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

Investigator: Carolyn Mofidi

California Experimental Subjects Bill of Rights

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
- Any common or important discomforts and risks.
- Any benefits you might expect.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a copy of this document.

Key Information about This Research Study

You are invited to participate in a research study. The purpose of this research is to investigate effects of inhaled aromatherapy – exposure to a strong-smelling scent – on pain, anxiety, and nausea in patients on an acute care unit. We would like to determine whether Elequil aromatherapy tabs show a measurable benefit in:

1. Reducing patient reported pain, anxiety and/or nausea
2. Reducing opioid, anxiolytic, or antiemetic medication

In addition, we would like to assess whether the use of aromatherapy assists with:

1. Improved sleep
2. Improved patient satisfaction and well-being

You are invited to be in this study because you are experiencing the fore-mentioned ailments and you meet the eligibility requirements set forth. Your participation in this research will involve one visit during your in-patient stay and will last about twenty-four hours. We expect about 100 patients at UC Davis on Tower 4, will participate in this research.

Participation in this study will involve the application of an aromatherapy tab to your hospital gown that is identified to treat certain symptoms. All research studies involve some risk. Risks of this study are minimal. These risks are described in detail later in this document. There is the possibility that you may benefit from participation in this study.

Here are some reasons you may not want to participate in this research: You:

- would rather utilize medications solely for decreasing pain, nausea or anxiety

- are concerned that the scent will inhibit your sleep or well-being
- are concerned that you will not be able to follow through with keeping the aromatherapy tab in place for a minimum of 12 hours for whatever reason(s)
- are afraid of any side effects that might occur with the use of aromatherapy, especially if you have never used aromatherapy

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. The treatment of your pain, anxiety or nausea will then be decided by you and your medical team. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions you need to help decide whether or not to join this study.

Information to help you understand research is online at
http://www.research.ucdavis.edu/policiescompliance/irb-admin/for-research-participants.

What if I have Questions?
The person in charge of this study Carolyn Mofidi. If you have questions or concerns about this study, please contact the Lead Researcher, at (916) 734-3333.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, you may talk to a team member at the Institutional Review Board (IRB) at (916) 703-9158, hs-irbeducation@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817. The IRB is a group of people who oversee research.

How is this research funded?
This research is being funded by Beekley Medical, the makers of Elequil, also called the sponsor. Sponsors may change or be added.
UC Davis is not being paid to conduct this study, and the investigators and research team have not received any direct income from the sponsor.

Why is this research being done?
The purpose of the study is to investigate the effects of aromatherapy on pain, anxiety, and nausea in patients on an acute care unit. We are researching to determine whether Elequil aromatherapy tabs show a measurable benefit in:

1. Reducing patient reported pain and/or anxiety,
2. Reducing the use of medications used for anxiety, nausea or pain,
3. Improving sleep

What happens if I say yes, I want to be in this research?

If you decide to participate in this research study, the researcher will ask you to sign a consent to participate in the study. After consent is obtained, a baseline assessment tool will be given to you to complete. You will be asked questions rating your pain, anxiety or nausea level at the time using a scale of 1 to 5. Upon completion of the assessment tool, you will be asked to identify your highest priority among the symptoms that you ranked. You will then be given the corresponding aromatherapy tab to treat that symptom.

You will have the option of choosing how much scent you 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 your patient gown. It should not be placed directly on your skin.

Your symptom(s) will be assessed after 12 hours of application. If desired, you may keep the aromatherapy tab on your gown for up to 24 hours. After the tab is removed, you will then be asked to complete a follow up survey which contains the same scale of 1 to 5 to rate your symptom(s).

- Consent
- Complete assessment tool
- Aromatherapy tab application
- After wearing the aromatherapy tab for 12 hours
  - If you are sleeping - no assessment will be done
  - If you are awake – you will complete end assessment tool
  - Satisfaction assessment

(Optional) If you prefer, you can continue to utilize aromatherapy, otherwise aromatherapy tab will be removed and the study is complete.

- After wearing the aromatherapy tab for 24 hours
  - If you are sleeping - no assessment will be done
  - If you are awake – you will complete end assessment
  - Satisfaction assessment

How is being in this study different from my regular health care?

People with pain, nausea, and anxiety usually are given a medication to assist in controlling these symptoms. If you take part in this study, you would be given an aromatherapy tab that will be attached to your hospital gown in order to treat or assist in treating your pain, nausea and anxiety.

If you take part in this study, the main difference between your regular care and the study is the addition of the use of aromatherapy to assist in decreasing your symptoms. This study is not part of your health care.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for adhering to the study for its duration of a minimum of twelve hours and honestly providing feedback on the results of the study, whether it be favorable or unfavorable.

Do I have to be in this study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. You can choose to be in the study or not be in the study. If you decide to be in the study, you can choose to leave the study at any time.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UC Davis Health or any services you receive from them. No matter what you decide, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Is there anyway being in this study could be bad for me?

There are risks to participating in this research. The study doctor and study team will monitor you to see if you are experiencing any harm related to your participation. If you experience any pain or discomfort, you must inform the study team as soon as possible.

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:

- You may develop an allergic reaction (rash, itching) to the scent, which is very rare. If you develop an allergic reaction you will receive treatment at the discretion of your physician.
- Allergic reactions can include the development of:
    - Dermatitis
    - Runny nose/nasal congestion (sinus issues)
    - Rash
    - Red or bumpy skin (indurations)
    - Increased discomfort
    - Anaphylactic symptoms
- You may not like scent that you are exposed to and may wish to have it removed, causing the completion of the study.
- Since this is a research study, not all risks may be known at this time; there may be unforeseen risks associated with study participation.

As with all research, there is a chance that confidentiality could be compromised. To minimize the risks of breach of confidentiality, we will not include any information that directly identifies you on the information we collect, and on the data resulting from the research.

Will being in this study help me in any way?

Participation in this study may assist you in providing you relief of or decreasing any symptoms of pain, anxiety, and/or nausea that you may be feeling during your hospitalization. The study treatment may work better than the standard of care for your condition, but we cannot promise this will happen. The study treatment might not work at all, or it might have bad side effects. Even if the study does not help you directly, your participation in this study may help other people in the future by helping us learn more about the effectiveness of aromatherapy.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures.

Will I be paid or receive anything for being in this study?

We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs.

What happens to the information collected for the research?

We will do our best to limit the use or disclosure of your personal information, including information from this research study and from your medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Some organizations may be required to inspect and copy your information including the IRB and other University of California representatives responsible for the management or oversight of this study.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will remove identifiable information from the data we collect about you. We will maintain your study data on encrypted computers and access to the information will be limited to only members of the research team who need the access to properly conduct the study.

While this study does not involve banking the data we collect with your identifiable information (e.g., your name, medical record number, or date of birth) for future use, we may still use your data or specimens to answer additional research questions or share them with other investigators for additional research. If we do so, we will remove all identifiable information before use or sharing. Once identifiers have been removed, we will not ask your consent for the use of sharing of your data or specimens in additional research.

However, we cannot promise complete confidentiality. If you agree to be in this study, Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. We may also show your medical records to study monitors, auditors, the IRB, and the FDA. These groups are obligated to maintain your confidentiality. The following is a list of individuals who may access your records:

- Members of the research team
- Offices and committees responsible for the oversight of research

Will I receive any results from this research?

You will not receive any formal results at the completion of the study. You will; however, be able to attest to your own experience with aromatherapy and its effectiveness.

Will information or leftover specimens be used for other research?

During this research, the study team will obtain information about you. They will also collect biological specimens from you such as blood or urine. The information and specimens will be used for this research and may also be used for other research studies here at UC Davis. We may also share the information and specimens with other institutions for research. Before using the information and specimens for other research, the study team will remove information that identifies you so the individuals performing the research will not know who the information and specimens came from. We will not ask for additional consent from you to use your information and specimens for the additional research.

Do not write below this line. For IRB stamp and version date only.

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1636824	September 18, 2020

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

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