective experimental study further supports the use of lavender oil in the reduction of pre-operative anxiety. Their study explored the use of the essential oil, lavandin, to reduce pre-operative anxiety in surgical patients. Pre-operative anxiety was measured with the visual analog scale (VAS), which has

shown to be as reliable as the STAI in measuring anxiety (Braden et al., 2009). Results in this study showed that lavandin significantly reduced pre-operative anxiety prior to the patient's transfer to the operating room. Conclusions drawn from the study also suggest lavandin as a low-risk, simple, and cost-effective intervention to reduce anxiety in pre-operative patients (Braden et al., 2009). Wotman et al.'s (2017) prospective and controlled pilot study explored the efficacy of lavender aromatherapy in reducing preoperative anxiety in ambulatory surgery patients undergoing procedures in general otolaryngology. Results from the study also revealed a statistically significant difference between the control and experimental group. Anxiety was measured with the VAS (Wotman et al., 2017). According to Welch's two sample t-test, it was revealed that there was a statistically significant reduction in anxiety in the experimental group in comparison to the control group ($p=0.001$) (Wotman et al., 2017). These studies show the positive effect of lavender oil in reducing pre-operative anxiety in patients and support its use in this setting (Braden et al., 2009; Fayazi et al., 2011; Wotman et al., 2017).

Lavender oil can also be used in the setting of anxiety and pain management. Karaman et al.'s (2016) prospective, randomized study evaluated the efficacy of lavender aromatherapy on peripheral venous cannulation pain and anxiety. Anxiety was measured with the VAS. Results from the study revealed statistically significant improvement in pain and anxiety scores after intervention with lavender aromatherapy in comparison to the control group, which consisted of a pure water placebo ($p=0.01$ for pain scores; $p<0.001$ for anxiety 2 scores) (Karaman et al., 2016). In addition to these findings, results from the study also showed significantly higher scores in patient satisfaction with the lavender group in comparison to the control group ($p=0.003$) (Karaman et al., 2016). As mentioned previously, psychological distress brought on by pre-operative anxiety can lead to increased use of narcotics and anesthetics (Wotman et al.,

2017). Lavender oil provided in this setting can help to reduce pre-operative anxiety and thereby offset the use of narcotics and anesthetics. This further supports the use of lavender oil in reduction of pre-operative anxiety.

Lavender oil has also been studied in the setting of reduction of anxiety scores and cortisol levels. Hosseini et al.'s (2016) single-blind, randomized clinical trial explored the effect of lavender essence inhalation on the level of anxiety and blood cortisol in candidates for open-heart surgery. Anxiety was measured with the STAI. Results from the study showed significant reduction in mean anxiety score after intervention in the study group, which inhaled lavender, in comparison to the control group, which inhaled distilled water ($p<0.001$) (Hosseini et al., 2016). Furthermore, ANCOVA test also revealed that the 69.6% decrease in blood cortisol level and 10.8% variance in anxiety score can be attributed to the inhalation of lavender, which was another significant finding (Hosseini et al., 2016). This further demonstrates the usefulness of lavender in the reduction of pre-operative anxiety and supports its use in this setting.

Multiple studies have explored the use of lavender oil in the reduction of anxiety (Braden et al., 2009; Fayazi et al., 2011; Franco et al., 2016; Hosseini et al., 2016; Karaman et al., 2016; Perry et al., 2012; Trambert et al., 2017; Wotman et al., 2017). Studies have also explored its use in the reduction of pre-operative anxiety in specific patient populations, namely women (Franco et al., 2016; Trambert et al., 2017). Franco et al.'s (2016) randomized controlled trial examined lavender fleur oil and unscented oil aromatherapy in the reduction of pre-operative anxiety in breast surgery patients. A total of 90 women completed the study and results revealed that both lavender fleur oil and unscented oil treatments decreased anxiety prior to breast surgery and were associated with improved sense of well-being in patients. STAI scores were compared between the control group, which received unscented oil, and the experimental group, which received

lavender fleur oil (Franco et al., 2016). Results from the study revealed that after intervention, those that received lavender fleur oil in the experimental group showed significant improvement in positive feelings compared with scores prior to treatment ($p=0.001$). With regard to the unscented oil group, STAI scores were also significantly higher after treatment ($p=0.003$) (Franco et al., 2016). Despite this, results from the study showed that after treatment with lavender fleur oil, STAI scores were statistically and significantly more positive compared with those receiving unscented oil ($p=0.001$) (Franco et al., 2016). In another study, the use of aromatherapy was examined in women undergoing breast biopsy (Trambert et al., 2017). Trambert et al.'s (2017) randomized-controlled study provided evidence to support aromatherapy to minimize anxiety in women undergoing breast biopsy. Results from the linear regression analysis in this study reveal that aromatherapy with lavender-sandalwood led to statistically significant reduction in self-reported anxiety with the STAI in comparison to the placebo control group ($p=0.032$) (Trambert et al., 2017). Pre-operative anxiety can lead to psychological distress prior to procedure, which can negatively impact healthcare outcomes (Wotman et al., 2017). Results in these studies highlight the usefulness of lavender in improvement in well-being and anxiety, which could lead to positive outcomes and further support its use in the pre-operative setting (Franco et al., 2016; Trambert et al., 2017).

In addition to its anxiolytic properties, lavender oil has also been utilized for reduction of stress and anxiety. Perry et al.'s (2012) systematic review of randomized clinical trials critically evaluated the effectiveness and efficacy of lavender for the reduction of anxiety and stress. A total of 15 randomized-controlled trials met inclusion criteria for systematic review. Sample sizes in the trials ranged from 16 to 340 subjects. A majority of trials used lavandula and utilized either the Hamilton Anxiety and Depression (HAD) scale or STAI to measure anxiety levels

(Perry et al., 2012). Results from seven trials support the use of lavender over controls for at least one relevant outcome, and one comparative trial revealed the effect of lavender to be as effective as lorazepam, which is an anxiolytic drug. Significant differences between control and experimental groups, which included lavender, could not be demonstrated in the remaining trials due to methodological limitations of the studies (Perry et al., 2012). As can be seen, multiple studies support the use of lavender as an anxiolytic (Braden et al., 2009; Fayazi et al., 2011; Franco et al., 2016; Hosseini et al., 2016; Karaman et al., 2016; Perry et al., 2012; Trambert et al., 2017; Wotman et al., 2017). Further research and stringent methodology is needed in order to further demonstrate and prove lavender's therapeutic use as an anxiolytic in the pre-operative setting (Perry et al., 2012). This supports the need for the project to further explore the effect of lavender in reduction of pre-operative anxiety.

Further need for research with regard to use of essential oils in reduction of anxiety can also be seen in Stea, Beraudi, and DePasquale's (2014) non-research literature review, which explored essential oils for complementary treatment of surgical patients. A total of 14 studies were included in the literature review, of which 9 studies included lavender and 5 studies did not involve lavender (Stea et al., 2014). Results from their literature review have generally shown positive results with the use of lavender, orange, and peppermint essential oils in the treatment of anxiety and nausea in the pre-operative setting. However, they concluded that results from randomized clinical trials were not definitive to provide evidence of the efficacy of essential oils in the reduction of pre-operative anxiety. Reason for this may be attributed to the source of essential oils, and methodological limitations of the studies (Stea et al., 2014). This further highlighted the need for the project in the determination of lavender's effect on pre-operative anxiety.

Several studies support the use of lavender oil in the reduction of pre-operative anxiety in adult patients (Braden et al., 2009; Fayazi et al., 2011; Franco et al., 2016; Hosseini et al., 2016; Karaman et al., 2016; Perry et al., 2012; Trambert et al., 2017; Wotman et al., 2017). Due to its many attributes, including ease of administration, low cost, and low adverse effect profile, lavender oil can be viewed as beneficial in the pre-operative setting (Wotman et al., 2017). In addition to this, studies have also revealed lavender oil's versatility in symptom management, including pain and stress, which often occur in conjunction with anxiety in adult pre-operative patients (Karaman et al., 2016; Perry et al., 2012). Use of lavender oil in this regard can help to offset any negative outcomes associated with psychological distress in this situation, and further supports the use of lavender in this situation. Further research is needed, however, to further elucidate the anxiolytic effect of lavender oil (Perry et al., 2012; Stea et al., 2014). This project explored the impact of lavender oil administration on pre-operative anxiety levels in adult pre-operative patients.

Theoretical Framework

The theoretical framework that guided this project was the Plan-Do-Study-Act (PDSA) cycle. The PDSA cycle is a simple and powerful tool used to accelerate quality improvement and is part of the Institute for Healthcare Improvement Model for Improvement (Agency for Healthcare Research and Quality [AHRQ], 2008). The PDSA cycle helps to test change and consists of four steps. The first step consists of the planning stage in which data is collected and a plan is made to carry out the test. The second step in the cycle is to do or carry out the test on a small scale. The third step is to study and analyze results. The final stage is to refine the change and act on what is learned (AHRQ, 2008). The PDSA cycle was appropriate for the project due to its logical cycle for quality improvement and its ability to generate and sustain change through

its rapid cycle process. In this way, the PDSA cycle provided a proper framework for the project in order to generate change and test for quality improvement.

In the same day surgery unit, improvement in practice was needed with regard to determination of lavender oil's effect on decreasing anxiety levels in adult pre-operative patients. With regard to the project, the planning stage consisted of a proposal to implement the STAI upon the patient's arrival to the unit and after administration of lavender oil in order to determine improvement in anxiety level. The next stage consisted of actually implementing the project, collection of STAI scores, and monitoring of progress. In the study stage, data analysis of STAI scores was evaluated in order to determine effect of lavender oil in the reduction of anxiety levels in adult pre-operative patients. In the final stage, results and data analysis from the previous stage were analyzed to determine success or need for further improvement. Results will be disseminated to stakeholders. Plan for sustainability of the change can lead to further PDSA cycles for continued quality improvement. A conceptual framework is included in Appendix C.

Methodology

The proposed project was a quality improvement project and involved the administration of STAI to subjects before and after the intervention of lavender oil. Quality improvement is a systematic and continuous process with a focus on the use of data to drive change, thereby leading to improvement in healthcare services and patient care (Moran et al., 2017). The quality improvement project approach was appropriate since lavender oil is already part of the standard of care at the project site, and data was collected for practical purposes in order to determine the effectiveness of the current practice of administration of lavender oil and its impact on pre-operative anxiety levels in adult pre-operative patients.

Setting

The setting for this project was in a same day surgery unit in a hospital located in Ridgewood, New Jersey. The hospital is a fully accredited, acute-care, not-for-profit hospital, with a 451 bed capacity. The hospital serves more than 440,000 people in 32 towns in Bergen County and adjoining communities in northern New Jersey. Patients in this setting are primarily white/non-Hispanic.

The hospital has a long-standing Same Day Services Program. On average, the same day surgery unit sees about 10,000 patients a year, including both pediatric and geriatric cases. More than half of the surgeries are performed on a same-day basis, and more than one-third of admissions are from same-day services. Patients are admitted to the same day surgery unit for a variety of cases, including surgeries involving cardiac, breast, gastrointestinal, gynecologic, genitourinary, neurologic, as well as a wide range of orthopedic surgeries and repairs. The same day surgery unit is comprised of 26 beds, with an average of about 35 to 65 cases performed a day (M. Sudano, personal communication, March 2, 2018). The unit is staffed with 22 registered nurses, most of which are employed part-time, and one full-time unit manager. Of the total staff nurses, currently 15 nurses are certified to administer lavender oil.

Study Population

This project included a convenience sample of patients, which consisted of men and women in the same day surgery unit. Inclusion criteria included men and women, 18 years of age or older in the same day surgery unit, who were alert, oriented, able to read, write, and speak in English, and were willing to receive lavender oil prior to any kind of scheduled operative procedure. Exclusion criteria included men and women who were allergic to lavender, those who

wore perfume or after-shave on the day of surgery, had a history of asthma or impaired sense of smell, and those patients who took benzodiazepines or any other anti-anxiety medications, and/or analgesic opioids prior to admission to the same day surgery unit. Patients who were pregnant, breastfeeding, or cognitively impaired were also excluded from participation. The project was limited to this subset of patients for convenience.

Having used Raosoft, Inc. (2004) for an a priori power analysis to calculate sample size, and with a population size of 50 with a 5% margin of error and 95% confidence level, the necessary sample size needed was 45 subjects.

Subject Recruitment

Efforts to recruit subjects were made via in-person upon patient admission to the same day surgery unit by the principal investigator (PI). Recruitment of subjects took place at the bedside by the PI after the patient was admitted and designated to a bed in the same day surgery unit. Recruitment of subjects would last for up to three months. Access to potential subjects was achieved through a generated list of the patient census provided by the same day unit staff identifying patients scheduled for any kind of operative procedure. Subjects were provided a handout summarizing the project, as well as contact information (email and telephone number) for any questions or concerns. Potential subjects were informed that participation in the project was voluntary and that there would be no compensation for participation in the project. Potential subjects were also informed that they could withdraw from the project at any time without penalty. Potential subjects were assured that decision whether or not to participate in the project, or withdrawal from the project, would not impact usual care provided or result in loss of benefits to which they were otherwise entitled. Providing potential subjects with this information reduced

the possibility that patients may feel coerced to participate to receive optimal care. A copy of the subject recruitment handout is included in Appendix D.

Consent Procedure

Each subject who met eligibility criteria and agreed to participate in the project signed a consent form. Consent was obtained in writing and subjects were informed of all possible risks and benefits. Consent was obtained by the PI at the patient's bedside behind a closed curtain in order to ensure privacy. Subjects were informed that participation in the project was voluntary and that there would be no compensation for participation in the project. Subjects were assured that they could withdraw at any point without penalty. Subjects were also informed that their decision whether or not to participate in the project, or withdrawal from the project, would not impact usual care provided or result in loss of benefits to which they were otherwise entitled. Each subject was given adequate time to review the consent form and to ask questions. The project, consent form, and supporting materials were reviewed and approved by the project site hospital's institutional review board of record, as well as by the Rutgers Institutional Review Board. A copy of the consent form used for the project is included in Appendix E.

Risks or Harms

Participation in this project posed minimal risk. In order to prevent risk, subjects were screened to confirm meeting of strict inclusion and exclusion criteria. Those who met eligibility criteria and were agreeable to participate in the project signed a consent form, which included a thorough description of any risks or harms that may be encountered through participation in the project. Subjects were also informed of any data that may affect their decision to participate in the project.

Potential risks associated with participation in the project included feelings of discomfort that could be elicited when subjects inhaled the lavender oil. Subjects were made aware of this possibility for discomfort and were assured that in case they felt any discomfort and no longer wished to continue with the project, they could choose to withdraw at any time without penalty. Also, questions asked in the STAI could cause subjects to think about feelings of being anxious or upset. In these instances, subjects were reminded that they could choose to withdraw from the project at any point without any penalty. There was also a small possibility that personal information collected may be inadvertently shared by participating in the project. In order to mitigate this issue, names and any personal information necessary for this project were collected and assigned a number. This allowed for the data to be reviewed without direct link to the subject's name. Only the PI had access to the master list linking the subject's name to the number associated with the data. Since there was no anticipated major risk for participants in this project, risk to participants was minimal. A complete description of risks or harms is included in the consent form in Appendix E.

Subject Costs and Compensation

There was no cost to participate in this project. Subjects did not receive any compensation for their participation in the project.

Study Intervention

There was a need to determine the effectiveness of current practice of the use of lavender oil and its impact on pre-operative anxiety levels. In order to accomplish this, the PI actively conducted the quality improvement project in the same day surgery unit. Recruitment of subjects was made in-person upon patient admission to the same day surgery unit by the PI. Recruitment

of subjects took place at the bedside by the PI after the patient was admitted and designated to a bed in the same day surgery unit. Subjects who met eligibility criteria and who were agreeable to participate in the project signed an informed consent form. Once informed consent was obtained, demographic characteristics of the patient, such as age and gender were obtained. Afterwards, the initial anxiety level of the patient was measured by use of the STAI Form Y-1 (state anxiety) and STAI Form Y-2 (trait anxiety), which was completed by the patient. A copy of the tool is included in Appendix F. Patients were given 10 minutes to complete both forms. Upon completion of the STAI, a lavender oil sniffer, consisting of Lavandula Angustifolia, was administered and the patient was instructed to periodically waft the sniffer through both nostrils for about 10 minutes. Afterwards, the patient completed the STAI Form Y-1 (state anxiety) after intervention with the lavender oil sniffer. The patient was given five minutes to complete this form. The STAI Form Y-2 (trait anxiety) was not repeated post intervention with the lavender oil since trait anxiety does not fluctuate as widely as a result of situational change. If at any point during the project the patient stated that they no longer wished to participate, the lavender oil sniffer would be removed. Total time for each session with patients would be approximately 30 minutes. Data was collected in this manner until a sample size of 45 had been achieved.

After completion of the project, two presentations will be held in order to disseminate the findings to nursing staff in the same day surgery unit and to increase their awareness regarding the effect of lavender oil on pre-operative anxiety. Presentations will take place in the nursing lounge as part of the staff huddle prior to the start of each shift. An opportunity to answer all questions from the staff will be included at the end of each presentation.

Outcomes to be Measured

Baseline anxiety scores and post-intervention anxiety scores were measured with STAI. STAI has been used in more than 1,000 peer reviewed studies and is considered the "gold standard" in the assessment of state anxiety (a transient situation) and trait anxiety (a baseline anxious personality) (Franco et al., 2016). STAI has proven to be a reliable and valid tool. Test-retest reliability coefficients have ranged from 0.65 to 0.75 over a two month interval, and internal consistency coefficients for the scale have ranged from 0.86 to 0.95. Its use in multiple studies provides considerable evidence that can attest to the construct and validity of the scale (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983).

State-Trait Anxiety Inventory for Adults: Forms Y-1 and Y-2 (STAI-AD) was used for the project (See Appendix F). License to reproduce the tool was obtained from Mind Garden, Inc. Form Y is the most popular version of the STAI and is appropriate for use in those with at least a sixth-grade reading level (Spielberger et al., 1983). The tool consists of 20 items for assessing state anxiety (Form Y-1) and 20 items to assess for trait anxiety (Form Y-2). All items are rated on a 4-point scale ("from Not At All" to "Very Much So" on Form Y-1; and "Almost Never" to "Almost Always" on Form Y-2). Scores range from a minimum of 20 to a maximum of 80 for either Form Y-1 or Form Y-2. Higher scores indicate greater anxiety (Spielberger et al., 1983).

Relevant variables collected in this project included demographic information, including the patient's age and gender. Any names and personal information necessary for this project were collected and assigned a number. This allowed for the data to be reviewed without direct link to the subject's name. Only the PI had access to the master list linking the subject's name to

the number associated with the data. Data was de-identified as soon as possible after data was transcribed and verified for accuracy. Only de-identified data was used for analysis.

Project Timeline

A complete GANTT Chart outlining key steps in the process for the entire project is included in Appendix G.

Resources Needed

The costs associated with this project were the sole responsibility of the PI. Costs included subject recruitment handouts, research expenses, such as the STAI manual, and license to reproduce the STAI-AD. There was no cost to participate in this project. Subjects did not receive any compensation for their participation in the project. An anticipated budget is located in Appendix H.

Evaluation Plan

Data Analysis

Descriptive statistics were used to describe the sample of participants. Analytical statistics were used to determine the efficacy of the project intervention. Data (pre- and post-intervention STAI scores) was collected to determine patient anxiety. The paired t-test was predicted to be utilized to examine observed differences in scores between two dependent measurements of time. The statistical software package SPSS was used for completion of data analysis.

Maintenance and Security

Patients were provided with an ID number by the PI to use on both the data collection and data analysis. Any names and personal information necessary for this project was collected and assigned a number. This allowed for the data to be reviewed without direct link to the subject's name. Only the PI had access to the master list linking the subject's name to the number associated with the data. Data was de-identified as soon as possible after data was transcribed and verified for accuracy. Only de-identified data was used for analysis. Completed surveys were stored in a locked cabinet only accessible by the PI, and separate from the master list linking the subject's name to the number associated with the data. Data analysis was done by the PI and results were stored on a USB flash drive that is password protected, encrypted, and stored in a locked cabinet. Only the PI maintained the key to the locked cabinet and had access to the data.

Upon completion of the project, closure of the IRB, and final writing of the manuscript, all data will be destroyed in accordance with Rutgers University guidelines. Hard copies of consents and aggregate data will be housed in Dr. Helen Miley's office at Rutgers University, 65 Bergen Street, Newark, NJ 07107 in room 1115.

Findings

Sample Characteristics

The target goal for subjects was achieved, and a total of 45 subjects from the same day surgery unit participated in the quality improvement project. The majority of subjects (N=29) were female (64.4%), while the remainder of the subjects (N=16) were male (35.6%). (See Table 1). Participants ranged in age from 21 to 86 years of age. The average age of the participants was

55.56 years, with a median of 54 years of age, and a mode of 49 years of age. (See Table 2). All 45 subjects completely filled out the STAI tool prior to and after administration of the lavender oil sniffer. There was no subject dropout during project implementation and no missing data.

Table 1

Participant Gender Demographics

Gender

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Male	16	35.6	35.6	35.6
	Female	29	64.4	64.4	100.0
	Total	45	100.0	100.0	

Table 2

Participant Age Demographics

Statistics

		Age	Gender
N	Valid	45	45
	Missing	0	0
Mean		55.56	
Median		54.00	
Mode		49[a]	
Std. Deviation		16.466	
Variance		271.116	
Range		65	
Minimum		21	
Maximum		86	

a. Multiple modes exist. The smallest value is shown

Duration of Project

Project implementation occurred over the course of a month from June to July. Eight 12-hour days were needed in order to achieve the target goal of 45 subjects. The predicted time of 30 minutes with each patient was adequate to complete data collection. With support from the staff in the same day surgery unit, data was able to be collected until a sample size of 45 had been achieved.

Anxiety Scores

As mentioned, STAI was administered to subjects before and after intervention with the lavender oil sniffer in order to determine baseline anxiety scores and post-intervention anxiety scores. The initial anxiety level of the patient was measured by use of the STAI Form Y-1 (state anxiety) and STAI Form Y-2 (trait anxiety). After intervention with the lavender oil sniffer for about 10 minutes, patients completed another STAI Form Y-1 (state anxiety). The STAI Form Y-2 (trait anxiety) was not repeated post intervention with the lavender oil since trait anxiety does not fluctuate as widely as a result of situational change. The STAI tool consisted of 20 items to assess state anxiety (Form Y-1) and 20 items to assess for trait anxiety (Form Y-2). All items were rated on a 4-point scale ("from Not At All" to "Very Much So" on Form Y-1; and "Almost Never" to "Almost Always" on Form Y-2). Scores ranged from a minimum of 20 to a maximum of 80 for either Form Y-1 or Form Y-2. Higher scores indicated greater anxiety (Spielberger et al., 1983).

A Pearson's Correlation was used in order to determine the strength and direction of association between baseline state and baseline trait anxiety scores prior to intervention with the lavender oil sniffer. Results from the test showed a strong, statistically significant positive

correlation between baseline state and baseline trait anxiety (r = .478, n = 45, p = .001), revealing that the greater the baseline trait anxiety, the more likely that there would also be a greater baseline state anxiety, and vice versa. (See Table 3).

Table 3

Pearson Correlation

Correlations

		Pre_State_Anxiety	Trait_Anxiety
Pre_State_Anxiety	Pearson Correlation	1	.478**
	Sig. (2-tailed)		.001
	N	45	45
Trait_Anxiety	Pearson Correlation	.478**	1
	Sig. (2-tailed)	.001	
	N	45	45

**. Correlation is significant at the 0.01 level (2-tailed).

In order to determine the effect of lavender oil on pre-operative anxiety levels in adult pre-operative patients, analytical statistics were performed and a Wilcoxon signed-rank test was used in order to determine the efficacy of the project intervention. It was originally thought that a paired t-test would be utilized for data analysis. However, during data analysis, it was discovered that not all of the data met the assumptions required for the paired t-test. Data analysis revealed that state anxiety prior to lavender oil was normally distributed. However, state anxiety post intervention with lavender oil was not normally distributed. (See Table 4). Based on these results, the paired t-test could not be utilized since it did not meet the criteria that all data needed to be normally distributed. In this way, a Wilcoxon signed-rank test was utilized since it is the nonparametric test equivalent to the paired t-test, and does not assume normality of the data, as is required for the paired t-test.

Table 4

Tests of Normality

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Pre_State_Anxiety	45	100.0%	0	0.0%	45	100.0%
Post_State_Anxiety	45	100.0%	0	0.0%	45	100.0%

Descriptives

			Statistic	Std. Error
Pre_State_Anxiety	Mean		39.51	1.870
	95% Confidence Interval for Mean	Lower Bound	35.74	
		Upper Bound	43.28	
	5% Trimmed Mean		39.15	
	Median		38.00	
	Variance		157.437	
	Std. Deviation		12.547	
	Minimum		20	
	Maximum		67	
	Range		47	
	Interquartile Range		20	
	Skewness		.273	.354
	Kurtosis		-.700	.695
Post_State_Anxiety	Mean		33.07	1.493
	95% Confidence Interval for Mean	Lower Bound	30.06	
		Upper Bound	36.08	
	5% Trimmed Mean		32.52	
	Median		32.00	
	Variance		100.336	
	Std. Deviation		10.017	
	Minimum		20	
	Maximum		60	
	Range		40	
	Interquartile Range		16	
	Skewness		.581	.354
	Kurtosis		-.142	.695

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Pre_State_Anxiety	.107	45	.200*	.962	45	.140
Post_State_Anxiety	.096	45	.200*	.948	45	.043

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

A Wilcoxon signed-rank test showed that lavender oil had a statistically significant effect in decreasing pre-operative anxiety levels in adult pre-operative patients (Z = -5.065, p = 0.001). In fact, the median state pre-operative anxiety score prior to intervention with lavender oil was 38.00, and decreased to 32.00 post intervention with the lavender oil. Furthermore, the mean state anxiety score prior to intervention with lavender oil score was 39.51, and decreased to 33.07 post intervention with lavender oil, all of which is statistically significant. (See Table 5).

Table 5

Wilcoxon Signed-Rank Test

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles 25th	50th (Median)	75th
Pre_State_Anxiety	45	39.51	12.547	20	67	30.00	38.00	49.50
Post_State_Anxiety	45	33.07	10.017	20	60	25.00	32.00	40.50

Wilcoxon Signed-Rank Test

Ranks

		N	Mean Rank	Sum of Ranks
Post_State_Anxiety - Pre_State_Anxiety	Negative Ranks	35[a]	22.47	786.50
	Positive Ranks	5[b]	6.70	33.50
	Ties	5[c]		
	Total	45		

a. Post_State_Anxiety < Pre_State_Anxiety
b. Post_State_Anxiety > Pre_State_Anxiety
c. Post_State_Anxiety = Pre_State_Anxiety

Test Statistics[a]

	Post_State_Anxiety - Pre_State_Anxiety
Z	-5.065[b]
Asymp. Sig. (2-tailed)	.000

a. Wilcoxon Signed Ranks Test
b. Based on positive ranks.

Sensitivity Analysis

A sensitivity analysis was also calculated in order to determine the significance of lavender oil on pre-operative anxiety levels in adult pre-operative patients when gender was taken into account. A Wilcoxon signed-rank test was also utilized and results were filtered in order to determine if there was significant effect on pre-operative anxiety levels in either males or females. With regard to adult males, the Wilcoxon signed-rank test showed that lavender oil had a statistically significant effect in decreasing pre-operative anxiety levels in this patient population (Z = -2.668, p = 0.008). With regard to females, the Wilcoxon signed-rank test also showed that lavender oil had a statistically significant effect in decreasing pre-operative anxiety levels in this patient population (Z = -4.305, p = 0.001). In this way, regardless of gender, results from this project revealed that lavender oil had a statistically significant effect in decreasing pre-operative anxiety levels in adult pre-operative patients. (See Table 6).

Table 6

Sensitivity Analysis

Males:

Wilcoxon Signed-Rank Test

Ranks

		N	Mean Rank	Sum of Ranks
Post_State_Anxiety - Pre_State_Anxiety	Negative Ranks	11[a]	7.59	83.50
	Positive Ranks	2[b]	3.75	7.50
	Ties	3[c]		
	Total	16		

a. Post_State_Anxiety < Pre_State_Anxiety
b. Post_State_Anxiety > Pre_State_Anxiety
c. Post_State_Anxiety = Pre_State_Anxiety

Test Statistics[a]

	Post_State_Anxiety - Pre_State_Anxiety
Z	-2.668[b]
Asymp. Sig. (2-tailed)	.008

a. Wilcoxon Signed Ranks Test
b. Based on positive ranks.

Females:

Wilcoxon Signed-Rank Test

Ranks

		N	Mean Rank	Sum of Ranks
Post_State_Anxiety - Pre_State_Anxiety	Negative Ranks	24[a]	15.33	368.00
	Positive Ranks	3[b]	3.33	10.00
	Ties	2[c]		
	Total	29		

a. Post_State_Anxiety < Pre_State_Anxiety
b. Post_State_Anxiety > Pre_State_Anxiety
c. Post_State_Anxiety = Pre_State_Anxiety

Test Statistics[a]

	Post_State_Anxiety - Pre_State_Anxiety
Z	-4.305[b]
Asymp. Sig. (2-tailed)	.000

a. Wilcoxon Signed Ranks Test
b. Based on positive ranks.

Discussion

Achievement of Objectives

The first objective was successfully met and pre-operative anxiety levels prior to and after the administration of lavender oil were measured in order to determine effect. In order to meet the second objective of the project, a total of two presentations will be given as outlined in the proposal in order to increase awareness of the nursing staff in the same day surgery unit of the project site regarding the effect of lavender oil on pre-operative anxiety.

Key Facilitators and Barriers

A major facilitator for the project included strong interest from key stakeholders, which included the director of nursing research, as well as the nurse manager, and staff nurses in same day surgery unit at the project site. Since lavender oil was already part of the standard of care at the project site, key stakeholders were interested to see if there was any effect with regard to the use of lavender oil in pre-operative anxiety levels in adult pre-operative patients. From their standpoint, this project was a practical measure in order to determine the effectiveness of the current practice of administration of lavender oil and its impact on pre-operative anxiety levels in adult pre-operative patients. Their interest in the results of the project helped to move the project to completion. In addition to this, support from the staff in the same day surgery unit also proved to be helpful, especially during project implementation and data collection. Support from the staff were instrumental in the project to help facilitate timely admission of the patient and to ensure that the PI had adequate time with the patient in order to implement the project and gather the necessary information. In this way, with great interest and support, the PI was able to reach the target goal of 45 subjects in a timely manner.

Barriers for the project included occasional interruption of the patient during the time that the lavender oil sniffer was administered to the patient. It was sometimes hard for the patient to just spend some time on their own with the lavender oil sniffer since there would be interruption with family coming in to see them, healthcare providers checking in on them, etc. Such interruptions made it difficult for patients to focus on the task at hand. In this way, a shorter time frame with the lavender oil sniffer may be considered for future projects in order to prevent such interruption. Furthermore, patients did not appreciate the length of questions presented on the STAI forms. A handful of patients complained that the questions were repetitive and felt the questionnaire to be too long. For future projects, the shorter version of the STAI form should be considered in order to address this common patient complaint.

Unintended Consequences

Just prior to the start of implementation at the project site, the PI was informed that project implementation needed to be completed by August since another project was to start at that time and the project site would not be able to accommodate both projects simultaneously. This fueled the need to complete project implementation in a timely manner in order to reach completion with regard to data collection by August. Despite this time constraint, project implementation was completed by mid-July and the target goal of 45 subjects was achieved.

Another consideration to be made is in regard to the project site and the possible influence of other factors in the result of the project. Since the same day surgery unit is not a controlled environment, there are other factors that may have played a role and should be considered when interpreting the results. For example, it was noted that calm and soothing instrumental music was playing in the background of the same day surgery unit. Also noted was that family presence was encouraged in the unit, and as a result, many patients had family in the

room with them when the lavender oil sniffer was administered. In this way, such variables should be considered in the results with regard to the significance of the effect of lavender oil in decreasing pre-operative anxiety levels in adult pre-operative patients.

Implications

Economic Impact

The increasing cost of healthcare comes as no surprise. Pre-operative anxiety is a common problem faced by many patients prior to a planned procedure, with a prevalence rate of as much as 80% in adult pre-operative patients (Fayazi et al., 2011). Such a state can be associated with physiologic responses such as nausea, sweating, elevated temperature, hypertension, and tachycardia, which can result in consequent need for more anesthesia during procedure, and places patients at higher risk for increased postoperative pain, resulting in higher consumption of analgesia (Wilson et al., 2016). In this way, pre-operative anxiety can increase the need for sedatives and analgesia, as well as potentially exacerbate pain, which is already widely known to be a significant health problem, and has an annual estimated cost to society of at least $560-635 billion (IOM, 2011; Wotman et al., 2017). Lavender oil is an essential oil that is used in aromatherapy and its properties make it a viable option as an alternative to traditional medicine as an anxiolytic therapeutic agent (Franco et al., 2016). Results from the project revealed that lavender oil had a statistically significant effect in decreasing pre-operative anxiety levels in adult pre-operative patients. This can translate to economic benefit to the project site and to reduction in the cost of healthcare in general with regard to the management of pre-operative anxiety in adult patients. Lavender oil's attributes include its ease of administration, low cost, and low adverse effect profile, thereby making it a viable option to reduce the amount

of sedatives and analgesics used, leading to reduced cost and decrease in the incidence of any negative adverse effects associated with the use of such agents prior to procedure (Braden et al., 2009; Franco et al., 2016; Wotman et al., 2017). In this way, the use of lavender oil in this manner can lead to economic benefit and decreased cost in healthcare.

Impact on Healthcare Quality and Safety

Advancement in healthcare requires commitment to a shared purpose in order to improve the health and functioning of the population. A healthcare system built around a core need to provide safe and effective care, for example, will be better able to meet patient needs, and thereby provide patients with care that is reliable, safe, and beneficial (IOM, 2001). There has been a growing need for alternative methods to help reduce pre-operative anxiety with minimal adverse effect to the patient. The WHO (2013) recognizes the positive contribution that alternative medicine can make to the health and well-being of patients, as well as its overall impact on the practice of traditional medicine. Aromatherapy is a form of complementary medicine that has grown in popularity and may offer an alternative approach to traditional medicine to help decrease pre-operative anxiety (Franco et al., 2016; Karaman et al., 2016). Traditionally, pharmacologic measures, such as sedatives, anxiolytics, and opioids have been utilized to help decrease pre-operative anxiety. However, these agents have been associated with multiple adverse effects, including restlessness, fatigue, and confusion, which can ultimately affect the patient's capacity to participate in their care (Wotman et al., 2017). Furthermore, these medications can adversely interact with anesthetic agents administered during procedure and can potentially lead to drowsiness and respiratory depression, further prolonging recovery and resulting in delay with patient discharge (Wilson et al., 2016). Results from this project have shown the benefit of lavender oil in the reduction of pre-operative anxiety levels in adult pre-

operative patients. This information can prove to be clinically significant and can translate to improved patient outcomes, safety, and improvement in the quality of healthcare. Lavender oil, with its properties, including ease of administration, low cost, and low adverse effect profile, make it a feasible alternative to traditional medicine as a therapeutic anxiolytic agent for pre-operative anxiety (Braden et al., 2009; Franco et al., 2016; Wotman et al., 2017).

Policy Implications

There is no better time than the present to call for a change in healthcare. This can be accomplished through the fostering of innovation, which could thereby lead to improvement in the delivery of care. Lavender oil presents a safe and economical alternative to traditional medicine in the management of pre-operative anxiety (Braden et al., 2009; Franco et al., 2016; Wotman et al., 2017). Both the literature and this project have shown the benefit of lavender oil in decreasing pre-operative anxiety levels in adult pre-operative patients (Braden, Reichow, & Halm, 2009; Fayazi et al., 2011; Franco et al., 2016; Hosseini, Heydari, Vakili, Moghadam, & Tazyky, 2016; Karaman et al., 2016; Perry, Terry, Watson, & Ernst, 2012; Trambert, Kowalski, Wu, Mehta, & Friedman, 2017; Wotman et al., 2017). In a report from the IOM regarding a new health system for the 21st century, one of the aims called for change in the healthcare environment, which would require change in the structure and processes of the environment in which healthcare professionals and organizations function, including change in policy (IOM, 2001). In this way, with the development of new evidence to inform practice, policies should therefore reflect the best evidence-based practice in order to achieve better patient outcomes (IOM, 2001).

Practice Implications

Change in the healthcare environment is no easy task, and part of the change that needs to occur lies in the application of evidence to healthcare delivery. Evidence has shown an average of 17 years before new knowledge is incorporated into practice. In order to rectify this, healthcare professionals need to take an active role in translating the evidence to practice for the improvement of healthcare (IOM, 2001). With regard to lavender oil, results from this project revealed that lavender oil had a statistically significant effect in decreasing pre-operative anxiety levels in adult pre-operative patients. This is supported by the literature, which also has shown the benefit of lavender oil in decreasing pre-operative anxiety levels in adult pre-operative patients (Braden, Reichow, & Halm, 2009; Fayazi et al., 2011; Franco et al., 2016; Hosseini, Heydari, Vakili, Moghadam, & Tazyky, 2016; Karaman et al., 2016; Perry, Terry, Watson, & Ernst, 2012; Trambert, Kowalski, Wu, Mehta, & Friedman, 2017; Wotman et al., 2017). In order to translate this knowledge to practice, the next step is to delineate practice guidelines with regard to the administration of lavender oil, design a proper care process, develop support tools to assist healthcare providers in applying the evidence-based practice, and continually evaluate and develop measures for assessing the quality of care (IOM, 2001). At the project site, lavender oil is already part of the standard of care and is used in conjunction with traditional pharmacologic measures to help reduce pre-operative anxiety in patients. Opportunity for improvement would be development of a system to continually measure and evaluate outcomes for the improvement of patient care. In this way, evidence-based practice may be used to achieve better patient outcomes.

Translation

Several studies support the use of lavender oil in the reduction of pre-operative anxiety in adult patients (Braden et al., 2009; Fayazi et al., 2011; Franco et al., 2016; Hosseini et al., 2016; Karaman et al., 2016; Perry et al., 2012; Trambert et al., 2017; Wotman et al., 2017). This project further elucidated the effect of lavender oil with results revealing a statistically significant effect of lavender oil in decreasing pre-operative anxiety levels in adult pre-operative patients. This can also translate to clinical significance when applied to practice. Due to its many attributes, including ease of administration, low cost, and low adverse effect profile, lavender oil can be viewed as beneficial in the pre-operative setting (Wotman et al., 2017). As mentioned, lavender oil is already part of the standard of care at the project site and is used in conjunction with traditional pharmacologic measures to help reduce pre-operative anxiety in patients. Improvement in this practice would be by way of continual measurement and evaluation of outcomes with regard to administration of lavender oil in order to improve delivery of care and improve patient outcomes.

Proper preparation of the workforce can also help to strengthen incorporation of evidence-based practice. It was noted at the project site that only certain staff nurses were allowed to administer lavender oil, since certification in administration of essential oils was required prior to administration of lavender oil to patients. Although a majority of nurses were certified to administer lavender oil to patients in the same day surgery unit, there were a few that were not certified. Based on the results of the project, in conjunction with supporting evidence in the literature, it would be to the benefit of patients at the project site if all nurses were encouraged to get certified in the administration of essential oils. Not only would this lead to improvement in pre-operative anxiety, but it would also lead to economic benefit, reduction in

the amount of sedatives and anxiolytics used, as well as offset any negative outcomes associated with the use of such drugs prior to procedure (Braden et al., 2009; Franco et al., 2016; Wotman et al., 2017). This translates to benefit not only for the project site, but to healthcare in general, and further highlights the importance of adequately training the workforce to improve healthcare. Change within the organization is necessary if there is to be growth and improvement (IOM, 2001). Continual emphasis of the importance of integrative medicine, teaching evidence-based practice, and providing multiple opportunities for certification in the administration of essential oils becomes priority in order to effect and maintain change within the organization. In addition, continual support for the use of lavender oil as evidenced by improved patient outcomes can help to preserve its use within the organization. As mentioned, development of a system to continually measure and evaluate outcomes for the improvement of patient care can help in this manner. In this way, use of evidence-based practice may lead to improvement in healthcare and better patient outcomes.

Dissemination

Project findings will be shared with Rutgers University, as well as to the public on January 14, 2019. A total of two presentations as outlined in the proposal will also be given at the project site in January. Dissemination of the project will be in the form of a DNP project poster and PowerPoint presentation to the stakeholders at the project site, Rutgers University, as well as to the public. Each presentation will be customized to the audience, with a focus on sharing the knowledge gained from the project, including the statistically significant results of lavender oil on decreasing pre-operative anxiety levels in adult pre-operative patients. Equally important to be included in all presentations will be the implications this project carries for

current practice, as well as for the future of healthcare. Further dissemination will be executed to ensure project recommendations are implemented according to requirements.

Professional Reporting

Presentation of findings to Rutgers University and the public will occur on January 14, 2019. The PI will present the project to the DNP committee to satisfy the curriculum requirement for completion of her DNP studies. Dissemination of the project will be in the form of a DNP project poster and PowerPoint presentation. In addition, the PI will present a poster at the Annual DNP Poster Presentation Day at Rutgers University April 15, 2019.

With regard to the project site, a total of two presentations will be shared at the project site in January 2019. Dissemination of the project will be in the form of a DNP project poster and PowerPoint presentation to the stakeholders at the project site. In addition, the PI is actively working to present her DNP project poster to an upcoming Annual Holistic Conference sponsored by the project site, scheduled for April 30, 2019. This will allow the PI to further disseminate results from the project regarding lavender oil and its statistically significant effect in decreasing pre-operative anxiety levels in adult pre-operative patients to experienced and aspiring holistic leaders, educators, and direct care nurses. Finally, the PI is actively developing a manuscript for submission to peer reviewed holistic nursing journals and other journals regarding complementary, alternative, and integrative medicine, such as *Holistic Nursing Practice: The Science of Health and Healing*.

Limitations

The design of the project was associated with certain limitations. Since the project was a quality improvement project, it was hard to control for variables in the setting. As mentioned,

since the same day surgery unit was not a controlled environment, there may have been other factors that may have played a role in the outcome of the project. For example, calm and soothing instrumental music played in the background at the project site. Also, family presence was encouraged in the unit, and many patients had family in the room with them when the lavender oil sniffer was administered. In this way, such variables may have played a role in the outcome of the project. Furthermore, since subjects knew that they were being administered lavender oil in the project, it was hard to blind them in this aspect, and patients may have had a preconceived bias of the effect of lavender oil.

Recommendations

Results from this project showed that lavender oil had a statistically significant effect in decreasing pre-operative anxiety levels in adult pre-operative patients. This is further supported by the literature in which several studies support the use of lavender oil in the reduction of pre-operative anxiety in adult patients (Braden et al., 2009; Fayazi et al., 2011; Franco et al., 2016; Hosseini et al., 2016; Karaman et al., 2016; Perry et al., 2012; Trambert et al., 2017; Wotman et al., 2017). Despite the limitations of the project, including lack of control and possible bias, findings from this project revealed that the current practice of administration of lavender oil in the project site had a statistically significant effect in the reduction of pre-operative anxiety levels in adult pre-operative patients. Such findings can also translate to clinical significance when applied to practice. Due to its many attributes, including ease of administration, low cost, and low adverse effect profile, lavender oil can be viewed as beneficial in the pre-operative setting (Wotman et al., 2017). Since lavender oil is already part of the standard of care at the project site and is used in conjunction with traditional pharmacologic measures to help reduce pre-operative anxiety in patients, sustainability would include change in policy to ensure that all

patients are offered lavender oil upon admission to the same day surgery unit, and that all nurses would be properly certified in order to administer lavender oil. Further improvement in this practice would be by way of continual measurement and evaluation of outcomes with regard to administration of lavender oil in order to improve delivery of care and improve patient outcomes.

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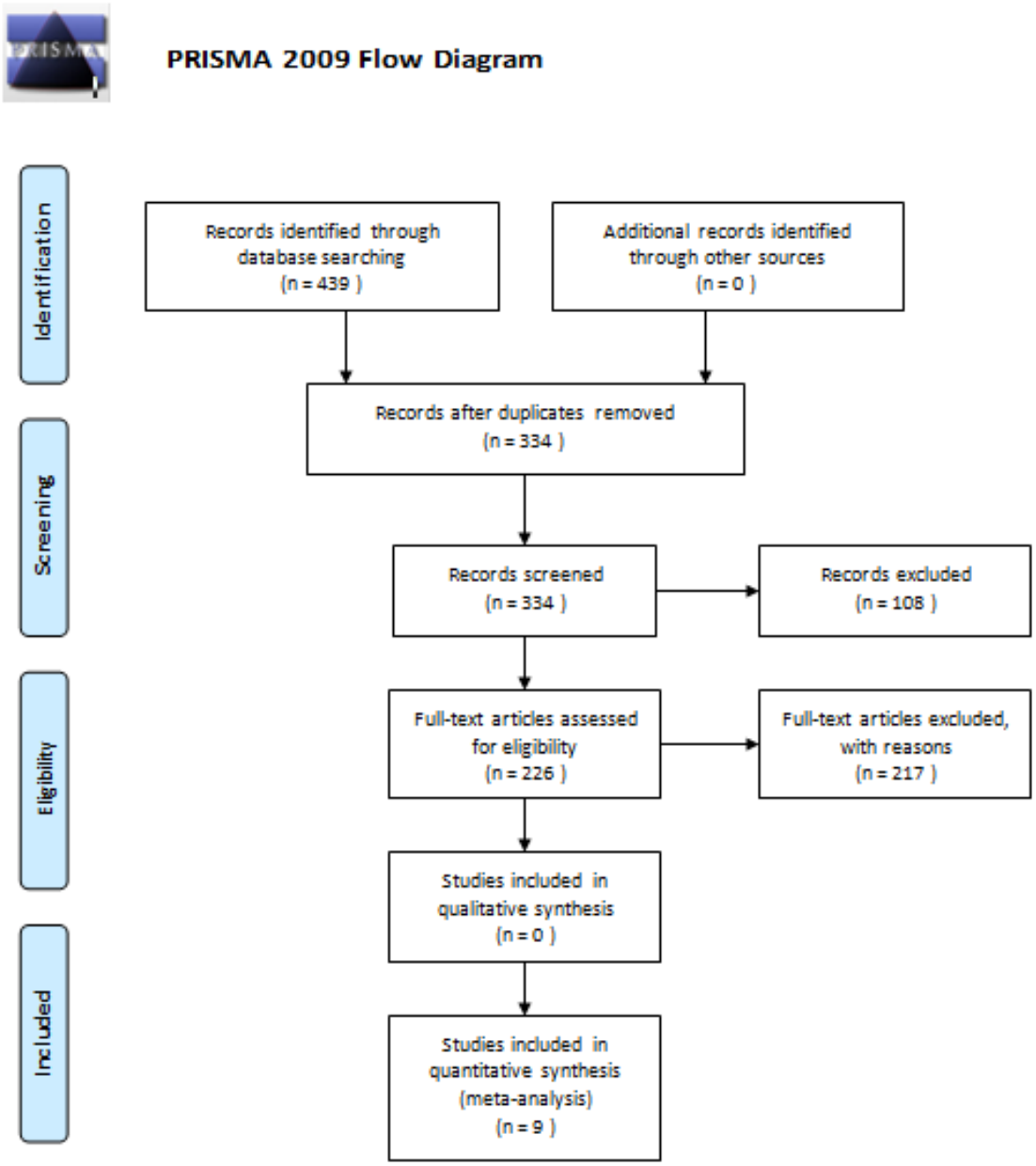
Appendix A

PRISMA Diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Appendix B

Table of Evidence

EBP Question: In adult pre-operative patients, will the administration of lavender oil lead to decreased STAI scores?

Article	Author, Date	Evidence Type	Sample, Sample Size, Setting	Study Findings that help answer EBP question	Limitations	Evidence Level & Quality
#1	Braden, R., Reichow, S., & Halm, M. A. (2009)	Prospective experimental study with pretest/posttest design	Convenience sample of 150. 50 Adult patients were randomly assigned to one of three groups: 1. control (standard care) 2. experimental (standard care plus essential oil lavandin) 3. sham (standard care plus jojoba oil) groups Midwestern tertiary medical center that performs approximately 9,700 inpatient and outpatient surgeries yearly.	Lavandin was associated with significantly lower anxiety on OR transfer, suggesting that it is a simple, low-risk, and cost effective intervention.	Convenience sample limits generalizability of the findings to larger populations undergoing surgery. Sample was not ethnically diverse. Intervention not tested in cognitively impaired patients. Findings may not be applied in these populations.	Research Level I Quality: Good
#2	Fayazi, S., Babashahi, M., & Rezaei, M.	Experimental clinical trial study	N=72 Purposive sampling	Inhalation aromatherapy had positive	Small sample size limits generalizability	Research Level I

	(2011)		Qualified patients were randomly divided into one of two groups: 1. inhalation aromatherapy 2. placebo inhalation 36 subjects for each group Patients were candidates for thorax and abdominal surgery and admitted in Golestan and Imam Khomeini hospitals in Ahvaz in Iran	effects on reducing anxiety in patients before the surgery. Experimental group: mean level of anxiety before the intervention was 51.00 and decreased to 38.61 after intervention. Independent t-test showed no significant statistical difference in both groups before the intervention; however, after the intervention both groups had a significant statistical difference ($p = 0.001$).	of the findings to larger populations Limited to Persian speaking patients. Sample was not ethnically diverse. Intervention not tested in cognitively impaired patients. Findings may not be applied in these populations.	Quality: Good
#3	Franco, L., Blanck, T. J. J.,	Randomized controlled trial	N=93 women enrolled;	LFO therapy was statistically	Possible placebo effect	Research

	Dugan, K., Kline, R., Shanmugam, G., Galotti, A., . . . Wajda, M. (2016)		2 withdrew; 1 removed from the study Randomization was updated to accommodate the loss of these patients 90 patients completed the study and were randomized into one of two groups: 1. lavender fleur oil (LFO) 2. Unscented oil (UO) 45 patients for each group; subjects were blind to their assigned treatment. Study conducted in the preoperative holding area of the ambulatory surgery	significant at improving a sense of well-being compared with UO. LFO had a stronger effect compared with UO in 8/10 positive questions and 2/10 negative questions. Both treatments were equally effective in decreasing negative attitudes and decreasing anxiety prior to breast surgery.	Lack of blinding of research coordinators Since lavender has a distinct odor, it is uncertain whether the subjects were truly blind to the treatment. The study only included female patients undergoing breast surgery. Therefore, the study cannot account for the effect of either LFO or UO on male subjects.	Level I Quality: High

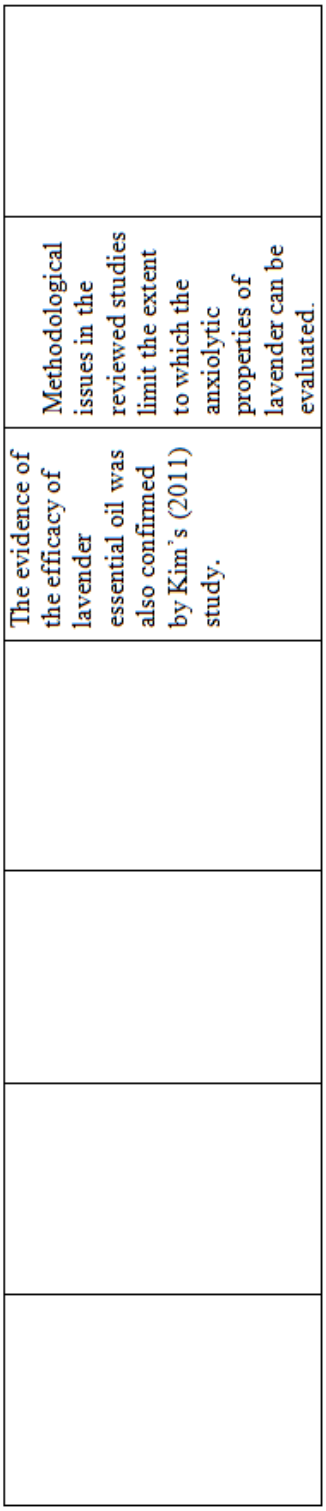
#4	Hosseini, S., Heydari, A., Vakili, M., Moghadam, S., & Tazyky, S. (2016)	Single-blind randomized clinical trial study	department of NYU Langone Medical Center. N=90 Random allocation of qualified patients into one of two groups: 1. Control (distilled water) 2. Intervention (lavender) 45 subjects for each group Type of essence was unknown for the patients Study was conducted in candidates for open heart surgery in Amir-al-Momenin Hospital in Kord Kouy in Iran	Inhalation of lavender could reduce the level of anxiety and cortisol in open-heart surgery patients before surgery. Overt and general anxiety levels significantly diminished in the intervention group Paired *t*-test showed a higher reduction in mean anxiety score in the study group compared to control [2.00 (1.26) vs. 1.11 (1.17); $p <$ 0.0001], which is significant.	Small sample size limits generalizability of the findings to larger populations Limited to Persian speaking patients. Sample was not ethnically diverse. Intervention not tested in cognitively impaired patients. Findings may not be applied in these populations. Lack of blinding of research coordinators	Research Level I Quality: Good
#5	Karaman, T.,	Prospective,	N=106 patients	Anxiety scores	Study could not	Research

	Karaman, S., Dogru, S., Tapar, H., Sahin, A., Suren, M., . . . Kaya, Z. (2016)	randomized, single-blind, parallel-group, placebo-controlled study	enrolled in the study Random allocation of qualified patients into one of two groups: 1. Control 2. Lavender 53 patients for each group After enrollment, 2 patients in the lavender group and 3 patients in the control group were excluded due to protocol violations. Study was conducted in patients scheduled for elective surgery at the Gaziosmanpasa University School of Medicine Hospital	in the lavender group were significantly lower than the control group (pure water placebo; $p < 0.001$). After cannulation, the pain and anxiety scores of the patients in the lavender group were significantly lower than the control group ($p=0.01$ for pain scores; $p < 0.001$ for anxiety 2 scores) Satisfaction of patients that received aromatherapy with lavender essential oil was significantly improved.	be conducted as a double-blind study due to the distinct odor of the lavender oil. Patients in the lavender group could not be truly blind to the use of lavender since it has a distinct odor.	Level I Quality: High
#6	Perry, R., Terry,	Systematic	7 electronic	7 trials showed	Methodological	Research

	R., Watson, L. K., & Ernst, E. (2012)	review	databases were searched to identify all relevant studies. 15 RCTs met inclusion criteria Included studies were published between 1995-2010, originated from 6 countries and were all written in English. Sample sizes ranged from 16 to 340. All methods of lavender administration were included. Data extraction and the assessment of the methodological quality of all included trials were conducted by two independent reviewers.	results appearing to favor lavender intervention for at least one relevant outcome. One comparative trial found that lavender was as effective as lorazepam. Results from the remaining studies suggest limited specific effects of lavender inhalation and massage on anxiety measures.	issues in the reviewed studies limit the extent to which the anxiolytic properties of lavender can be evaluated. Some clinical trials appropriate for review may have been missed despite thorough search strategy.	Level I Quality: High

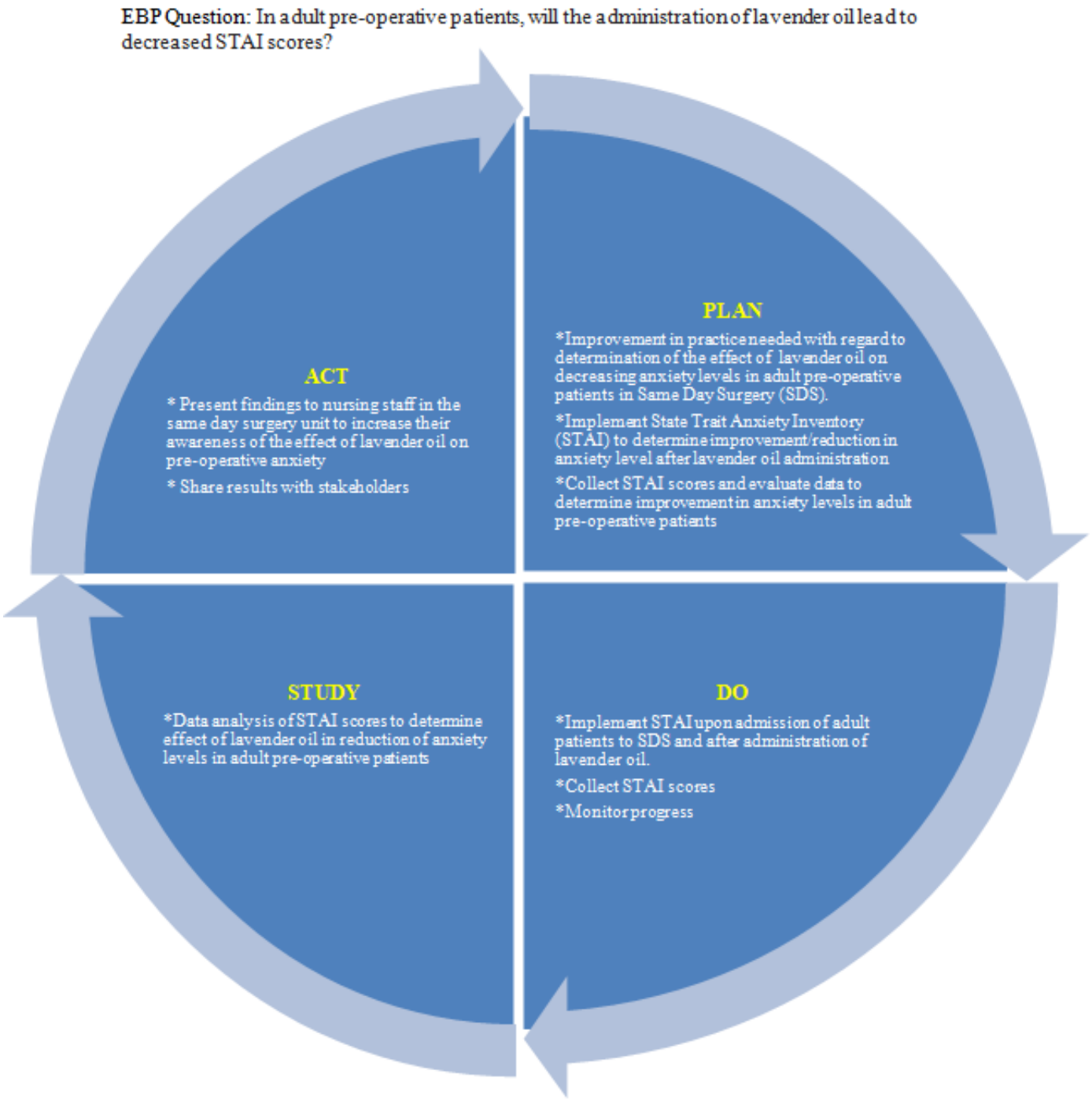
#7	Trambert, R., Kowalski, M. O., Wu, B., Mehta, N., & Friedman, P. (2017)	Randomized, placebo-controlled study	N= 87 women Random allocation of qualified patients into one of three groups: 1. Control (28 women) 2. Lavender-sandalwood (30 women) 3. Orange-Peppermint (30 women) Study was conducted in women undergoing image-guided core needle biopsy for suspicion of breast cancer at Morristown Medical Center.	Linear regression analysis indicate that lavender-sandalwood aromatherapy is statistically significant at reducing anxiety ($p = .032$) compared with placebo use. Lavender-sandalwood also exhibited a significant difference compared with orange-peppermint ($p = .038$) in reduction of anxiety.	Small sample size Sample was not ethnically diverse and did not include males. Patients in the lavender group could not be truly blind to the use of lavender since it has a distinct odor.	Research Level I Quality: Good
#8	Wotman, M., Levinger, J., Leung, L., Kallush, A., Mauer, E., & Kacker, A. (2017)	Prospective and controlled pilot study	Convenience sample of 100 patients. 50 patients in the control group (no aromatherapy)	Welch's two sample t-test revealed the mean reduction in anxiety was statistically greater in the	Experimental and control groups were non-blinded, allowing for the possibility of a placebo effect to	Research Level II Quality: Good

			and experimental group (lavender). Control group (22 females; 28 males) Experimental group (26 females; 24 males) Study was conducted in patients who were admitted to New York Presbyterian/ Weill Cornell Medical Center for ambulatory surgery from 01/15-08/15.	experimental group than the control group ($p = 0.001$). Majority of the subjects reported that they felt calmer with the intervention and found the lavender scent pleasant.	have influenced the results. Sample size small and non-randomized Convenience sample is subject to selection bias and may limit the generalizability of the results.	
#9	Stea, S., Beraudi, A., & De Pasquale, D. (2014)	Literature Review	14 studies included in literature review with regard to essential oils and preoperative anxiety (9 studies included lavender; 5 studies did not involve lavender).	Braden's (2009) study results indicate that the lavandin group showed significantly lower anxiety during operating room transfer.	Limited literature review and lack of rigorous research appraisal may bias results and limit generalizability of findings.	Non-research Level V Quality: Good


The evidence of the efficacy of lavender essential oil was also confirmed by Kim's (2011) study.
Methodological issues in the reviewed studies limit the extent to which the anxiolytic properties of lavender can be evaluated.

Appendix C

Conceptual Framework



Appendix D

Subject Recruitment Handout

RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

Are you scheduled for a surgical procedure?

Looking for willing participants to take part in a quality improvement project to determine the effect of lavender oil on anxiety levels in adult pre-operative patients.

Eligibility criteria include but are not limited to:

- Men or women 18 years of age or older
- Speak English
- Present in the same day surgery unit and scheduled for an operative procedure
- Willing to receive a lavender oil sniffer

Total duration of the project will take approximately 30 minutes to complete.

Participation is voluntary and is of no cost to you. There will be no compensation for participation in the project. You may withdraw at any time without penalty. Decision whether or not to participate in the project, or withdrawal from the project, will not impact usual care provided or result in loss of benefits to which you are otherwise entitled.

For any questions or concerns, please contact Gertrude Y. Figueroa, principal investigator, at 973-986-0541 or email: gfiguero@sn.rutgers.edu.

Version 1. 04/04/18

Appendix E

Consent Form

CONSENT FORM

Title: Evaluating the Effect of Lavender Oil on Anxiety Levels in Adult Pre-Operative Patients

Protocol No.:	N/A
Sponsor:	The Valley Hospital
Principal Investigator:	Gertrude Y. Figueroa
Email:	gfiguero@sn.rutgers.edu
Daytime Phone Number:	973-986-0541

You are being invited to take part in a quality improvement project. A person who takes part in a quality improvement project is called a subject.

What should I know about this project?

- Someone will explain this project to you.
- Taking part in this project is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you do not understand, ask questions.
- Ask all the questions you want before you make a decision.

Why is this project being done?

The overall aim of the project is to determine the effect of lavender oil on anxiety levels in adult pre-operative patients.

Who may take part in this project and who may not?

Men and women 18 years of age or older who are alert, oriented, and can read, write, speak English, and who are admitted to the same day surgery unit and willing to receive lavender oil prior to their operative procedure may participate in the project.

Men and women who are allergic to lavender, those who wear perfume or after-shave on the day of surgery, have a history of asthma or impaired sense of smell, and those patients who took anti-anxiety medication or pain medication prior to admission to the same day surgery unit will be excluded from participation in the project. Patients who are pregnant, breastfeeding, or cognitively impaired will also be excluded from participation.

How long will the project take and how many subjects will take part?

The project will take approximately 30 minutes to complete for each subject. A total of 45 subjects will participate in the project, which will take place over the course of three months.

What will I be asked to do if I take part in this project?

Once informed consent has been signed, each subject will be asked to fill out the STAI Form Y-1 and STAI Form Y-2. Subjects will be given 10 minutes to complete both forms. After completion of the forms, each subject will be given a lavender oil sniffer and will be instructed to periodically waft the sniffer through both nostrils for about 10 minutes. Afterwards, the subject will complete another STAI Form Y-1 after intervention with the lavender oil sniffer. The subject will be given five minutes to complete this form. This will complete the subject's participation in the project.

Could being in this project hurt me?

Potential risks associated with participation in the project may include feelings of discomfort that may occur when subjects inhale the lavender oil. If subjects feel any discomfort and no longer wish to continue with the project, they may choose to withdraw at any time without penalty.

Also, questions asked in the STAI may cause subjects to think about feelings of being anxious or upset. In these instances, subjects can choose to withdraw from the project at any point without any penalty. There is also a small possibility that personal information collected may be inadvertently shared by participating in the project. In order to resolve this issue, names and any personal information necessary for this project will be collected and assigned a number. This will allow for the data to be reviewed without direct link to the subject's name. Only the principal investigator will have access to the master list linking the subject's name to the number associated with the data. Since there is no anticipated major risk for participants in this project, risk to participants is minimal.

Will it cost me money to take part in this project?

There will be no cost to you to take part in this project.

Will being in this project benefit me?

The benefits of taking part in this project may be improvement or feeling of decreased pre-operative anxiety. However, it is possible that you may not receive any direct benefit from taking part in this project.

What other choices do I have besides taking part in this project?

There are no alternative treatments available. Your alternative is not to take part in this project.

What happens to the information collected for this project?

All efforts will be made to keep your personal information confidential. Subjects will be provided with an ID number by the principal investigator to use on both the data collection and data analysis. Any names and personal information necessary for this project will be collected and assigned a number. This will allow data to be reviewed without direct link to the subject's name. Only the principal investigator will have access to the master list linking the subject's name to the number associated with the data. Data will be de-identified as soon as possible after data are transcribed and verified for accuracy. Only de-identified data will be used for analysis. Completed surveys will be stored in a locket cabinet only accessible by the principal investigator, and separate from the master list linking the subject's name to the number associated with the data. Data analysis will be done by the principal investigator and results will be stored on a USB flash drive that will be password protected, encrypted, and stored in a locked cabinet. Only the principal investigator will maintain the key to the locked cabinet and have access to the data. Upon completion of the project, closure of the IRB, and final writing of the manuscript, all data will be destroyed in accordance with Rutgers University guidelines. Hard copies of consents and aggregate data will be housed in Dr. Helen Miley's office at Rutgers University, 65 Bergen Street, Newark, NJ 07107 in room 1115.

Who can answer my questions about this project?

If you have questions, concerns, complaints, or think this project has hurt you or made you sick, talk to the principal investigator at the phone number listed above on the first page.

This quality improvement project is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concems, or complaints that are not being answered by principal investigator.
- You are not getting answers from the principal investigator.
- You cannot reach the principal investigator.
- You want to talk to someone else about the project.
- You have questions about your rights as a subject.

What happens if I agree to be in this project, but I change my mind later?

It is your choice whether to take part in the project. You may choose to take part, not to take part, or you may change your mind and withdraw from the project at any time.

During the course of the project, you will be updated about any new information that may affect whether you are willing to continue taking part in the project.

If you do not want to enter the project or decide to stop taking part, you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Gertrude Y. Figueroa at gfiguero@sn.rutgers.edu.

Will I be paid for taking part in this project?

You will not be paid to take part in this project.

Statement of Consent:

Your signature documents your consent to take part in this project.

Signature of adult subject capable of consent	Date
Signature of person obtaining consent	Date

Appendix F

State-Trait Anxiety Inventory for Adults: Forms Y-1 and Y-2 (STAI-AD)

SELF-EVALUATION QUESTIONNAIRE STAI Form Y-1
Please provide the following information:

Name_____ Date_____ S_____
Age_____ Gender (*Circle*) **M** **F** T_____

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
1. I feel calm	1	2	3	4
2. I feel secure	1	2	3	4
3. I am tense	1	2	3	4
4. I feel strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am presently worrying over possible misfortunes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I am jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

SELF-EVALUATION QUESTIONNAIRE

STAI Form Y-2

Name_____ Date_____

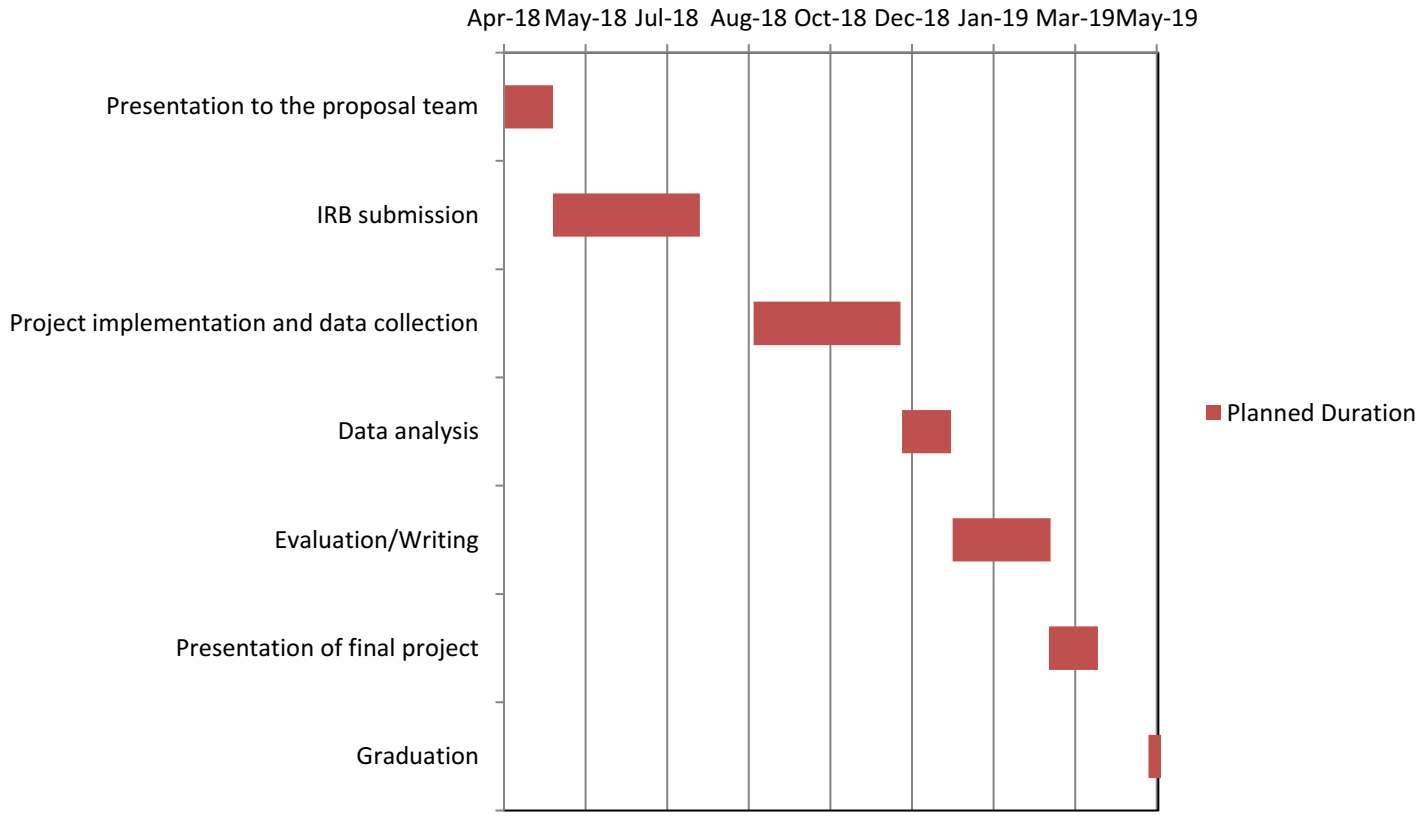
DIRECTIONS

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you *generally* feel.

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
21. I feel pleasant	1	2	3	4
22. I feel nervous and restless	1	2	3	4
23. I feel satisfied with myself	1	2	3	4
24. I wish I could be as happy as others seem to be	1	2	3	4
25. I feel like a failure	1	2	3	4
26. I feel rested	1	2	3	4
27. I am "calm, cool, and collected"	1	2	3	4
28. I feel that difficulties are piling up so that I cannot overcome them	1	2	3	4
29. I worry too much over something that really doesn't matter	1	2	3	4
30. I am happy	1	2	3	4
31. I have disturbing thoughts	1	2	3	4
32. I lack self-confidence	1	2	3	4
33. I feel secure	1	2	3	4
34. I make decisions easily	1	2	3	4
35. I feel inadequate	1	2	3	4
36. I am content	1	2	3	4
37. Some unimportant thought runs through my mind and bothers me	1	2	3	4
38. I take disappointments so keenly that I can't put them out of my mind	1	2	3	4
39. I am a steady person	1	2	3	4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests	1	2	3	4

Appendix G

GANTT Chart



Appendix H

Budget

Expense	Cost	Total Cost
Subject Recruitment Handouts	$ 0.15 x 45 copies	$6.75
STAI Manual	$50	$50.00
License to Reproduce STAI-AD	$2.50 x 50 copies	$125.00
Binding of Final Project	$50 x 5 copies	$250.00
Dissemination Posters	$75	$75.00
Total Budget		$506.75