

Protocol Title: Does Aromatherapy Improve Mood and Reduce Pain in Women with Scheduled Cesarean Procedures?

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Population: Scheduled cesarean section patients at Memorial Hermann Memorial City Hospital

Number of Sites: Memorial Hermann Memorial City Hospital

Study Duration: State duration of study: 2 Years

Subject Duration: Intervention: Pre-admit testing to discharge (3-6 days in total)

General Information

Aromatherapy presents a patient-centered approach to care, offering complementary methods to improve relaxation, comfort, and sleep. Historically, essential oils have been used to alleviate pain, anxiety, stress, and insomnia, particularly during pregnancy, labor, and postpartum period. This technique is cost-effective and has minimal side effects.

This randomized controlled study investigates the effects of lavender sandalwood aromatherapy tabs on women undergoing planned cesarean sections.

The study aims to assess changes in mood, pain levels, and overall patient satisfaction. Emotional states will be evaluated using the Positive and Negative Affect Schedule (PANAS), while pain levels will be measured with the Defense and Veterans Pain Rating Scale (DVPRS). Patient satisfaction will be assessed using patient experience survey scores and Net Promoter Scores, providing insight into the effects of aromatherapy on the well-being and recovery of patients undergoing cesarean section.

Background Information

Historical Context

The practice of aromatherapy has a history spanning thousands of years, with evidence of its use in ancient civilizations such as Egypt, China, and India dating back over 6,000 years (Ali et al., 2015). Greek physicians, such as Hippocrates, also relied on aromatic plants for therapeutic applications, emphasizing their benefits in treating various ailments (Hedigan, Sheridan, & Sasse, 2023). Over centuries, plant

derived essential oils were recognized for their ability to support both physical and psychological wellness.

Modern inhalation aromatherapy is grounded in the interaction between essential oil molecules and the olfactory and respiratory systems. When inhaled, these molecules stimulate olfactory nerves, which in turn activate specific regions of the brain, such as the limbic system, responsible for regulating emotions, stress, and pain. Neurochemical responses triggered by essential oils, like lavender, lead to the release of neurotransmitters such as serotonin and dopamine, enhancing mood and alleviating discomfort (Vora et al., 2024).

Aromatherapy in General Health Care Settings

Across health care settings, aromatherapy is used as a complementary intervention to promote comfort, relaxation, sleep, and symptom relief. Evidence suggests it may help reduce anxiety, nausea, and pain when used alongside standard care (Farrar & Farrar, 2020; Lakhan, Sheaffer, & Tepper, 2016). Lin et al. (2021) found that inhaled aromatherapy supported autonomic nervous system regulation during acute stress and specifically evaluated sandalwood and a sandalwood-lavender blend. These findings support evaluating lavender sandalwood aromatherapy tabs as a low-risk adjunct for postoperative pain, stress, and sleep disruption after cesarean delivery.

Lavender's active compounds, linalool and linalyl acetate are particularly noteworthy for their calming and analgesic properties (Ali et al., 2015). Research has shown that lavender essential oil modulates both peripheral and central nervous activity to deliver anxiolytic and anti-stress effects (Caballero-Gallardo et al., 2025). This deep-rooted mechanism positions lavender as a potent agent in promoting relaxation and pain relief.

Aromatherapy and Peripartum Care

Aromatherapy has shown results in reducing stress and anxiety in obstetric patients. Research indicates that using essential oils, particularly lavender, can positively influence health outcomes during the antepartum, intrapartum, and postpartum periods. For example, a systematic review by Bertone and Dekker (2021) highlighted the effectiveness of lavender oil in alleviating pain during labor and post cesarean recovery. Similarly, studies conducted by Hadi and Hanid (2011) demonstrated a decrease in pain levels among cesarean-section patients using lavender aromatherapy. Lavender and sandalwood essential oils are also known for their anxiolytic properties (Caballero-Gallardo, Quintero-Rincón, Olivero-Verbel, 2025). Furthermore, a systematic review by Tabatabaeichehr and Mortazavi (2020) emphasized that aromatherapy involving lavender significantly reduced labor pain and anxiety.

Enhancing emotional well-being and pain relief after cesarean sections is vital to improving health outcomes for both mothers and newborns. Incorporating complementary therapies like aromatherapy into standard medical practices provides a holistic approach to effectively addressing these critical needs.

Risk and Benefit Assessment

Potential Risks

The Beekley Medical Lavender Sandalwood Aromatabs Safety Data Sheet (2020) serves as the primary source for risk information, identifying eye irritation, skin irritation and skin allergic reactions as side effects. Individuals with a history of multiple allergies should be carefully monitored for possible cross-reactivity or intolerance. According to Antonelli and Donelli (2020), adverse effects associated with aromatherapy are rare, typically limited to skin sensitivity and allergic responses. However, the safety profile of aromatherapy is not comprehensively reported in the literature, with some studies failing to mention adverse events or lacking detailed safety data. This underscores the importance of ongoing vigilance and thorough documentation when implementing aromatherapy interventions in clinical settings.

There are no anticipated social, legal, or economic risks, and overall risk remains low with proper screening and use.

This protocol does not include benefits from alternative procedures; the current intervention is considered minimal risk. If a participant shows signs of sensitivity or an adverse reaction to the aromatherapy intervention, use of the lavender sandalwood aromatabs will be discontinued, and the participant will receive standard care.

Potential Benefit

Aromatherapy using lavender sandalwood essential oils as an adjunct to standard post-cesarean care offers several benefits for women after planned cesarean sections. Physically, clinical studies demonstrate that aromatherapy may contribute to improved pain management, with reductions in perceived pain intensity and opioid consumption, thereby supporting enhanced comfort and facilitating early postoperative mobility (Ali et al., 2015; Vora et al., 2024). Lin et al. (2021) found that sandalwood and sandalwood-lavender aromatherapy supported autonomic nervous system regulation during acute stress, providing physiologic support for its potential role in stress recovery. Psychologically, exposure to lavender scents has been associated with decreased anxiety, improved mood, and greater emotional well-being, which can positively influence recovery, patient satisfaction, and overall birth experience (Hedigan, Sheridan, & Sasse, 2023; Caballero-Gallardo et al., 2025). Socially, participants may benefit from increased satisfaction with care and a sense of empowerment in their recovery journey, potentially reducing the risk of postpartum depression and fostering stronger mother-infant bonding. While no legal or economic benefits have been directly attributed, the broader societal impact included potential reductions in healthcare utilization and enhanced quality of life for new mothers.

Hypothesis

The hypothesis to be tested in this study is that women undergoing planned cesarean deliveries who receive aromatherapy with the lavender sandalwood essential oil will experience greater improvement in mood, reduced pain levels, and enhanced patient satisfaction compared to those receiving standard care alone. This hypothesis aligns with the study rationale and objectives, which focus on evaluating the impact of aromatherapy on positive and negative affect, pain relief, and overall patient experience during the post-cesarean recovery period.

Study Objectives

The primary aim of this research is to evaluate the impact of aromatherapy on mood, pain relief, and patient satisfaction in women undergone planned cesarean deliveries.

The specific research questions include:

- Do women after planned cesarean sections, who are exposed to aromatherapy, report greater improvements in positive affect (measured by PANAS-P) compared to those who are not?
- Do women after planned cesarean sections, who experience aromatherapy, report reduced negative affect (measured by PANAS-N) compared to women who do not receive aromatherapy?
- Do women after planned cesarean sections, who are exposed to aromatherapy, report lower pain levels (measured by the DVPRS), compared to women who do not receive aromatherapy?
- Do women who experience aromatherapy post-cesarean section report enhanced patient experience (measured by net promoter scores (NPS) or patient satisfaction scores) compared to those who are not exposed to aromatherapy?

OBJECTIVES	OUTCOME MEASURES (a.k.a. ENDPOINTS) Include TIMEPOINTS for each Outcome Measure
Primary	
To determine if aromatherapy influences mood of women after cesarean section surgery.	Mood is measured by the Positive and Negative Affect Schedule (PANAS) at 24 hour and 48 hours after surgery.
Secondary	
To determine if aromatherapy influences pain among women who had cesarean section surgery.	Pain as measured by The Defense and Veterans Pain Rating Scale (DVPRS), at 24 hours (± 4 hours) after surgery, and again at 48 hours post-surgery or prior to discharge (± 4 hours, or at the last recorded pain score before discharge).
Tertiary/Exploratory	

To determine if aromatherapy influences patient experience.	Patient experience as measured by the Qualtrics adult survey – Net promoter score. Surveys are electronically sent after the patient has been discharged and responses are accepted up to 2 weeks after the link is sent out.
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Significance

Aromatherapy has long been employed as a method to alleviate pain and anxiety in obstetric patient populations, but its application in postpartum care following planned cesarean sections remains underexplored. This study seeks to bridge that gap by evaluating the benefits of lavender aromatherapy tabs on mood, pain, and patient satisfaction. The study is significant because it examines the broader impact of aromatherapy beyond isolated variables, offering insights into its potential to address multiple dimensions of postpartum recovery. This includes reducing negative emotional states, enhancing positive moods, relieving pain, and fostering greater patient satisfaction.

Unlike previous research conducted in other countries using essential oil-soaked cotton balls or diffusers, this study utilizes Elequil Aromatabs, which are 100% pure and undiluted, delivering consistent therapeutic exposure for 24 hours per tab (Beekley Medical, 2025). This approach not only avoids the messiness and inconsistency of traditional methods but also ensures measurable and replicable outcomes.

By using PANAS for mood assessment, DVPRS for pain levels, and patient satisfaction scores, the study establishes a framework for measuring its effectiveness. The findings have the potential to inform clinical practices and highlight aromatherapy as a viable treatment option to enhance postpartum care and recovery.

Study Design

The study employs a randomized controlled design to evaluate the effects of aromatherapy on mood and pain in postpartum patients following planned cesarean deliveries. A consecutive sampling method, a type of non-probability sampling, is used to recruit participants who meet the inclusion criteria.

The randomized controlled trial evaluates the impact of Lavender Sandalwood Elequil Aromatabs on mood, pain, and patient satisfaction in postpartum patients after planned cesarean deliveries. Participants are assigned to either an intervention group receiving lavender aromatabs or a control group receiving standard care. Each lavender aromatab has customizable scent intensity and is applied for a 24-hour period. Baseline assessments are performed, followed by intervention and monitoring. Outcome measures—including mood, pain, and satisfaction—are collected during the hospital stay and via follow-up electronic surveys up to two weeks post-discharge.

Scientific Rational for Study Design

The study utilizes a superiority randomized controlled design to evaluate the effects of aromatherapy on mood, pain, and patient satisfaction in postpartum patients following planned cesarean deliveries. By comparing an intervention group receiving Elequil Lavender Sandalwood Aromatabs to a control group receiving standard care without aromatherapy, the design enables differentiation of the therapeutic impact of the aromatherapy intervention on outcomes such as mood and pain. Randomization reduces selection bias and helps ensure the groups are comparable.

Rationale for Dose

Lavender Sandalwood Elequil Aromatabs provide standardized dosing, consistent administration, and procedural safety. Each Aromatab contains a premeasured amount of lavender sandalwood essential oil, which helps ensure that each participant receives the same intended dose and reduces variation that could occur with manual preparation or delivery. The marked tear points support consistent administration by allowing participants to select either minimal or maximum scent exposure in a controlled and repeatable manner. The tabs release vapor steadily over time and are placed within the participant's breathing zone. Because they are hands-free, device-free, and require no skin contact, Aromatabs are easy to use and may lower the risk of skin irritation.

Study Population

The study population consists of scheduled cesarean section patients at the Women's Department of Memorial Hermann Memorial City Hospital. To achieve 80% statistical power, a sample size of 91 patients per group is required, accounting for a 30% attrition rate.

Inclusion Criteria

Eligible participants are those scheduled for cesarean section, identified during pre-admission testing, and admitted to the postpartum unit after delivery.

Exclusion Criteria

Individuals will be excluded from the study if they have a known allergy to lavender essential oil, are admitted to the labor and delivery unit before their scheduled cesarean section, are not admitted to the postpartum unit, have a newborn requiring NICU admission, or are younger than 18 years of age.

During recruitment, trained research team members identify eligible participants during pre-admission testing sessions by screening patients against the study's inclusion and exclusion criteria. Participants who meet these criteria are approached in a relaxed setting, where the study is explained and informed consent is obtained by a member of the research team. The consent process emphasizes that participation is voluntary and that withdrawing from the study will not affect their care.

All screen failures will be documented in a secure log, including the specific eligibility criterion not met and any other relevant details. Individuals who do not meet eligibility requirements during the initial screening will not be re-screened. Participants who meet exclusion criteria after delivery will be

excluded from the study. Once a screen failure is confirmed, the participant will be excluded from further study participation.

Withdrawal Criteria

Reasons for discontinuing the study intervention or product include a participant's voluntary withdrawal at any point in the study, adverse reactions, or unforeseen medical circumstances that make continued participation inappropriate. Because the study involves minimal risk, oversight by a Data and Safety Monitoring Board (DSMB) is not required. The study has been submitted to the U.S. Food and Drug Administration (FDA), which has exercised enforcement discretion based on the study's minimal risk. Any discontinuation and the reason for it will be documented in the Excel log.

Subject Replacement

Subjects who withdraw from the study will not be replaced; their vacancies will remain, and no new participants will be enrolled. This policy preserves randomization and prevents bias. The attribution rate is included in the sample size calculation. Data collected up to withdrawal will be analyzed as per protocol, and all reasons and numbers for discontinuation will be documented.

Randomization

A computer-generated randomization sequence was created in Microsoft Excel to assign participants to either control or experimental group in a 1:1 ratio. Each participant will receive a study identification number corresponding to the pre-generated group assignment to ensure unbiased allocation.

Study Procedures

Preadmission Visit

Everyone who is scheduled for Cesarean Sections comes to the Pre-Admit Testing one to three days prior to the scheduled surgery. During the pre-admission visit, members of the research team who are trained in obtaining informed consent will invite patients to participate in the study. Patients will be approached in relaxed and comfortable settings, where the process the consent forms for review and sign. The research team members will go over the form in detail, emphasizing that participation is entirely voluntary and that withdrawing will not impact on the quality of care they receive during their hospital stay.

In this study, attending physicians will not be individually notified when their patients are enrolled in the research trial. Instead, department leaders and the principal investigator will provide general advance notification to physicians that their patients may be approached for study participation. Recruitment and consent procedures are carried out independently by a member of the study team during the preadmission visit.

The research team will document the consented participants information such as scheduled Cesarean Section date and time. A separate linking log will store participants' medical record numbers, name and unique study identifiers.

All data in the Excel spreadsheet will be securely stored on Memorial Hermann's protected health information (PHI) drive. Signed consent forms will be part of medical records and will be uploaded to the patient's electronic medical record (EMR) system.

Unexpected unmasking of the randomisation code may occur if a participant is mistakenly allocated to a treatment arm other than that designated by the randomisation system, or if the randomisation sequence is inadvertently revealed ahead of schedule. In the event of such an error or breach, the principal investigator will promptly document the incident and submit a report to the Institutional Review Board (IRB).

Intervention in the Postpartum Unit

The intervention will take place in the postpartum unit after cesarean surgery. Twenty-four hours after delivery, a member of the research team will visit each participant, administer the survey, and inform the participant of their group assignment (control or experimental). Participants in the experimental group will then receive lavender sandalwood aromatherapy tabs. At 48 hours after delivery, both the control and experimental groups will complete the post-intervention PANAS survey. If a participant is discharged before 48 hours, the survey will be completed before discharge. The anticipated hospital stay after cesarean delivery is two to three days.

Surveys will be completed via Microsoft Forms and stored in Microsoft Excel using unique study identifiers.

Study Product Storage

The lavender sandalwood aromatabs should be stored according to the manufacture's guidelines to ensure product integrity and efficacy. Tabs are kept in their original, sealed packaging until use, in a cool, dry place, ideally at room temperature and away for direct sunlight or sources of excessive heat or humidity. For security and safety, the tabs should be stored in a locked room within the postpartum unit, accessible to the research team.

Study Drug Formulations

The Elequil Lavender Sandalwood Aromatabs contain 100% pure lavender sandalwood essential oil in a self-adhesive tab formulation designed for controlled, convenient administration. Each tab is individually packaged and sealed to preserve the aromatic properties of the lavender sandalwood oil and maintain product integrity until use.

Study Drug Administration

Lavender Sandalwood Aromatabs will be administered to participants in the experimental group as self-adhesive tabs placed on the upper chest. The tabs are intended for passive inhalation only and are designed for easy application and removal. Participants may adjust the intensity of lavender and sandalwood exposure by tearing along the marked points to select either minimal or maximum exposure. No ingestion or other routes of administration will be used. Participants will be instructed to avoid exposing the tab to excessive moisture, heat, or sunlight, as these conditions may compromise its stability and effectiveness.

Specific Restrictions / Requirements

There are no restrictions on standard medications, herbs, or vitamins during study participation. However, the research team will ask participants about any new or ongoing use of essential oils or aromatherapy products other than the provided lavender sandalwood aromatabs, because concurrent use could affect study outcomes or increase the risk of skin irritation or allergic reactions. Participants should continue all routine medications prescribed by their healthcare provider unless the clinical team advises otherwise.

Assessment Tools & Data Collection

Positive and Negative Affect Schedule (PANAS)

The PANAS will serve as the primary tool for assessing participants' moods throughout the study. PANAS is a self-reported instrument designed to measure attributes such as character strength, life satisfaction, positive emotions, and coping abilities (Positive Psychology.com, 2019). The assessment comprises 20 questions, evenly divided into two categories: 10 questions measure positive affects, and the other 10 questions measure negative affects (Positive Psychology.com, 2019). Each question is scored on a 5-point Likert scale, with total scores ranging from 10 to 50 in each category (Positive Psychology.com, 2019). PANAS is regarded as a reliable and valid method for evaluating emotional states (Positive Psychology.com, 2019).

In this study, the PANAS survey will be administered twice: 24 hours after surgery as a baseline measurement ("pre") and again 48 hours after surgery when the aromatherapy tab is removed ("post"). Participants in the control group will follow the same schedule, completing the PANAS assessment both preoperatively and 48 hours postoperatively.

To facilitate data collection, participants will access the PANAS survey using a QR code using their unique survey identifier. Responses will be recorded using Microsoft Forms and stored in Excel spreadsheets on the organization's protected PHI drive.

Defense and Veterans Pain Rating Scale (DVPRS) & Data Collection

The DVPRS is a 10-point scale ranging from 0 (no pain) to 10 (severe or intense pain). Compared with traditional pain scales, the DVPRS incorporates visual cues, functional word descriptors, and color-coded bars to facilitate communication about pain and its impact on patients' overall well-being (Blackburn et al., 2018). This tool supports more meaningful dialogue between patients and healthcare providers by capturing pain from a broader, more functional perspective (Blackburn et al., 2018). In this study, the DVPRS will be used to assess and compare pain levels between the experimental and control groups. The tool is already used in clinical practice at the study site. DVPRS pain scores will be collected for all participants at approximately 24 hours ($\pm$ 4 hours) after delivery and again at 48 hours post-surgery or before discharge ($\pm$ 4 hours). For both groups, these data will be obtained from the Epic electronic medical record system.

Overall Patient Experience

Patients' experience and overall satisfaction with their care will be assessed and compared between the intervention and control groups. Memorial Hermann administers a post-discharge survey to patients who are not included in other mandatory survey procedures; this survey includes one question about how likely the patient is to recommend the hospital to a friend or relative. Patients respond using a 10-point scale, where higher scores are associated with higher likelihood of recommending the hospital. The Qualtrics –administered survey includes questions about whether the nurse demonstrated concern for the patient's comfort, whether the nurse explained medications, whether the nurse explained things in a way that was easy to understand and whether the nurse treated the patient with courtesy and respect. Each of these questions are associated with a five-point Likert scale, where higher scores are associated with more favorable impressions. To accomplish this, the study team will obtain this data from MH Consumer Experience for patients enrolled and conduct statistical analysis on de-identified data.

Other Variables

In addition to primary outcome measures, several supplementary variables will be collected to further assess the impact of the intervention. These include: the number of previous cesarean sections each participant has undergone, the specific type of anesthesia administered during the procedure (such as spinal, epidural, or general anesthesia), the presence and extent of abdominal adhesions encountered during surgery, the total duration of the surgical procedure, the type of incision, the quantity and types of additional pain medications given postoperatively, use of essential oils before and/or concurrently. Collecting and analyzing these variables will enable a more comprehensive evaluation of how the intervention may influence recovery, pain, and overall comfort outcomes, as well as help control for potential confounding factors in the study.

Data and Safety Monitoring

The research team will convene meeting every two weeks during the initial phases of the project. These sessions will focus on reviewing study progress, evaluating data collection practices, ensuring adherence to the protocol, and identifying safety issues and opportunities for improvement.

Adverse events (AEs) and protocol deviations (PDs) will be promptly reported to the Institutional Review Board (IRB) according to established guidelines. All AEs will be documented, and any unexpected events will be communicated to the IRB without delay. Protocol deviations will also be tracked and reported in accordance with IRB requirements to ensure participant's safety and maintain study compliance.

Efficacy Assessment

The following study procedures and evaluations will be conducted to determine efficacy, in line with the primary and secondary objectives

Positive Affect Assessment (PANAS-P): Participants will complete the Positive and Negative Affect Schedule (PANAS) both 24 hours and 48 hours after delivery or prior to discharge. The PANAS-positive subscale (PANAS-P) will be used to measure improvements in positive affect. The scores will be calculated for each participant. These scores will then be compared between the intervention group (aromatherapy) and the control group to determine whether aromatherapy leads to greater improvements in positive affect.

Negative Affect Assessment (PANAS-N): The PANAS-negative subscale (PANAS-N) will also be administered 24 hours and 48 hours post operatively or prior to discharge. The PANAS-N scores will be evaluated to assess whether aromatherapy reduces negative affect compared to control.

Pain Evaluation (DVPRS): Pain levels will be measured using the Defence and Veterans Pain Rating Scale. Assessments will occur at approximately 24 hours (± 4 hours) after delivery and again at 48 hours post-surgery or prior to discharge (± 4 hours). These measures will be recorded in Excel log from the hospital's electronic medical record for all participants.

All survey responses (PANAS) will be collected via QR code using Microsoft Forms and securely stored in Excel spreadsheets.

These procedures collectively support the assessment of the study's efficacy outcomes, as they directly measure positive and negative affect changes as well as pain levels, in accordance with the protocol's defined objectives.

Safety and Other Assessments

The following study procedures and evaluations will be conducted to monitor safety, understand the safety profiles of the intervention, and support other study-related activities such as screening, eligibility, and enrolment:

Screening and Eligibility Assessments: Potential participants will be screened according to predefined inclusion and exclusion criteria to ensure eligibility for the study. This may involve reviewing medical history, current medications, allergies, and any contraindications to aromatherapy or study participation. Informed consent will be obtained prior to any study procedures. We are requesting a

Waiver for Screening and Recruitment to access MHHS EPIC for the purpose of identifying potentially eligible participants for this research study. The identifiers to be accessed and retained for screening and recruitment purposes will be participant name and medical record number (MRN).

Enrollment Procedures: Eligible participants who provide informed consent will be formally enrolled into the study.

Monitoring for Adverse Events: Throughout the study, participants will be closely monitored for any adverse events, and unexpected and expected reactions related to the intervention (aromatherapy) or other study procedures. All adverse and unanticipated events will be documented, assessed for severity and relatedness to the intervention, and reported according to protocol.

Data Management and Confidentiality: All assessment data will be securely collected and managed using standardized electronic systems. The study team will receive education on study procedures, data collection requirements, and safety log documentation to promote consistent protocol implementation and study quality. Completion of this education will be recorded in the team education and delegation log.

Statistics

A priori power analysis was conducted to estimate the minimum sample size. With a power set at .8, an alpha level set at .05, and a moderate effect size of .25 (f) for a repeated measures multivariate of variance (MANOVA) (2 groups x 2 time points x 2 subscales) on the primary outcome mood measures, a minimum sample size required to reach adequate power is 128 (64 in each group). This sample size is also sufficient for the secondary outcome pain levels in the repeated measures ANOVA ($n=46$). Other outcomes are exploratory, so the sample size calculation is based on the mood outcome. After considering 30% attrition rate or invalid cases, a total of 182 participants (91 in each group) will be recruited at the beginning of the study.

Test family		Statistical test	
F tests		MANOVA: Repeated measures, within-between interaction	
Type of power analysis			
A priori: Compute required sample size - given α , power, and effect size			
Input Parameters		Output Parameters	
Determine =>	Effect size $f(V)$	Noncentrality parameter λ	8.0000000
	α err prob	Critical F	3.9163246
	Power ($1-\beta$ err prob)	Numerator df	1.0000000
	Number of groups	Denominator df	126
	Number of measurements	Total sample size	128
		Actual power	0.8014596
		Pillai V	0.0588235

Statistical Procedures:

For each endpoint, descriptive statistics (mean, standard deviation, median, interquartile range) will be presented. Pearson's correlation will first be run to evaluate the relationships of the two subscales in mood. If the subscales are moderately correlated to each other, repeated measures MANCOVA/MANOVA will be conducted to assess changes of the positive and negative mood from 24 hours to 48 hours post-surgery in each group and compare group difference at each time points. The MANCOVA approach will also allow us to include selected covariates (e.g. any key demographics or clinical indicators) if appropriate. To determine what covariates should be included as a confounding factor, bivariate analyses (i.e. independent t test, chi-square 18 test, and correlation) will be conducted to examine how demographics/clinical indicators (see other variable section) are related to mood at baseline and pain level at 24 hours post-surgery, as well as the differences of demographics/clinical indicators between two groups.

For the pain outcome measures, repeated measures analysis of variance (ANOVA) or analysis of covariance (ANCOVA) will be performed to examine the difference between the two groups on the pain levels from 24 to 48 hours post-surgery while controlling for key demographic/clinical variables. If unexpected missingness occurs in the data, a linear mixed model will be used as a sensitivity analysis to examine mood and pain levels, where treatment and time will be the fixed effect, group-by-time is the interaction, and participant-level is a random effect to account for repeated measures within participants.

Finally, patients' experiences and satisfaction will be compared between the two groups using an independent t test on the Net Promoter Score and pain related satisfaction scores. Statistical significance will be set at the conventional alpha level (e.g., $p < 0.05$). All analyses will be conducted using validated statistical software.

Data/ Measure	Measurement	Source of the Data
Patient demographics	Age group (<20; 20-30; 31-40; 41+) Gravity/Parity(First; 2-3; 3+) Race (White, Asian, Black, Other)	Patients' medical records in Epic EMR system
PANAS scale	Self-administered PANAS Survey in Microsoft Forms	Using Microsoft Forms Survey with QR code (MS Forms & Excel)
DVPRS scale	Ten-point pain scale: Defense and Veterans Pain Rating Scale (DVPRS)	At 24 hours and at 48 hours: Epic EMR records

Patient satisfaction scores	Qualtrics adult survey – Net promoter score & patient satisfaction responses	Qualtrics / Sigma database
Other Variables:	Number of previous C/section Abdominal adhesion Length of surgery Type of anesthesia Type of incision Number PRN oral pain meds received Number of IV pain meds received Essential oil used before and/or now	Chart Audits in Epic

Efficacy Analysis

The primary efficacy endpoint in this study is the PANAS score, which measures changes in mood. Secondary endpoints include the DVPRS score for pain assessment and patient satisfaction scores. Additional covariates to be considered include the number of previous cesarean sections, presence of abdominal adhesions, duration of surgery, type of anesthesia, type of surgical incision, number of oral and intravenous as-needed pain medications administered, and whether essential oils were used before or during the study.

PANAS Scale: These scores will be analyzed as continuous variables, summarized using means and standard deviations. The subscales of the mood will be measured at 24 hours and 48 hours post-surgery or prior to discharge.

DVPRS scale: The Defense and Veterans Pain Rating Scale (DVPRS) is a ten-point pain scale, with assessments recorded at 24 and 48 hours or before discharge using Epic EMR records.

Patient Satisfaction Scores: Patient satisfaction will be assessed using the Qualtrics adult survey, which includes the Net Promoter Score and other patient satisfaction measures. Scores will be calculated according to Qualtrics guidelines, and patient satisfaction responses will be summarized descriptively.

Safety Analysis

The use of lavender sandalwood aromatabs in this study is considered to pose minimal risk, and no laboratory tests are required as part of the protocol. The main expected side effects are eye irritation, skin irritation and allergic reactions, with research indicating no other significant adverse effects. The research team will proactively monitor and document all adverse events, skin irritation and allergic reactions, for each safety endpoint. In addition to expected side effects, unexpected adverse events will

also be recorded. All adverse reactions will be categorised by severity (mild, moderate, or severe) and logged in the Excel Safety Log.

Safety endpoint data will be summarized using descriptive statistics. Because the intervention is administered over a short 24-hour period, results will be reported as frequencies and percentages of participants in the intervention group who experience each adverse event. Adverse events will be tabulated by their relatedness to the intervention, severity, and whether they lead to discontinuation of therapy. Events will be categorized into three groups: eye and skin irritation (mild), skin allergic reaction (moderate), and severe allergic reactions or anaphylaxis (severe). All safety data will be reviewed continuously throughout the study.

Because lavender sandalwood aromatabs are minimal risk, noninvasive, and used for a short duration, no formal interim statistical analyses are planned. However, the research team will monitor safety events throughout the study. The study may be paused if more than two severe adverse events potentially related to the aromatherapy intervention occur or if more than five mild to moderate adverse events are reported. All adverse events and safety concerns will be reported to the IRB in accordance with institutional policy, and further guidance will be requested regarding whether the study should be stopped.

Ethics

At the “Pre-Admission Visit,” participants will be provided with a consent form in accordance with the study protocol. Each participant will personally give consent for their involvement. A qualified member of the research team will obtain face-to-face consent during this visit, making sure all questions are answered and that participants thoroughly understand the study requirements.

The consent form will clearly explain that participation in the study is entirely voluntary and that individuals have the right to decline or withdraw their involvement at any point, without facing any negative consequences or penalties. The study will use the consent form downloaded from the Iris portal.

Data Handling and Record Keeping

The study ensures robust data handling and record keeping by implementing several layers of security and confidentiality. Outcome measures, consent forms, and data logs are stored securely on the PHI drive within the Memorial Hermann network, accessible only to authorized members of the research team. Electronic data and associated files are retained on a protected drive maintained by Memorial Hermann, providing an additional safeguard for sensitive information.

Identifiers are managed through two separate logs: one linking medical record numbers to study IDs, and another containing research data associated only with study IDs. This separation minimizes the risk of identification and strengthens participant confidentiality. All logs and electronic files are kept exclusively on secure, institution-managed drives, ensuring compliance with institutional and regulatory requirements.

In addition, the research team conducts periodic audits of surveys and data logs to ensure accuracy and completeness. Any discrepancies are collaboratively addressed and corrected, with oversight from the principal investigator and co-investigators. This process is further supported by user-friendly spreadsheets designed to minimize entry errors, and ongoing monitoring by co-investigators from the Institute for Nursing Excellence to uphold the highest standards of research integrity. All data are retained according to institutional and regulatory guidelines, ensuring proper record keeping for future reference.

Study documents such as outcome measures and data logs will be securely stored on the PHI drive within the Memorial Hermann network with only study ID, with access to authorized research team members. Electronic data and related files will also be kept on a protected drive managed by Memorial Hermann, adding another layer of security. This process ensures that all sensitive information is safeguarded and remains accessible for future reference in compliance with institutional and regulatory standards. The paper consent form will be sent to the medical records department and scanned into the patients' chart.

Quality Control and Assurance

The research team will conduct periodic audits of the surveys to ensure the data is accurate and complete. Any discrepancies arise, the team will hold collaborative discussions to address and correct these issues, fostering a culture of learning and improvement. The principal investigator and coinvestigators will oversee the entire process, ensuring it is carried out effectively. To streamline data management, the team will design a user-friendly spreadsheet to minimize entry errors for accurate analysis. Throughout the study, scientists from the Institute for Nursing Excellence (co-Investigators) will closely monitor the process to maintain the highest standards of research integrity.

Publication Plan

The research outcomes will be disseminated through multiple channels to ensure maximum impact and engagement. Presentations will be delivered at the hospital's Magnet meeting and unit-specific gatherings, fostering critical dialogue among healthcare professionals. Furthermore, the findings are planned to be showcased through visually compelling poster presentations and detailed podium sessions at both national and regional conferences. The research team also intends to submit the results for inclusion in Memorial Hermann's Nursing and Clinical Innovation Summit, emphasizing the practical implications of the study. Finally, the findings will be prepared for publication in peer-reviewed professional journals, contributing to the broader body of scholarly knowledge and encouraging further innovation in clinical practice.

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