1) Protocol Title

Title: **Aromatherapy for management of pain, anxiety, and nausea in the acute care setting**

Protocol Version Date: *2/20/20*

2) Objectives

The purpose of the study is to investigate the effects of aromatherapy on pain, anxiety, and nausea in patients on an acute care unit. The primary objective of this project is to determine whether Elequil aromatherapy tabs show a measurable benefit in reducing patient reported pain, anxiety, and nausea, thus reducing the use of anxiolytic, antiemetic, or opioid medications. The secondary objective is to identify the effectiveness of aromatherapy on improved sleep and improved patient satisfaction and well-being.

Aromatherapy has been studied and shown effective for the decreased effects of pain, anxiety, and nausea. We are hypothesizing that the use of aromatherapy has a positive effect in decreasing patient-reported pain, anxiety, and nausea, and increasing sleep and overall patient satisfaction.

3) Background

People are hospitalized every day, with many of them experiencing ailments such as pain, nausea, and anxiety, on top of the symptoms that are related to their admitting diagnoses. As nurses, the primary responsibilities are to function as a caregiver to help manage physical conditions, treat illness, and educate to prevent further worsening of health conditions. Assessing, managing, and treating uncomfortable symptoms is an integral part of nursing care. Interventions for these primarily include pharmaceutical interventions. The use of aromatherapy is an alternative treatment that can be used in addition to medications. Clinical aromatherapy is the controlled and therapeutic use of essential oils in the clinical setting for specific, measurable outcomes and is a natural therapy increasingly being used to improve symptoms and maintain health and well-being during a hospital stay.[1]

The encouragement of alternative, non-pharmaceutical means to decrease symptoms is not a wide-spread practice. Hospitals do not necessarily see the use of essential oils as an effective means to decrease somatic complaints. This study will try to expand upon the limited literature and studies regarding the use of aromatherapy and its effectiveness in decreasing the presence of pain, nausea, and anxiety in the hospital setting.

There is limited evidence that shows that the use of aromatherapy is effective

[1] Buckle, J. The role of aromatherapy in nursing care. Nurs Clin North Am. 2001;36(1):57-72.

in decreasing somatic complaints. One study concluded that essential oils generally resulted in significant clinical improvements based on their intended use.[2] Cho found that aromatherapy use resulted in reduced anxiety, increased sleep, and stabilized blood pressure.[3] Moeini and colleagues demonstrated that the use of aromatherapy significantly improved the quality of sleep with the use of essential oils.[4] While the majority of aromatherapy studies were done in the intensive care unit (ICU) setting, or outpatient setting, all concluded that further studies needed to be done. In an effort to provide non-pharmacologic adjunctive treatments for symptom management, aromatherapy has been explored in the inpatient setting.

We will be using Elequil aromatabs® to determine the effectiveness of aromatherapy in the hospital setting. The following scents, their common uses and estimated aromatab® duration of use are:

- Lavendar: Promotes relaxation, comfort, and sleep. Lasts 8 hours.
- Lavendar-Sandalwood: Promotes relaxation, comfort, and sleep. Lasts 8 hours or more.
- Lavendar-peppermint: Promotes relaxation during pain, calm anxiousness, and soothe queasiness. Lasts 8 hours.
- Orange-Peppermint: Uplifts, energizes, and soothes queasiness. Lasts 8 hours.[5]

The chosen essential oils will be inhaled by the patient when the aromatherapy tab is opened and affixed to their hospital gown.

4) Inclusion and Exclusion Criteria

Setting:

Upon admission to Tower 4- an acute care, remotely monitored telemetry unit at UC Davis Medical Center in Sacramento, CA., if the patient is interested in participating in the study, the patient will first be evaluated on whether they meet

[2] Johnson, Rivard, Griffinm Kolste, Joswiak, Kinney, Dusek. The effectiveness of nurse-delivered aromatherapy in an acute care setting. Complementary Therapies in Medicine. 2016; 25: 164-169.
[3] Cho M, Min E, Hur M. Effects of Aromatherapy on the Anxiety, Vital Signs and Sleep Quality of Percutaneous Coronary Intervention Patients in Intensive Care Units. Evid Based Complement Alternat Med. 2013; 2013: 381381.
[4] Moeini M, Khadibi M, Bekhradi R, Mahmoudian S, Nazan F. Effect of aromatherapy on the quality of sleep in ischemic heart disease patients hospitalized in intensive care units of heart hospitals of the Isfahan University of Medical Sciences. Iran J Nurs Midwifery Res. 2010 Autumn; 15(4): 234-239.
[5] Elequil Aromatab Informational handout. https://www.beekley.com/

the inclusion criteria to participate in the study.

Inclusion criteria:

- Age 18 years or older
- Admission to Tower 4 for an anticipated inpatient stay >24 hours
- Alert and oriented
- Capable of using a visual scale to self-report symptoms
- Naïve to the use of aromatherapy for the use of decreasing pain, anxiety, and/or nausea to participate.
- Not on a pediatric service

The specific criteria for subject selection are patients admitted to Tower 4, an acute care/telemetry unit, who are conscious and able to communicate, that understands the purpose of the study and is competent and can give consent. The patient must not include any of the following:

Exclusion criteria:

- Cognitively impaired
- Post-op from an otolaryngologic surgery
- Known impaired olfactory function (limited or no sense of smell)
- On any psychiatric holds (e.g., 5150's)
- Known allergies to essential oils.
- Sensitive or allergic to plants (specifically to lavender plants, orange blossoms, sandalwood trees, or peppermint leaves) as essential oils are natural aromas derived from plants.
- Active participant of another Research Protocol
- Admitted as a "short stay" or on "observation" status.
- Has known history of Atrial Fibrillation
- Is a prisoner.
- Known pregnancy, or

- Expected to be transferred out of Tower 4 and/or discharged from the hospital within 24 hours.

5) Study Timelines

Participants of the study will ideally wear the aromatherapy tab on their gown for at least 8 hours to assess its effectiveness. After a minimum of 8 hours has elapsed, they will be given a follow up assessment tool to evaluate their symptoms and their experience in using aromatherapy.

- Identification of eligibility
- Consent
- Assessment 1 (Hour 0)
  Awake - complete assessment tool.
- Aromatherapy tab application
- Assessment 2 (Hour 8)
  Sleeping - no assessment/document sleep
  Awake – complete end assessment tool.
  Satisfaction assessment

If patient prefers, they can continue to utilize aromatherapy, otherwise tab is to be removed, and study is complete.

- Assessment 3 (Hour 12-24)
- Aromatherapy tab removal (after the maximum 24 hours worn)
- Additional data collection as noted below (medication use)

Individual subject participation will total up to 8 hours to a maximum of twenty-four hours.

We anticipate that our goal enrollment of one hundred subjects will be accomplished within six months (from first subject enrolled to last subject). Our total estimate for study completion is twelve months.

6) Study Endpoints

Primary endpoint: Elequil aromatherapy tab use is effective on

1. Patient-reported pain score

2. Patient-reported anxiety score

3. Patient-reported nausea score

Secondary endpoints: Elequil aromatherapy tab use is effective in decreasing the following as measured by the corresponding scales:

1. Total anxiolytic medication use
2. Total antiemetic medication use
3. Total opioid medication use
4. Observed and patient-reported sleep.
5. Patient-reported patient satisfaction
6. Patient-reported well-being

7) Procedures Involved

Methods:

Staff education will be completed prior to the start of the study. Staff will watch a short instructional video. https://vimeo.com/276457486. They will then practice how to open the Elequil tabs. Staff will be educated on how to introduce the study to eligible patients.

Upon admission to Tower 4 - an acute care, remotely monitored telemetry unit at UC Davis Medical Center in Sacramento, CA., the bedside RN will introduce the study to the patient. If they are interested in participating, the patient will be evaluated by a member of the research team on whether they meet the inclusion criteria to participate in the study. If inclusion data is met, the research team member will fully introduce and explain the study to the patient. If the patient is interested in participating in the study, the research team member will consent the patient.

After consent is obtained, a baseline assessment tool will be given to the subject for completion, asking them to rate their pain, anxiety and/or nausea using a Likert scale.

Upon completion of these assessment tools, the subject will be asked to identify their highest priority among the symptoms ranked to which they will then be given the corresponding aromatherapy tab to treat that symptom.

The research team member will then provide the tab that is identified to treat that symptom.

- Lavendar: Promotes relaxation, comfort, and sleep. Assists with decreasing anxiety.
- Lavendar-sandalwood: Promotes relaxation, comfort, and sleep. Assists with aches and restlessness.
- Lavendar-peppermint: Promotes relaxation during pain, calm

anxiousness, and soothe queasiness.

- Orange-peppermint: Uplifts, energizes, and soothes queasiness/nausea.

Subjects will have the option of choosing how much scent they receive by determining how much of the essential oil pad is exposed. MAX SCENT will be used for the full effect of the essential oil or MIN SCENT for a lighter effect of the essential oil. The aromatherapy tab will then be attached to the front of the patient gown in the proximity of the clavicle area. It should not be placed directly on skin.

1. Recruitment of participants
2. Consent of participants
3. Baseline survey completion and assessment
    a. Demographic characteristics of subjects (age, gender)
    b. Baseline assessment scores
        i. Likert Scales
4. Offer of aromatherapy tab to participant
5. Application of aromatab to the patient's gown or clothing in the proximity of the clavicular area
6. Assessment/observation after 8 hours of application to a maximum of 24 hours
    a. Anxiety
    b. Pain
    c. Nausea
7. Removal of aromatherapy tab after a maximum of twenty-four hours
8. Follow up survey completion after 8 hours.
    a. Follow up assessment scores.
        i. Likert Scales
9. Additional data retrieval (from medical chart in the EMR)
    a. Anxiolytic medication use

b. Pain relieving medication use

c. Antiemetic medication use

d. Medication use for treating insomnia.

e. Patient report of satisfaction on exit survey

10. Data analysis

The collected data will be analyzed by the study team in consultation with Susan Stewart, CTSC Statistician, and Lori Madden, Clinical Nurse Scientist.

11. Reporting/dissemination

The deidentified information and findings collected from this study will be reported/disseminated with stakeholders within the institution. Investigators also intend to disseminate findings on a broader scale (e.g., professional meeting presentation, publication).

8) Data and/or Specimen Management and Confidentiality

Individual's responses/statements will not include any information that identifies the individual, but the responses/statements will be coded and linked to their identity on a separate document or in a separate database.

All identifiable electronic data will be maintained on an encrypted device requiring a password for access. Passwords will not be shared and will be protected from access.

I understand that if this study involves the use of the UC Davis Health Electronic Health Record (EMR/EPIC) which also contains the clinical data for Marshall Medical Center (MMC), that MMC patient data cannot be accessed for research purposes and that I must take the necessary steps to ensure that MMC data is not accessed, used, or disclosed for UC Davis Health research purposes. Identifiable information from medical records will be stored on a password protected, encrypted device. Investigators will follow applicable university policies (UC Davis Hospital Policy 1313, UCDHS P&P 23002499, and UC Business and Finance Bulletin on Information Security (IS-3).

All paper records will be stored in a locked room/file-cabinet with access limited to only individuals who have a right and need for access.

9) Data and/or Specimen Banking

Data will not be banked.

10) Withdrawal of Subjects

Subjects may withdraw consent at any time, and they will be reassured that their clinical care will not be compromised if they were to withdraw. Subjects will be withdrawn from the study for the following reasons:

- Subject changes their mind and decides to opt out of the study before utilizing aromatherapy.
- Development of an allergic reaction (rash, indurations, increased discomfort, anaphylactic symptoms) to the use of aromatherapy
    - The aromatherapy tab will be removed and sequestered so as to not be used again.
    - Subject will be monitored with provider notification of patient's allergic reaction.
- Hospital discharged within 12 hours of admission.
    - Aromatherapy tab will be removed before discharge.
    - Subject will be asked to complete the survey, and the time of completion (since aromatherapy initiated) will be noted.
- Transferred off the unit (to ICU or a different unit)
    - Aromatherapy tab will be removed before transfer.
    - Subject will be asked to complete the survey, and the time of completion (since aromatherapy initiated) will be noted.

Subjects are free to withdraw from the study at any time upon request. Subject participation in the study may be stopped at any time at the discretion of the Investigator or Attending Physician. When a subject withdraws from the study, the reason(s) for withdrawal will be recorded by the Investigator.

11) Risks to Subjects

Even though the products that will be used are diluted and we will not be applying concentrated solutions directly to the skin, the following are identified risks related to aromatherapy use:

- Allergic reaction to the use of aromatherapy, including the development of
    - Dermatitis

- Runny nose/nasal congestion (sinus issues)
- Rash
- Red or bumpy skin (indurations)
- Increased discomfort
- Anaphylactic symptoms

The rates of allergic reactions for each essential oil that will be used for this study are as follows:

Sandalwood: 0.9%, orange and peppermint: 0.6% [6]

Lavender: 2.2% [7]

The patient will notify the nurse immediately if any of these symptoms appear.

12) Potential Benefits to Subjects

Subjects may experience relief of or decrease in their symptoms of nausea, pain, anxiety, and/or insomnia with the use of aromatherapy. They may resultantly use less medications and have fewer associated undesirable side effects from those medications.

The results of this study may contribute to our knowledge about aromatherapy as a non-pharmacologic intervention to relieve or minimize pain, anxiety, nausea, and/or insomnia. Future individuals who have such symptoms may benefit as a result.

13) Sharing of Results with Subjects

Results will be shared with subjects. Any peer reviewed manuscripts that result from the study will be made available to the subjects on request.

14) Prior Approvals

The research team has already obtained approval from the Product Standards

---

[6]. Frosch, P.J., Johansen, J.D., Menné, T., Pirker, C., Rastogi, S.C., Andersen, K.E., Bruze, M., Goossens, A., Lepoittevin, J.P. and White, I.R. (2002), Further important sensitizers in patients sensitive to fragrances. Contact Dermatitis, 47: 279-287. doi:10.1034/j.1600-0536.2002.4704171.x

[7] Bingham, LJ, Tam, MM, Palmer, AM, Cahill, JL, Nixon, RL. Contact allergy and allergic contact dermatitis caused by lavender: A retrospective study from an Australian clinic. *Contact Dermatitis*. 2019; 81: 37– 42. https://doi.org/10.1111/cod.13247

Committee. The team has also communicated with and will continue to coordinate with the manufacturer of the aromatherapy tabs, Beekley Medical, regarding procurement. A letter of support noting the agreement from the manufacturer to supply 100 aromatherapy tabs at no cost is enclosed (Attachment A).

15) Provisions to Protect the Privacy Interests of Subjects

Steps will be taken to protect subjects' privacy interests. Subjects will only interact with approved study personnel who have successfully completed human subjects training. This includes those involved in the study visits, consent, and in any study related procedures. We will do our best to make sure that the personal information in the subject's medical record is kept private. However, no study can guarantee 100% protection of confidential information despite all our measures to protect each subject's privacy. Subjects will be made aware of this during the consent process.

16) Compensation for Research-Related Injury

The research study does not involve more than Minimal Risk. If a subject is injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by University or the study sponsor or may be billed to the subject's insurance company just like any other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, call the IRB administration at (916) 703-9151 or email at IRBAdmin@ucdmc.ucdavis.edu.

17) Economic Burden to Subjects

No expenses will be billed to conduct the study, printing costs for study document and analysis are supported by the Center for Nursing Science. No study-related procedures or costs are billed to subjects.

18) Drugs or Devices

No drugs or devices will be used for this study. The aromatherapy tabs will be intended to supplement subjects' medication plan. Per Elequil, the aromatherapy tabs are neither considered a drug or device. See letter from Elequil (Attachment B).

19) Review Requirements

There are no contractual obligations or other considerations that require IRB review of this research, or review at intervals other than those required by the Common Rule or FDA.

Assessment Tools

Anxiety Likert Scale: This one-item scale consisted of five evenly spaced numbers each anchored to a level of anxiety (0 = not at all anxious, 2 = a little anxious, 3 = moderately anxious, 4 = very anxious, 5 = extremely anxious).

The Numerical Rating Pain Scale measures pain experienced right now based on a 11-point Likert scale with choices of 0 = no pain, 5 = Moderate pain, 10 = Worst possible pain. We will be utilizing this 0-10 scale for pain because it is one of the most commonly used pain scales that is used at the bedside.

Nausea Scale: 0-5 Nausea Scale

- Each patient room has a laminated copy of the scale.
- When assessing patients, nurses show the scale to patients who can read; nurses tell patients who can't read about it.
- Nurses read the scale levels and the descriptors. Patients select their rating and tell the nurse.
- Nurses ask patients what would help them with their signs and symptoms. Patients may choose a pharmaceutical or nonpharmaceutical intervention.
- Nurses assess the patient prior to medication administration and within 30 minutes afterwards to assess effectiveness of interventions. They record both ratings in computer-based documentation and on the medication administration record (MAR).
- Nurses record the patient rating prior to nonpharmaceutical interventions and 30 minutes later in the computer-based documentation or progress notes.
- A report is run daily by unit to ensure that signs and symptoms are being assessed and outcomes recorded.

	Measure	Definitions
0	None	No nausea
1	Anticipated	Nausea is *anticipated* and prophylaxis medications may be given.
2	Mild	Nausea reported. Able to tolerate food or medications by mouth.
3	Moderate	Nausea persisting. Lacks appetite. Able to eat small meals occasionally.
4	Great	Nausea ongoing. No appetite. Unable to tolerate food/medications by mouth.
5	Severe	Nausea with dry heaves reported.

Halpin, Angela MN, RN, CNS; Huckabay, Loucine M. PhD, RN, PNP, FAAN; Kozuki, Jessica L. MSN, RN, AOCNP, CNS, NP, OCN; Forsythe, Deborah RN, OCN. Nursing2010: November 2010 - Volume 40 - Issue 11 - p 18-20. doi: 10.1097/01.NURSE.0000389030.33760.7a

Attachment A

elequil®
aromatabs®
aromatherapy designed
for the clinical setting

Relax. Relieve. Refresh.®
100% pure essential oils

Dear Carolyn Mendoza Modifi,

Beekley Medical will provide complimentary boxes of Elequil aromatabs for the UCDMC study.

You will be sent the following at no charge:

#370 Lavender-Sandalwood

#371 Orange-Peppermint

#372 Lavender

This is a value of $321 that is being waived to support your study.

Sincerely,

Melissa Vibberts

Senior Product Manager

mvibberts@beekley.com

860-583-4700 x 427

Beekley Medical®
when your diagnosis must be right®

One Prestige Lane, Bristol, CT 06010 1.844.ELEQUIL elequil.com

Attachment B

BEEKLEY MEDICAL®
when your diagnosis must be right®

Thank you for your inquiry.

Elequil aromatabs® is an aromatherapy product that is not intended to treat or prevent disease. Therefore, FDA clearance or approval is not required as it is not a medical device nor pharmaceutical product.

Should you have any questions or need further assistance, please do not hesitate to contact us at 1-800-BEEKLEY (233-5539).

Beekley Corporation One Prestige Lane, Bristol, CT 06010 Tel: 860.583.4700 Fax: 1.800.735.1234 Web: www.beekley.com