Fair Oaks Hospital

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Dear Clinical Trials,

Please see attachments regarding the Study Protocol, Statistical Analysis Plan (SAP) and Informed Consent Form (ICF)

ClinicalTrials.gov ID: NCT04882501

Unique Protocol ID; U19-07-3670
Brief Title: Effects of Aromatherapy on Nausea Levels
Official Title: Effects of Aromatherapy in Decreasing Nausea Levels in the Post-Operative Bariatric Patient Population on a Surgical Unit

Document dates:
Protocol, SAP, ICF: June 13, 2023

IRB #U19-07-3670 The Use of Aromatherapy in Decreasing Nausea Levels in the Post-Operative Bariatric Patient Population on a Surgical Unit

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Sponsor:
Inova Health System

Site of Investigation:
Inova Fair Oaks Hospital

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ABSTRACT

Title: Effects of Aromatherapy in Decreasing Nausea Levels in the Post-operative Bariatric Patient Population on a Surgical Unit

Short Title: Effects of Aromatherapy on Nausea Levels

Rationale: Aromatherapy is the therapeutic use of essential oils from plants for the improvement of physical, emotional, and spiritual well-being. Healthcare providers play an important role in improving the care of patients with nausea. Aromatherapy is a complementary therapy that may help with post-operative nausea in the adult post-operative bariatric patient population.

Purpose: The purpose of this study is to evaluate the effects of aromatherapy intervention on nausea levels with post-operative bariatric patients once they are on the surgical unit.

Objectives: Hypotheses include the following: 1) Patients using aromatherapy with the initial episode of nausea on the surgical unit will have a greater decrease in mean nausea levels compared to control group. 2) The use of aromatherapy will decrease the utilization of antiemetic medication in the first 24 hours in the post-operative bariatric patient population.

Study Type: Single blinded, parallel arm, placebo- controlled, randomized clinical trial.

Study Design: Inclusion criteria includes: Patients ≥ 18 years of age admitted to the Surgical Unit who are experiencing an initial episode of nausea status post laparoscopic/ robotic sleeve gastrectomy, and/or laparoscopic/robotic Roux-En-Y (RNY) surgery, and/or revisional bariatric surgery; must be able to read and speak English; able to follow directions; bariatric surgeon is part of Inova Medical Group (IMG) and patient is an inpatient. **Exclusion criteria include**: Patients < 18 years of age; non-English speaking; not able to follow directions; inability to smell (anosmia); allergy to peppermint, spearmint, ginger and/or lavender; receiving bariatric surgery for gastroparesis; pregnant or breastfeeding; vulnerable subjects; receiving complementary therapy (healing touch and/or music therapy) or presently enrolled in another research study. The study location is the Surgical Unit at Inova Fair Oaks Hospital. The proposed sample size is 180 subjects.
Hypotheses include the following: 1) Patients using aromatherapy with the initial episode of nausea on the surgical unit will have a greater decrease in mean nausea levels compared to control group per the visual analog scale (VAS) from 0-3. The 0-3 VAS was used in prior aromatherapy research (Dienemann,2012; & Hunt,2013). 2). The use of aromatherapy will decrease the utilization of antiemetic medication in the first 24 hours in the post-operative bariatric patient population.

Study Methodology:
Subjects will be provided with information about this research study by the following means: a member of the research team (IMG Nurse Practitioners) will discuss the research study during the patient's second pre-operative visit; study information will be uploaded to their MyChart portal; and flyers will be available in the IMG office (refer to appendix A: IMG office flyer). Interested patients will be able to fill out a brief form (refer to appendix B: Interested patient card) requesting to be contacted for further information, this form will be placed in a secure box at the reception desk or the patients can indicate interest by contacting one of the research team members. A member of the research team may need to access medical record information in order to confirm potential patient's phone number and or email address for further contact. A member of the research team will contact any interested patients and answer any questions regarding the research study. Consent will be obtained while the patient is in the peri-operative holding area on day of surgery by a member of the research team, excluding the IMG Nurse Practitioners. The research team member will determine if the patient is eligible for the study, discuss the study, answer any questions, and obtain consent (refer to appendix C: Consent). All members of the research team have completed Informed Consent Training. Once the consented post-operative bariatric patient complains of initial nausea on the Surgical Unit, the direct care nurse or research team member will ask the patient to rate their nausea level using a VAS on a 0-3 scale. Patients will be provided with either product A or B based on randomization scheme calculated by SAS (ver.9.4, Cary, NC). The patient will receive a one-time aromatherapy intervention. Nausea levels will be reassessed 5 minutes after the aromatherapy intervention. If the nausea level does not improve after the study drug intervention an antiemetic medication will be offered (refer to appendix D: Data Collection Form A).

On day of discharge a member of the research team will ask the patient the following questions regarding the Aromatherapy QueaseEASE™ product (refer to appendix E: Data Collection Form B).
The study will occur Monday through Thursday.

Did you use the QueaseEASE™ product?	Yes	No
If yes:		
How beneficial was the aromatherapy?	0 1 2 3 4 5	
	no benefit	very beneficial

Would you consider using QueaseEASE™ in the future for nausea?	Yes/No
Would you recommend QueaseEASE™ to family / friend?	Yes/No
Did the participant experience any side effects from the product?	Yes/No
If yes, what side effect (s): Dizziness Lightheadedness Headache	Other_____

Primary outcome will be an improved patient reported nausea level after receiving the aromatherapy intervention with QueaseEASE™. Secondary outcome will be a decrease in the utilization of antiemetic medication in the first 24 hours in the post-operative bariatric patient population on the surgical unit. Tertiary outcome will be a determination if aromatherapy is more effective for a particular type of bariatric surgery over another (sleeve gastrectomy, Roux-En-Y, revisional bariatric surgery) with post-operative nausea.

Statistical Methodology:
Data will be presented as mean ± SD or frequency (percent), where appropriate. Group differences will be compared using Student's t-test, or chi-square tests of association, where appropriate. Data will be assessed for departures from normality with group comparisons adjusted accordingly. The primary hypothesis efficacy endpoint is the incidence rate of nausea following surgery. Rates of nausea and 95% confidence intervals will be presented and group comparison will be via chi-square tests. The primary efficacy analysis will only include surgery groups sleeve gastrectomy and Roux-En-Y. However, to expand our knowledge regarding the effect of aromatherapy, we will recruit patients undergoing revisional bariatric surgery but these patients will only be considered for secondary analyses. As this is an RCT, we anticipate potential cofounders (e.g., gender, type of surgery, etc) and effect modifiers to be distributed equally. However, in the event of a failed distribution of clinical or demographic characteristics, mixed effects modeling will be substituted to test the primary hypothesis. All analyses will be conducted using SAS (Ver.9.4, Carey, NC) with statistical significance considered as $p \leq 0.05$, two-tailed.

1. INTRODUCTION

1.1 Specific Aims

The use of integrative approaches to health and wellness has grown within care settings across the United States. Integrative health is when complementary approaches are utilized in mainstream health care (National Center for Complementary and Integrative Health (www.nccih.nih.gov; Downloaded 2/7 /19, Complementary, Alternative, or Integrative Health: What's In a Name).

Aromatherapy is one type of complementary approach. It is the use of essential oils for the purposes of healing. It has been used for years to relieve pain, promote healing, kill bacteria, and maintain health. It has been accepted as a part of nursing in many countries but only recently has been a part of nursing in the United States. Clinical aromatherapy is the use of essential oils for specific, measurable outcomes (Kreitzer 2014 - book). Certain essential oils (lavender, lavandin, mandarin, rose, bergamot, and frankincense) have their own relaxing properties and all have been shown their potential to reduce stress (Buckle, 2015).

Primary Aim: To determine the effectiveness of using aromatherapy as a first line intervention in place of an antiemetic in post-operative bariatric patients who experience nausea on the surgical unit at IFOH.

Secondary Aim: To determine if aromatherapy utilization for the treatment of post-operative nausea is more effective with a particular post-operative bariatric patient population (sleeve gastrectomy , Roux-En-Y, revisional bariatric surgery) on a surgical unit than with another.

1.2 Hypothesis

(1) Patients using aromatherapy with the initial episode of nausea on the surgical unit will have a greater decrease in mean nausea levels compared to control group and (2) The use of aromatherapy will decrease the utilization of antiemetic medication in the first 24 hours for the post-operative bariatric patient population on the surgical unit.

1.3 Background and Significance

Inova Fair Oaks Hospital performs over 550 bariatric surgeries per year. These surgeries consist of laparoscopic sleeve gastrectomy and laparoscopic Roux-En-Y bypass. These patients receive general anesthesia and insufflation of gas in the peritoneal cavity for surgical visualization. According to Brown and colleagues (2018) general anesthesia causes an increased risk for post- operative nausea and vomiting (PONV) when compared with regional anesthesia. In addition, the nursing literature states that laparoscopic surgeries are associated with a higher incidence of PONV.

PONV occurs in one-third of post-operative patients (Ferruggiari, 2012; O'Malley 2016 & Stalling-Welden 2018). According to Adib-Hajbaghert and Hosseini, F. (2015) "patients who experience PONV describe it as one of the most stressful complications of surgery and prefer postoperative pain over it" (p. 827). PONV can result in discomfort, fluid and electrolyte imbalance, dehydration, increased blood pressure, strain on the surgical site, reduced patient satisfaction and delayed discharge (Abid-Hajbaghery, 2015; Brown, 2018; Hodge, 2014; Lee, 2017; O'Malley, 2016; Asay, 2018).

Traditionally, PONV is treated with the administration of antiemetic medications. However antiemetic medications have the following side effects: hypotension, dry mouth, excessive sedation, restlessness, fatigue, extrapyramidal reactions and limited dosing (Hodge, 2014; Adib-Hajbaghery, 2015; Karaman, 2019). Many patients would like the option of a non-pharmacological intervention for PONV. The American Society of Peri-Anesthesia Nurses (2006) developed clinical practice guidelines for the prevention and management of PONV. These guidelines cite aromatherapy as an intervention to consider for PONV in the post anesthesia care unit (Stalling-Welden, 2018). According, to O'Malley (2016) "aromatherapy provides an alternative therapy to manage nausea, one which is free of medication side effects and sedation" (p. 318).

Aromatherapy is the use of essential oils for the purposes of healing. It has been used for centuries to help relieve pain, kill bacteria, and promote health. It has been accepted as a part of nursing in many countries but only recently in the United States. Clinical aromatherapy is the controlled and therapeutic use of essential oils in the clinical setting for specific, measurable outcomes and is a natural therapy that is being used during hospitalization to improve symptoms (Johnson, 2016). According to Buckle (2009), "peppermint, spearmint, and ginger are the classic essential oils to inhale for nausea" (p. 402).

Lua and Zakaria (2012) reviewed five research articles which included 328 subjects who received essential oils via inhalation for the alleviation of nausea and vomiting. The results suggest that inhaled vapors of peppermint or ginger essential oils did reduce the incidence and severity of nausea and vomiting, decreased the utilization of antiemetic medication and improved patient satisfaction. Peppermint oil has been shown to be effective in the treatment of morning sickness, dyspepsia, gastrointestinal complaints due to its antispasmodic properties (Buckle, 2015 & Lua, 2012). Ginger has shown to be effective with motion sickness, pregnancy induced nausea and post-operative nausea (Buckle, 2015 & Lua, 2012).

A prospective exploratory study in 2015 utilized the produce QueaseEASE™ for the treatment of post-discharge nausea in same day abdominal surgery patients (n=25). Ninety- six percent of participants had either a laparoscopic cholecystectomy or hernia repair. Fourty-seven episodes of post-discharge nausea was reported, and all of the subjects had a decrease in their nausea scale (0-10) after using the product and 22 of those 47 episodes (47%) reported a nausea scale of 0 after using the product. The mean decrease in nausea scale for the 25 participants was 4.78 ($\pm$2.12)

after using the QueaseEASE™ product (Mcilvoy, 2015). This study found that aromatherapy was an effective treatment for post-discharge nausea in same day abdominal surgery patients.

Lee and Shin (2017) conducted a quasi-experimental study with nonequivalent control group utilizing ginger essential oil and normal saline (NS) via an aromatherapy necklace. Sample size was 60, 30 subjects received ginger and 30 subjects received NS. The purpose of the study was to examine the effectiveness of aromatherapy with ginger essential oil on nausea and vomiting in abdominal surgery patients. The mean post-operative nausea and vomiting (PONV) scores in the experimental group (ginger) decreased significantly to an average of 1.14 (scale 2-32, the higher the score the more severe the nausea), while those in the control group (NS) had an average of 8.91.

Another study by Adib-Hajbaghery (2015) examined the effect of ginger essence of post-nephrectomy patients and PONV. This study was a randomized controlled trial study with a convenience sample of 120 patients utilizing ginger essence and normal saline. The mean nausea intensity in the treatment group was significantly lower than the control group ($p<0.001$) and the differences between the two groups regarding the number of vomiting episodes was also statistically significant ($p<0.001$). Adib-Hajbaghery (2015), states that the main ingredients in ginger are gingerol and shagoal. These "ingredients have antiemetic, antipyretic, antitussive and anti-inflammatory effects and can relieve gastrointestinal disorders as well as limit gastric contractions" (p. 828). This study supported that inhaling ginger essence had a positive effect on PONV in the post-operative nephrectomy patient population.

A 2014 prospective randomized two group design study conducted by Hodge, McCarthy, & Pierce compared the use of QueaseEASE™ versus an unscented inhalant in relieving PONV on a surgical unit for the first 24 hours. Three hundred and thirty nine patients were enrolled and 112 patients experienced PONV, the 112 subjects were randomized into the treatment group (QueaseEASE™ inhaler) and control group (placebo inhaler). Findings were the following: perceived effectiveness of aromatherapy was significantly higher in the treatment group ($p<0.001$) and there was a significant difference between the two groups ($p=0.03$). Hodge and colleagues (2014) noted that the nurse is not always able to respond as promptly as the patient desires in regards to the administration of antiemetic medication. The aromatherapy device is immediately available for the patient and if it does not completely relieve PONV, it may help the patient during the waiting time for the antiemetic to be administered. Asay (2018) conducted a systematic review of the literature regarding the use of aromatherapy in postoperative nausea and vomiting, and the synthesis of evidence did support the use of aromatherapy for PONV. Asay and colleagues stated the following "aromatherapy has a positive effect on PONV, and therefore should be considered as a complementary therapy or as an adjunct to antiemetic medications" (p. 1).

Hudgen, Hunt, Dienemann, Norton and Hartley (2013) conducted a randomized control trial of three aromatherapy agents (ginger, isopropyl alcohol and a blend of essential oils). Normal Saline was used as the control. The purpose of the study was to investigate the effectiveness of aromatherapy agents on the treatment of PONV for patients after surgery. Sample size was 301 subjects, who were randomly given one of the four agents upon initial complains of PONV via a gauze pad and instructed to inhale the aroma. Findings included: change in nausea was most significant for the aromatherapy blend agent ($p=0.0001$), then the ginger agent ($p=0.0006$) and there was no significant finding for isopropyl alcohol compared to NS. The number of antiemetic medication that was requested after the blended aromatherapy intervention was reduced.

Hines, Steels, Chang and Gibbons (2018) conducted a systematic review regarding the use of aromatherapy for the treatment of postoperative nausea and vomiting, this review included sixteen studies with a total of 1036 participants. The time points at which data was collected varied in the studies from 2 minutes to discharge from the Post Anesthesia Care Unit or Same Day Surgery Unit. According to Hines et al (2018) "aromatherapy was not effective in reducing nausea severity at greater than three minutes after treatment in comparison to saline, water or controlled breathing placebo (6 studies with 241 participants) but more participants who received aromatherapy were nausea free at the end of the treatment (4 studies, 193 participants) and fewer participants who received aromatherapy required anti-nausea medications (7 studies with 609 participants) (p. 4)".

In 2018, Karaman conducted a randomized 4-armed placebo controlled study with 184 subjects. This study studied the effects of water (placebo), ginger, lavender and rose with PONV in the recovery room. Results showed that ginger and

lavender essential oils were superior to water and rose oil in decreasing nausea scores. There were also statistically significant findings between the groups in regards to vomiting and antiemetic medication administration (p=0.00).

Several studies have been conducted using a variety of aromatherapy agents for the treatment of PONV. The results for this type of intervention are positive, yet there is no consensus on which aromatherapy agent/product is most effective at reducing PONV in the bariatric post–operative patient population. Additional nursing research is also needed to validate if aromatherapy using the QueaseEASE™ product is evidence based practice for the treatment of PONV particularly in the post-operative bariatric patient population. Nursing practice would also benefit from additional research regarding the effectiveness of aromatherapy to help promote its use and gain acceptance as an efficacious complementary therapy.

1.4 Preliminary Studies

The principal investigator has been in involved in another complementary/ integrative therapy research at Inova. This study utilized the aromatherapy product Calm Essential Oil Blend AethereoStick as an intervention to help decrease pain and anxiety scores in adult patients admitted to a community hospital on the Medical Unit or Telemetry Unit (pilot study concluded in August 2018). Findings from this pilot study were the following: ninety-six percent of the participants would use aromatherapy if offered again, would use in in the future, and would recommend its use to family and friends. Pain and anxiety levels were assessed prior to administration of a medication, within 60 minutes of receiving pain medication, and within 60 minutes of receiving aromatherapy. Both pain and anxiety improved after the aromatherapy with a p value of <0.001. Manuscript accepted and published in 2019 (Lindgren, V., McNicholl, L., et al).

2 STUDY DESIGN AND SUBJECT SELECTION

2.1 Study Type

Single blind, parallel arm, placebo- controlled, randomized clinical trial.

2.2 Setting/Location

Participants will be recruited from the Bariatric IMG during their second preoperative visit and/or via MyChart portal. Consents will be obtained when the patient is in pre-operative bay on the day of surgery by a member of the research team, excluding the IMG Nurse Practitioners. Inova Fair Oaks Hospital is a top-ranked 182-bed acute care community hospital serving the rapidly growing suburbs of Northern Virginia. Inova Weight Loss Surgery Program is a nationally recognized weight loss (bariatric) surgery program designed to meet each patient's unique needs. Located at Inova Fair Oaks Hospital, it is a fully accredited Comprehensive Center for Bariatric Surgery since 2006. Inova Fair Oaks Hospital is committed to providing safe care, excellent service and is continuously striving to improve each patient's unique experience.

2.3 Duration of Study

Participants in the study will receive a one-time one aromatherapy encounter utilizing either QueaseEASE™ inhaler product A or product B for post-operative nausea on the surgical unit. Product A will be the actual product that contains peppermint, spearmint, lavender and ginger. Product B will be the placebo product that contains distilled water. The participant will be instructed on self-administration with the aromatherapy inhaler product after reviewing standardized printed instructions with them (refer to appendix F: Aromatherapy patient education sheet). The aromatherapy product A or B, based on randomization scheme will be offered to the consented patient upon their initial complaint of nausea on the Surgical Unit by the direct care nurse or a member of the research team. The direct care nurse or a member of the research team will ask the participant pre and post nausea levels and collect this data on the data collection form (see Appendix D: Data Collection Form A). Questions regarding the product will be asked on day of discharge (see Appendix E: Data Collection Form B) by a member of the research team.

2.4 Number of Subjects

Total number of subjects is 180.

2.5 Study Population

2.5.1 Gender of Subjects

Both men and women will be included in the proposed study.

2.5.2 Age of Subjects

Study participants will be 18 years of age or older.

2.5.3 Racial and Ethnic Origin

The study does not include any racial or ethnic enrollment restrictions. Persons of diverse racial/ethnic backgrounds will be recruited equitably.

2.5.4 Vulnerable Populations

The following groups will be excluded from the study: children, pregnant women, prisoners, and persons with decisional incapacity.

2.6 Recruitment

All members of the research team will collaborate with one another Monday to Thursday in order to identify potential participants. Other members of the research team who have undergone the required training to obtain consent will approach potential participants and advise them of the study. Consent will be obtained from the patients after they have been provided an informed consent form to view, read, and have any questions answered. The study will be explained using the script below:

Study Recruitment Script:

"I am collaborating with nurse researchers at Inova on a research study to explore the effects of an investigational aromatherapy on nausea in the post-operative bariatric patient population on the Surgical Unit. Aromatherapy is the therapeutic use of essential oils from plants.

If you agree to participate in the study you will be randomized (assigned by chance) to a product group (product A or product B) and will receive either the active intervention or placebo. There is a 50% or 1 in 2 chance of you receiving either product A or product B upon your initial complaint of nausea when on the Surgical Unit. You will receive a one-time dose for your nausea using either product A or product B based on trial randomization.
This intervention will be in addition to your usual care and also not interfere with your care.

In order to participate in this study, you will need to provide informed consent. I am happy to answer any questions you may have about the study and review the consent form with you."

Study Recruitment Script: See Appendix G

2.7 Inclusion Criteria

Inclusion criteria includes: patients ≥ 18 years of age admitted to the Surgical Unit who are experiencing an initial episode of nausea status post laparoscopic sleeve gastrectomy or laparoscopic Roux-En-Y (RNY) surgery and/or revisional bariatric surgery; must be able to read and speak English; able to follow directions; not allergic to peppermint, spearmint, ginger and/or lavender; bariatric surgeon is part of IMG group and patient is an inpatient.

2.8 Exclusion Criteria

Exclusion criteria include: patients < 18 years of age; non-English speaking; not able to follow directions; inability to smell (anosmia); allergy to peppermint, spearmint, ginger and/or lavender; receiving bariatric surgery for gastroparesis; pregnant or breastfeeding; vulnerable subjects; receiving complementary therapy (healing touch, music therapy) or presently enrolled in another research study.

3 STUDY METHODS AND PROCEDURES

3.1 Study Treatment/Intervention

Once consent is obtained, the licensed prescriber will enter an order into the patient's electronic medical record (EMR) for the aromatherapy product. It will be a one-time order to administer the aromatherapy product for complaints of nausea while on the surgical unit for the first 24 hours post-operatively. This order will appear on the medication administration record (MAR) in the EMR.

Pharmacy will review and release the aromatherapy order. Pharmacy will be provided with the study Subject Identification (SID) number, a copy of the patient's research consent and randomization scheme generated by SAS which will determine the protocol drug (aromatherapy product A or B). Pharmacy will apply a patient label to study drug and one label on the delivery sheet. The pharmacy will dispense the study drug to the Surgical Unit. The study drug will be placed in the patient's medication bin in the medication room closet to the patient's room. Pharmacy will maintain all delivery sheets in a secure location.

If the enrolled post-operative bariatric patient complains of nausea for first time (initial) while on the surgical unit within the first 24 hours post-operatively, the participant will be offered a one-time aromatherapy intervention with either product A or product B (based on the randomization scheme) for their nausea treatment. A member of the research team will instruct the patient on the use of the QueaseEASE™ aromatherapy product (A or B) and also provide them with the educational handout (refer to appendix F: Aromatherapy patient education sheet). The instructions to use are the same for product A as product B.

The direct care nurse will assess the patient's nausea level prior to the intervention. The direct care nurse will provide the patient with their randomized product, and the patient can utilize the product for up to 5 minutes. The nurse will document this one time aromatherapy administration via the MAR. The nurse or a member of the research team will then reassess the patient's nausea level at 5 minutes.

After the aromatherapy intervention the nurse will remove and discard the patient label from the study drug and dispose of the study drug in the appropriate receptacle.

If the patient still complains of nausea following the one-time aromatherapy intervention with QueaseEASE™ product A or product B, an antiemetic medication will be offered. The direct care nurse will complete the data collection form A (refer to appendix D: Data Collection Form A). The PI/SI will collect the completed data collection form A and store in a secure locked location. On day of discharge, a member of the research team will query the patients on the aromatherapy session using form B (refer to appendix E: Data Collection Form B). The PI/SI will collect and securely store the data collection form B once completed.
A member of the research team will complete the demographic /outcomes sheet (refer to Appendix H: demographic/outcomes sheet) and the PI/SI will collect the completed demographic/outcomes sheet and store in a secure locked location.

Refer to Appendix I --for tentative time table for this study.

3.2 Control Group

Consented patients will be randomized into the control group and will receive aromatherapy product B. Pre and post nausea levels will be assessed and if the nausea level is not decreased an antiemetic will be administered as ordered.

3.3 Randomization

Upon enrollment in the trial, each subject will be randomized to one of two treatment groups: Product A (aromatherapy inhaler product), Product B (Placebo product: inhaler with distilled water). Each product will look the same. SAS will be used to generate the randomization table using random numbers to determine which treatment subject #1 will receive; subject #2 will receive, etc., resulting in a total of 90 subjects for each treatment group. The randomization scheme will be located in a secured location in the pharmacy department and access will be granted to Pharmacy and designated research team members.

3.4 Endpoints/Outcomes Measurements

3.4.1 Primary outcome.

Primary end-point: Post-operative bariatric patients that use aromatherapy will have a greater decrease in mean nausea levels compared to control group.

3.4.2 Secondary outcomes

Secondary end-points: A decrease in the use of antiemetic medication administration in the post-operative bariatric patient population; determine if aromatherapy utilization for nausea is more beneficial with a particular post-operative bariatric patient population (sleeve gastrectomy, Roux-En-Y, revisional bariatric surgery).

3.5 Consent/Assent

Informed written consent will be obtained by either the PI or SI. The PI or SI will provide consent document to all willing participants after they have met the inclusion criteria listed above and have not met any exclusion criteria. The participant will have an opportunity to view the consent, read the contents, and have time to ask any questions. If they are willing to be a participant in the study the consent will be signed and witnessed by the PI or SI. See attached Informed Consent Document from potential participants (refer to appendix C: Consent).

3.6 Monitoring Subjects and Criteria for Withdrawal of Subjects from the Study.

Participants may withdraw from the study at any time, as desired.

4 STATISTICAL CONSIDERATIONS/DATA ANALYSIS

4.1 Sample Size

To test the primary hypothesis that aromatherapy will lead to a decrease in post-operative nausea among patients undergoing laparoscopic/robotic sleeve gastrectomy, Roux-En-Y, and/or revisional bariatric surgery we will use a Pearson Chi-Square test for proportion difference. Assuming an expected incidence of nausea among controls of 80%, an alpha level of 5 percent, and a 1:1 treatment to control group ratio, we anticipate 90 subjects per group (n= 180 total) provides at least 80% power will to detect a statistically significant 20% reduction in the incidence of nausea among aromatherapy patients. The randomization scheme was calculated with SAS (ver.9.4., Cary, NC) using a two-group (treatment vs. placebo), simple randomization block (n=15) design. The total randomization scheme was increased to 180 (15 blocks of 12 patients) to allow for drop out and screen failures. Sample size will be increased to 180 subjects, this allows for a 20% (n=30) adm/screen fail/etc. error.

4.2 Method of Data Analysis

Data will be presented as mean ± SD or frequency (percent), where appropriate. Group differences will be compared using Student's t-test, or chi-square tests of association, where appropriate. Data will be assessed for departures from normality with group comparisons adjusted accordingly. The primary hypothesis efficacy endpoint is incidence rate of nausea following surgery. Rates of nausea and 95% confidence intervals will be presented and group comparison will be via chi-square tests. The primary efficacy analysis will only include surgery groups sleeve gastrectomy and Roux-En-Y. However, to expand our knowledge regarding the effect of aromatherapy, we will recruit patients undergoing revisional bariatric surgery but these will only be considered for secondary analyses. As this is an RCT, we anticipate potential cofounders (e.g., gender, type of surgery, etc.) and effect modifiers to be distributed equally. However, in the event of a failed distribution of clinical or demographic characteristics, mixed effects modeling will be substituted to test the primary hypothesis. All analyses will be conducted using SAS (Ver.9.4, Carey, NC) with statistical significance considered as $p \leq 0.05$, two-tailed.

4.3 Data Storage

Data will be stored in a secure area in a locked cabinet. All electronic data will be stored on a password protected, secure server. All computers will be password protected. REDCap, a HIPAA compliant, secure web-based application for building and managing online surveys and databases will be used to store the data.

4.3.1 Data Management

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Privacy and confidentiality of all enrolled participants will be maintained. Participants will be de-identified using an ID# that will only be accessible to the research team. The key to the PIN will be kept separate from the collection data and secured in a locked cabinet. All data will be stored on a password protected secure server. REDCap will be used. A Data Usage Agreement (DUA) will be executed by Inova to an external consultant in order to ensure the privacy and protection of data.

4.3.2 Records Retention

Data will be stored for three years and then will be destroyed.

5 HUMAN SUBJECTS PROTECTION (RISKS, BENEFITS, AND ALTERNATIVES)

5.1 Risks

Minimal risks, if any, are anticipated. Participants may experience dizziness, lightheadedness and/or headache.

5.2 Benefits

There is potential for participants in this study to receive direct benefits from participating in the study by decreasing nausea levels.

5.3 Alternatives

The alternative is to not be a participant in the study.

5.4 Confidentiality

Confidentiality of the data will be ensured as follows:

- All study data will be coded with a PIN. The PIN will be used in lieu of any identifiable information to ensure confidentiality.
- Only the research team will have access to hardcopy study data. Hardcopy study data will be kept in a locked file cabinet or locked area.
- Only the research team will have access to electronic databases with the study data. The electronic database will be held on a password protected computer. REDCap will be used.
- Data will be made available only to the investigators and staff working on the study.
- Data will be reported in aggregate.

6 SUBJECT COMPENSATION

6.1 Costs

There are no costs to participants.

6.2 Payment

There will be no payment for participation.

7 ADVERSE EVENT REPORTING

There are no known anticipated potential adverse events as a result of this study. However, any adverse events will be reported to the IRB. Protocol deviations will also be reported as required.

8 FUNDING

This proposed study is non-funded.

The company Soothing Scents will be donating the QueaseEASE™ aromatic inhalers and placebo inhalers free of charge under the Ease the Quease product evaluation program. Disclaimer states: "enrollment in this program in no way obligates your facility to purchase any product or pay any fees to soothing scents (product costs, set-up cost, shipping & handling, etc.). You can stop the program at any time. Soothing Scents also reserves the right to cancel the program at any time" (refer to appendix J: Soothing Scents Disclaimer).

9 CONFLICTS OF INTEREST

There are no conflicts of interest. Refer to disclaimer from Soothing Scents (refer to appendix J: Soothing Scents Disclaimer).

10 FACILITIES AND EQUIPMENT

The Surgical Unit at Inova Fair Oaks Hospital will be the study site. No extra equipment or investigational equipment is needed for this study.

11 OUTSIDE CONSULTANTS/COLLABORATORS

All members of the research team have completed CITI or WCG training and are Inova employees.

12 CONTRACTURAL AGREEMENTS

There are no contractual agreements.

13 CLINICAL TRIALS

A description of this clinical trial will be available on https://www.clinicaltrials.gov/ as required by U.S. law.

14 REFERENCES

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APPENDICES

Appendix A: IMG office flyer
Appendix B: Interested patient card
Appendix C: Patient Consent (C1) and HIPAA (C2)
Appendix D: Data Collection Form A
Appendix E: Data Collection Form B
Appendix F: Aromatherapy patient education sheet
Appendix G: Study recruitment script
Appendix H: Demographic/outcomes data
Appendix I: Study timetable
Appendix J: Soothing Scents Disclaimer

Appendix A

Attention Pre-Operative Patients:

We need *YOU* to participate in a research study!

What study?

"The Use of Aromatherapy in Decreasing Nausea Levels in the Post-Operative Bariatric Patient Population on a Surgical Unit"

What's it about?

Aromatherapy is a complementary therapy that uses essential oils from plants for the potential improvement of well-being. QueaseEASE™ is an investigational aromatherapy treatment we are studying to see if it decreases post-operative nausea in the adult post-operative bariatric patient.

Why does it matter?

We believe that conducting research will help us to continually refine our treatments.

Will I still get medication for nausea if I need it?

YES! This is just one possible treatment for nausea. Medications will always be used when needed for ALL study participants.

How do I Participate?

It's easy! Just reply back to this message or email one of the nurses conducting the study listed below and someone will contact you prior to surgery to explain the details.

If you have any questions or concerns please contact
Carmen.Spencer@Inova.org or Laura.Mcnicholl@inova.org

Appendix B

Please contact me with more information about the Aromatherapy Research Study!

Please Print-

First Name: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Last Name: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Date of Birth (month/date/year): ☐☐/☐☐/☐☐☐☐

I prefer to be contacted by: Email Phone My Chart

Appendix C1

Informed Consent for a Research Study

TITLE:	The Use of Aromatherapy in Decreasing Nausea Levels in the Post-Operative Bariatric Patient Population on a Surgical Unit
PROTOCOL NO.:	U19-07-3670 IRB Protocol #20204191 U19-07-3670
SPONSOR:	Inova Health System
INVESTIGATOR:	Laura McNicholl, CNS, MS, RN Inova Fair Oaks Hospital 3600 Joseph Siewick Fairfax, Virginia 22033 United States
STUDY-RELATED PHONE NUMBER(S):	703-391-4892 888-534-6682 (24 Hours)

Introduction
You may be eligible to take part in a research study because will be having bariatric surgery and may experience post-operative nausea. Participation is voluntary. This research consent form gives you important information about the study. It explains why this research study is being done, what is involved in participating in the research study, the possible risk and benefits of participation, choices for participation and your rights as a research participant.

Please take your time to review this information carefully. You may also wish to talk to others (for example, your family, friends, or doctors) about your participation. The decision to participate is yours. You may leave the study at any time without losing any benefits you would have normally received. If you decide to take part in the study, you will be asked to print, sign, and date at the end of this form.

The purpose of the study
The purpose of the study is to find out whether aromatherapy will have an effect on your nausea level after your bariatric surgery. Aromatherapy is the therapeutic use of essential oils from plants. The results of this study will be used to determine if the investigational aromatherapy is beneficial with post-operative nausea in post-operative bariatric patients. About 180 people are expected to take part in this study. While participating in this study, you may not take part in any other research study without approval from the principal investigator.

What will happen if I take part in this research study?
This research study is designed to better understand the effects of aromatherapy on nausea following bariatric surgery. If you participate you may receive one session with either the active aromatherapy study ingredients or placebo when you initially experience nausea on the surgical floor. You have an equal chance of receiving aromatherapy vs. placebo. Both the aromatherapy and placebo will be referred to as "study product".

- You will be asked by a member of the research team to sign this informed consent form to participate in the aromatherapy study.
- If you sign the consent, a member of the research team will instruct you on the use of the study product.
- When you initially experience nausea on the surgical unit, the nurse will assess your nausea level and then

provide you with the study product. You will be able to use the study product for 5 minutes.
- After 5 minutes the nurse will reassess your nausea level and collect the study product.
- If your nausea level does not improve, a medication to treat nausea will be administered as ordered by your doctor.
- On day of discharge, a member of the research team will ask you a few questions regarding the study product.
- Your direct participation will end once you have been discharged from the hospital.
- Completion of the study should take approximately 20 minutes.
- There is no cost to you to participate in this study.

What risks or benefits can I expect from being in the study?
If you choose to take part in this study, there is a chance that you may experience a headache, dizziness or lightheadedness from the essential oils used in aromatherapy. The product is called QueaseEASE™. Notify the nurse immediately if you have a reaction to the aromatherapy.

You may or may not benefit from participation in the research. The information gained may benefit other patients with post-operative nausea in the future.

The most important non-medical risk is the disclosure of your protected health information (PHI). PHI is any health information that is collected about you, including your history and new information collected during this study. You will have an opportunity to review the ways in which your PHI may be used and disclosed in the separate HIPAA authorization form.

There may be unknown risks from participation.

Will I be paid for being in the study?
You will not be paid for being in this study.

Will my medical information be kept private?
Efforts have been made to protect your identity. The signed consent form will be separated from the completed survey by the research team immediately upon receipt. Only group data will be reported and responses will not be person-identifiable. Once data analysis is complete and the research results are reported, the individual surveys will be shredded. You may request a copy of the research results by contacting Laura McNicholl at 703-391-4892 or via email Laura.mcnicholl@inova.org.

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:
- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

What other choices do I have if I do not take part in this study?

Your alternative is not to participate. You may receive treatment for your nausea without taking part in the research.

Taking part in this research study is voluntary. If you choose not to participate, or you may withdraw and there will be no penalty or loss of benefits to which you are otherwise entitled.

Who can answer my questions about the study?
If you have any questions, concerns, or complaints regarding this research study or believe you have suffered a research related problem, please contact Laura McNicholl at 703-391-4892. If you would like more information about your rights as a participant in a research study, contact the Inova Health System Institutional Review Board (IRB) at 1-888-534-6682.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

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

SIGNATURE:
I have been informed about this research study's purpose, procedures, and possible risks and benefits. I voluntarily consent to participate in this research study. I will contact a member of the research team if I have any questions.

Printed Name of Participant	Signature of Participant	Date

Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

The following witness lines may be left blank, unless an impartial witness is required.

An impartial witness, **who is a witness to the informed consent process that is not involved in the conduct of the research,** is required when a non-English speaking subject is encountered, an interpreter is used and consent is documented through the use of a short form or when the subject cannot read the consent form.

Signature of Impartial Witness	Printed Name of Impartial Witness

Appendix C2

IRB Protocol Number[U19-07-3670] Principal Investigator:[Laura McNicholl, MS, RN, CNS-BC, RN-BC]

HIPAA Research Authorization Template

AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

I agree to permit the Inova Health System, and any of my doctors or other health care providers (together "Providers"), Principal Investigator and [*his /her/their/its*] collaborators and staff (together "Researchers"), to obtain, use and disclose health information about me as described below. Authorized staff not involved in the study may be aware that I am participating in a research study and may have access to my information. If the study is related to my medical care, any study-related information may be placed in my permanent hospital, clinic or physician's office records.

1. **The health information that may be used and disclosed may include:**

☒ All information collected during the research and procedures described in the Informed consent Form for the Research as described in the accompanying study specific Informed Consent Form ("the Research"): and

☒ Health information in my medical records that is relevant to the Research, includes my past medical history including medical information from my primary care physician and other medical information relating to my participation in the study; and

[For each box that has been checked, the associated lines must be separately initialed by you in order to permit access to these records.]

_____ ☐ HIV/AIDS status:
HIV-related information, which includes any information indicating that I have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that I have been potentially exposed to HIV.

_____ ☐ Sexually transmitted diseases (STDs)

_____ ☐ Mental health treatment records governed under state law (including mental health records relating to involuntary or voluntary mental health treatment.) *Mental health records may include substance abuse information.*

_____ ☐ Substance abuse (drug and alcohol) treatment records.

_____ ☐ Sexual assault information

2. **The Providers may disclose health information in my medical records to:**
   - the Researchers;
   - representatives of government agencies,
   - any applicable Cooperative Groups, review boards, and other persons who watch over the safety, effectiveness, and conduct of research; and
   - the sponsor of the Research [Inova Health System]
   - and its agents, monitors and contractors (together "Sponsor").

IRB Protocol Number[U19-07-3670] Principal Investigator:[Laura McNicholl, MS, RN, CNS-BC, RN-BC]

3. **The Researchers may use and share my health information:**
   - among themselves, with the Sponsor, with any applicable Cooperative Groups, health care facilities, research sites, independent data and safety monitoring boards, study monitors and with other participating Researchers (internal and/or external) to conduct theResearch;
   - Federal and State agencies that have oversight of the study or whom access is required under the law. These may include FDA, OHRP, NIH and Virginia Department of Health; and
   - as permitted by the Informed Consent Form.

4. **The Sponsor and any applicable Cooperative Groups may use and share my health information** for purpose of the Research, data safety and monitoring and as permitted by the consent form.

   Contract Research organization(s): [Inova Health System]

5. **Once my health information has been disclosed to a third party,** federal privacy laws may no longer protect it from further disclosure.

6. **I hereby authorize the Sponsor to observe any medical procedures I undergo as part of the Research.**

7. **Please note that:**
   You do not have to sign this Authorization, but if you do not, you may not participate in the Research. If you do not sign this authorization, your right to other medical treatment will not be affected.

   You may change your mind and revoke (take back) this Authorization at any time and for any reason. To revoke this Authorization, you must write to either of the following:

   Principal Investigator Name:[*Laura McNicholl, MS, RN, CNS-BC, RN-BC*
   Address:[*3600 Joseph Siewick Drive Fairfax, VA 22033*
   Tel. No.:[*703-391-4892*]

   Inova Health System, Human Research Protections Office
   Address: 3300 Gallows Road
   Falls Church, VA 22042
   Tel. No.: 1-888-534-6682

   However, if you revoke this Authorization, you will not be allowed to continue taking part in the research. Also, even if you revoke this Authorization, the Providers, Researchers, any applicable Cooperative Groups and the Sponsor may continue to use and disclose the information they have already collected to protect the integrity of the research or as permitted by the Informed Consent Form.

**Study personnel must send copies of participant revocations to:*
Office of Privacy and Compliance at Inova AND the Human Research Protections Office at Inova.

Inova Health System - Office of Privacy and Compliance 8110 Gatehouse Road Falls Church, VA 22042 703-205-2337	NAME: _____ MRN: _____
AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION	Last 4 Digits of SS#: _____

While the Research is in progress, you may not be allowed to see your health information that is created or collected by the Inova Health System in the course of the Research. After the Research is finished, however, you may see this information as described in the *Inova Health System*, Notice of Privacy Practices.

8. **This Authorization does not have an expiration (ending) date.** There is no set date at which your information will be destroyed or no longer used. This is because the information used and created for the study may be analyzed for many years, and it is not possible to know when this will be complete.

9. **You will be given a copy of this Authorization after you have signed it.**

_____	_____
Signature of participant or participant's legal representative	Date
_____	_____
Printed name of participant	Printed name of legal representative (if applicable)
	_____
	Representative's relationship to participant

For questions, contact the Human Research Protections Office at 1-888-534-6682

****

Study personnel must send copy with signature to the Office of Privacy and Compliance at Inova.

Appendix D

Appendix D

Patient Identification Number (PIN): _____

Aromatherapy and nausea level study on Surgical Unit for post-operative Inova Medical Group Bariatric Surgery

Data Collection Form A

1. **When patient complains of nausea: assess nausea level before aromatherapy intervention**

   Nausea level before aromatherapy: 0 No Nausea 1 Some 2 A lot 3 Severe

   Date: ____/____/____ Time: _____

2. **Administer Aromatherapy product/ Intervention**
   Aromatherapy product given: Product A Product B

   Date: ____/____/____ Time: _____

3. **Reassess nausea level after aromatherapy:**

   Nausea level 5 minutes after aromatherapy: 0 No Nausea 1 Some 2 A lot 3 Severe

   Date: ____/____/____ Time: _____

4. Did the patient request an antiemetic after the aromatherapy intervention?

   YES NO

   Date: ____/____/____ Time: _____

Add Patient Label

Appendix E

Patient Identification Number
(PIN): _____

Aromatherapy and nausea level study on Surgical Unit for post-operative Inova Medical Group Bariatric Surgery

Data Collection Form B

1. ***TO ASK ON DAY OF DISCHARGE***

Aromatherapy (QueaseEase™) Questions: Research Member to ask the patient the following questions:

Did you use the QueaseEASE product? Yes No

If yes-

How beneficial was the aromatherapy? 0 1 2 3 4 5
no benefit maximal or very beneficial

Would you consider using QueaseEase™ in the future for nausea? Yes/No

Would you recommend QueaseEase™ to family / friend? Yes/No

Did participate experience any side effects from the product? Yes/No

If yes, what was the side effect (s): Dizziness Light-headedness Headache Other

Please provide any additional comments or feedback below: _____

_____

_____

_____

Appendix F

Thank you for being part of our investigational QueaseEASE™ aromatherapy research study

Inhaling essential oils is the fastest method of getting essential oils into the body (2-3 minutes for onset). Smell is a chemical reaction; receptors in the brain respond to chemicals (odor molecules) within the essential oil. As you breathe in, the odor molecules move up behind the bridge of the nose and attach to structures that play an important part in odor recognition, emotional responses, learning, and memory. The olfactory receptors are very sensitive and can be stimulated by very subtle scents.

How to Use the Investigational QueaseEASE™ Inhaler:

1. Remove tab from product
2. Place under nose 2-3 inches
3. Inhale and exhale deeply 3 times or more as desired

What are the benefits of using QueaseEASE™?

You may or may not benefit from the QueaseEASE™ aromatherapy product. You may feel satisfaction that you are helping us to better understand how to improve care for our patients. We hope the information learned from this aromatherapy study will benefit others in the future.

What are the risks of using QueaseEASE™?

Minimal risks, if any, are anticipated. You may experience dizziness, lightheadedness and or a headache.

Appendix G

Study Recruitment Script:

"I am collaborating with nurse researchers at Inova on a research study to explore the effects of an investigational aromatherapy on nausea in the post-operative bariatric patient population on the surgical unit. Aromatherapy is the therapeutic use of essential oils from plants.

If you agree to participate in the study you will be randomized (assigned by chance) to a product group (product A or product B) and will receive either the active intervention or placebo. There is a 50% or 1 in 2 chance of you receiving either product A or product B upon your initial complaint of nausea when on the surgical unit. You will receive a one-time dose for your nausea using either product A or product B based on trial randomization. This intervention will be in addition to your usual care and also not interfere with your care.

In order to participate in this study, you will need to provide informed consent.
I am happy to answer any questions you may have about the study and review the consent form with you."

Appendix H

Appendix H

Demographic/Outcomes Sheet

Name: _____

MRN # _____

Date of Admission: _____ Private Room Semi-Private

Gender: Female Male Unidentified Declined

Age: _____

Race: American Indian Asian African American Other Pacific Islander
White

Ethnicity: Hispanic Not Hispanic

BMI: _____

Surgery Date: _____

Type of surgery: Sleeve gastrectomy Roux-En-Y Revisional bariatric surgery

ICD Codes: Sleeves: 43775 RNY: 43644 RNY Rev: 43860
Band removal to sleeve: 43775 + 73774 Band removal: 73772

Band removal + components: 73774

Method: Laparoscopic Robotic

Hiatal hernia repair: Yes No

Length of surgery (total minutes):_____

Type of anesthesia: Gas TAP On Q pump

Botox injection: Yes No

Amount of IVF administered in the OR: _____

Antiemetic received in PACU: YES No

If YES, name of antiemetic received _____/ dose _____/time _____

Aromatherapy intervention product: product A or product B

Initial antiemetic administered on the surgical unit:

time _____ / drug name _____/ dose _____

Appendix H

Time span (total minutes) between QueaseEASE™ aromatherapy and first antiemetic on surgical unit: _____

Subsequent antiemetics administered on the surgical unit (first 24 hours):

time _____/drug name_____/dose_____

Subsequent antiemetics administered on the surgical unit (first 24 hours):

time _____/drug name_____/dose_____

Subsequent antiemetics administered on the surgical unit (first 24 hours):

time _____/drug name_____/dose_____

Subsequent antiemetics administered on the surgical unit (first 24 hours):

time _____/drug name_____/dose_____

Subsequent antiemetics administered on the surgical unit (first 24 hours):

time _____/drug name_____/dose_____

Subsequent antiemetics administered on the surgical unit (first 24 hours):

time _____/drug name_____/dose_____

Number of times patient received an antiemetic after QueaseEase™aromatherapy intervention (first 24 hours) _____

Date of discharge: _____

Did participate experience any side effects? YES NO

If yes, what was the side effect(s)? Dizziness Headache Lightheadedness

Other_____

Appendix I

Aromatherapy Time Table

	Months 1-2	Month 2	Month 3	Month 4	Month 5-6	Month 6-7
Obtain final IRB approval						
Finalize data collection tools						
Introduce Study to Surgical Unit staff						
Enroll Patients						
Conduct Aromatherapy Intervention for Nausea						
Data Entry & Cleaning						
Data Analysis						
Submit Final Reports						

Appendix J

SOOTHING SCENTS

EASE THE QUEASE PRODUCT EVALUATION PROGRAM

The Ease the Quease Product Evaluation Program is a special opportunity for your facility to trial QueaseEASE Aromatic Inhalers for PONV and Chemo-induced nausea for FREE to evaluate the cost and efficacy of the product.

Soothing Scents will provide FREE OF CHARGE a 3 month supply of QueaseEASE to your facility. All we ask in exchange is feedback from a designated contact person on the progress of the Program. We also offer an In-Service meeting with your facility to educate your staff on the proper use of QueaseEASE.

DISCLAIMER: Enrollment in this program IN NO WAY obligates your facility to purchase any product or pay any fees to Soothing Scents (product costs, set-up costs, shipping& handling, etc.). You can STOP the program at any time. Soothing Scents also reserves the right to cancel the program at any time.

Contact Name: _____

Facility Name: _____

PACU Nurse Manager OR Contact Person: _____

Materials Management Buyer/Contact: _____

Date Requesting Program to begin: _____

Estimated number of surgeries/PACU patients per month: _____

Estimated QueaseEASE Inhalers required per month (surgeries/10): _____

_____ _____

Signature of person requesting Program Enrollment Date

FOR OFFICE USE ONLY

Date Requested_____ Product Type Offered: ❑ QE1HCT_____ ❑ QE Quick Pack_____

Shipping Address:_____

Notes:_____

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